Gujarat Technological University

University Academic

Home

TEACHING SCHEME / DETAIL SYALLBUS

BPHARM | 90 - PHARMACY | Sem

2017-18 | Subject Code | Enter Subject Name | Search

*L=lectures,T=tutorial,P=Practical,E=TheoryExternal,M=TheoryInternal,I=Practical Internal,V=Practical External,On Job Training(OJT) is equivalent to Practical

						Hours			Credit	Max Marks				
Exp.	Subcode	Branch code	Eff_from	SubjectName	Category	Sem /Year	L.	T.	P.	Total	E	M	I	V	Total
	BP101TP	90	2017-18	Human Anatomy and Physiology I		1	3	1	4	6	80	20	20	80	200
	BP102TP	90	2017-18	Pharmaceutical Analysis I		1	3	1	4	6	80	20	20	80	200
	BP103TP	90	2017-18	Pharmaceutics I		1	3	1	4	6	80	20	20	80	200
	BP104TP	90	2017-18	Pharmaceutical Inorganic Chemistry		1	3	1	4	6	80	20	20	80	200
	BP105TP	90	2017-18	Communication Skills*		1	2	0	2	3	35	15	15	35	100
	BP106TP	90	2017-18	Remedial Biology*		1	2	0	2	3	35	15	15	35	100
	BP107TT	90	2017-18	Remedial Mathematics*		1	2	0	0	2	35	15	0	0	50
	BP201TP	90	2017-18	Human Anatomy and Physiology II		2	3	1	4	6	80	20	20	80	200
	BP202TP	90	2017-18	Pharmaceutical Organic Chemistry I		2	3	1	4	6	80	20	20	80	200
	BP203TP	90	2017-18	Pharmaceutical Engineering		2	3	1	4	6	80	20	20	80	200
	BP204TP	90	2017-18	Computer Applications in Pharmacy*		2	3	0	2	4	35	15	15	35	100
	BP205TT	90	2017-18	Environmental Sciences*		2	3	0	0	3	35	15	0	0	50
	BP301TP	90	2017-18	Pharmaceutical Organic Chemistry II		3	3	1	4	6	80	20	20	80	200
	BP302TP	90	2017-18	Physical Pharmaceutics I		3	3	1	4	6	80	20	20	80	200
	BP303TP	90	2017-18	Biochemistry		3	3	1	4	6	80	20	20	80	200
	BP304TT	90	2017-18	Pathophysiology		3	3	1	0	4	80	20	0	0	100
	BP305TP	90	2017-18	Pharmacognosy and Phytochemistry I		3	3	1	4	6	80	20	20	80	200
	BP401TT	90	2017-18	Pharmaceutical Organic Chemistry III		4	3	1	0	4	80	20	0	0	100
	BP402TP	90	2017-18	Medicinal Chemistry I		4	3	1	4	6	80	20	20	80	200
	BP403TP	90	2017-18	Physical Pharmaceutics II		4	3	1	4	6	80	20	20	80	200
	BP404TP	90	2017-18	Pharmacology I		4	3	1	4	6	80	20	20	80	200
	BP405TT	90	2017-18	Pharmaceutical Jurisprudence		4	3	1	0	4	80	20	0	0	100
	BP501TT	90	2017-18	Medicinal Chemistry II		5	3	1	0	4	80	20	0	0	100

BP502TP	90	2017-18	Pharmacology II		5	3	1	4	6	80	20	20	80	200
BP503TP	90	2017-18	Pharmacognosy and Phytochemistry II		5	3	1	4	6	80	20	20	80	200
BP504TP	90	2017-18	Pharmaceutical Microbiology		5	3	1	4	6	80	20	20	80	200
BP505TT	90	2017-18	Pharmaceutical Biotechnology		5	3	1	0	4	80	20	0	0	100
BP506TP	90	June 2020	Contributor Personality Development Program	Personality development Elective	5	4	0	0	4	80	20	20	30	150
BP507TP	90	June 2020	Integrated Personality Development Course	Personality development Elective	5	4	0	0	4	80	20	20	30	150
BP601TP	90	2017-18	Medicinal Chemistry III		6	3	1	4	6	80	20	20	80	200
BP602TP	90	2017-18	Pharmacology III		6	3	1	4	6	80	20	20	80	200
BP603TP	90	2017-18	Herbal Drug Technology		6	3	1	4	6	80	20	20	80	200
BP604TT	90	2017-18	Biopharmaceutics and Pharmacokintetics		6	3	1	0	4	80	20	0	0	100
BP605TP	90	2017-18	Industrial Pharmacy I		6	3	1	4	6	80	20	20	80	200
BP701TP	90	2017-18	Instrumental Methods of Analysis		7	3	1	4	6	80	20	20	80	200
BP702TT	90	2017-18	Industrial Pharmacy II		7	3	1	0	4	80	20	0	0	100
BP703TT	90	2017-18	Pharmacy Practice		7	3	1	0	4	80	20	0	0	100
BP704TT	90	2017-18	Novel Drug Delivery System		7	3	1	0	4	80	20	0	0	100
BP705PP	90	2017-18	Practice School		7	0	0	12	6	0	0	100	0	100
BP706TT	90	2017-18	Quality Assurance		7	3	1	0	4	80	20	0	0	100
BP801TT	90	2017-18	Biostatistics and Research Methodology		8	3	1	0	4	80	20	0	0	100
BP802TT	90	2017-18	Social and Preventive Pharmacy		8	3	1	0	4	80	20	0	0	100
BP803TT	90	2017-18	Pharma Marketing Management	Elective II	8	3	1	0	4	80	20	0	0	100
BP804TT	90	2017-18	Pharmaceutical Regulatory science	Elective II	8	3	1	0	4	80	20	0	0	100
BP805TT	90	2017-18	Pharmacovigilance	Elective I	8	3	1	0	4	80	20	0	0	100
BP806TT	90	2017-18	Quality Control and standardization of Herbals	Elective I	8	3	1	0	4	80	20	0	0	100
BP807TT	90	2017-18	Computer Aided Drug Design	Elective II	8	3	1	0	4	80	20	0	0	100
BP808TT	90	2017-18	Cell and Molecular Biology	Elective II	8	3	1	0	4	80	20	0	0	100
BP809TT	90	2017-18	Cosmetic Science	Elective I	8	3	1	0	4	80	20	0	0	100
BP810TT	90	2017-18	Experimental Pharmacology	Elective I	8	3	1	0	4	80	20	0	0	100
BP811TT	90	2017-18	Advanced Instrumentation Techniques	Elective II	8	3	1	0	4	80	20	0	0	100
BP812TT	90	2017-18	Dietary Supplements and Nutraceuticals	Elective I	8	3	1	0	4	80	20	0	0	100
BP813PP	90	2017-18	Project Work		8	0	0	12	6	0	0	50	100	150
BP814TT	90	Dec 2020	Pharmaceutical Product Development	Elective I	8	3	1	0	4	80	20	0	0	100
BP815TT	90	Dec 2020	Epidemiology	Elective II	8	3	1	0	4	80	20	0	0	100

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: HUMAN ANATOMY AND PHYSIOLOGY-I
Subject Code: BP101TP

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Sr No	Course Contents	Total Hrs
1	**Introduction to human body:** Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology **Cellular level of organization:** Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine **Tissue level of organization:** Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.	10
2	**Integumentary system:** Structure and functions of skin **Skeletal system:** Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction **Joints** Structural and functional classification, types of joints movements and its articulation	10
3	**Body fluids and blood:** Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system **Lymphatic system:** Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system	10
4	**Peripheral nervous system:** Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves **Special senses:** Structure and functions of eye, ear, nose and tongue and their disorders.	8
5	**Cardiovascular system:** Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.	7

Practical

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books:

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview, MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: PHARMACEUTICAL ANALYSIS
Subject Code: BP102TP

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

1. understand the principles of volumetric and electro chemical analysis
2. carryout various volumetric and electrochemical titrations
3. develop analytical skills

Sr No	Course Contents	Total Hrs
1	**(a) Pharmaceutical analysis**- Definition and scope i) Different techniques of analysis ii) Methods of expressing concentration iii) Primary and secondary standards. iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate **(b)Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures (c)Pharmacopoeia, Sources of impurities in medicinal agents,limit tests	10
2	**Acid base titration**: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl	10
3	**Precipitation titrations**: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride. **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate. **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate. Basic Principles,methods and application of diazotisation titration.	10
4	**Redox titrations:** (a) Concepts of oxidation and reduction (b) Types of redox titrations (Principles and applications) Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate	8
5	**Electrochemical methods of analysis** **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications. **Potentiometry -** Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications. **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications	7

Practical

Preparation and standardization of
(1) Sodium hydroxide
(2) Sulphuric acid
(3) Sodium thiosulfate
(4) Potassium permanganate
(5) Ceric ammonium sulphate

Assay of the following compounds along with Standardization of Titrant
(1) Ammonium chloride by acid base titration
(2) Ferrous sulphate by Cerimetry
(3) Copper sulphate by Iodometry
(4) Calcium gluconate by complexometry
(5) Hydrogen peroxide by Permanganometry (6) Sodium benzoate by non-aqueous titration (7) Sodium Chloride by precipitation titration

Determination of Normality by electro-analytical methods
(1) Conductometric titration of strong acid against strong base
(2) Conductometric titration of strong acid and weak acid against strong base
(3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions):

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: PHARMACEUTICS- I
Subject Code: BP103TP

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

1. Know the history of profession of pharmacy
2. Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
3. Understand the professional way of handling the prescription
4. Preparation of various conventional dosage forms

Sr No	Course Contents	Total Hrs
1	**Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia **Dosage forms:** Introduction to dosage forms, classification and definitions **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area	10
2	**Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques	10
3	**Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions. **Biphasic liquids:** **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.	8
4	**Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples	8
5	**Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms	7

Practical

1. Syrups:
a) Syrup IP'66 b) Compound syrup of Ferrous Phosphate BPC'68
2. Elixirs:
a) Piperazine citrate elixir **b**) Paracetamol pediatric elixir
3. Linctus
a) Terpin Hydrate Linctus IP'66 b) Iodine Throat Paint (Mandles Paint)
4. Solutions:
a) Strong solution of ammonium acetate b) Cresol with soap solution c) Lugol's solution
5. Suspensions:
a) Calamine lotion b) Magnesium Hydroxide mixture c) Aluminimum Hydroxide gel
6. Emulsions:
a) Turpentine Liniment b) Liquid paraffin emulsion
7. Powders and Granules
a) ORS powder (WHO) b) Effervescent granules c)Dusting powder d)Divded powders
8. Suppositories
a) Glycero gelatin suppository b) Coca butter suppository c) Zinc Oxide suppository
8. Semisolids
a) Sulphur ointment b) Non staining-iodine ointment with methyl salicylate c) Carbopal gel
9. Gargles and Mouthwashes
a) Iodine gargle b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: PHARMACEUTICAL INORGANIC CHEMISTRY
Subject Code: BP104TP

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals

Objectives: Upon completion of course student shall be able to

1. know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
2. understand the medicinal and pharmaceutical importance of inorganic compounds

Sr No	Course Contents	Total Hrs
1	**Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate **General methods of preparation**, assay for the compounds superscripted with **asterisk (*),** properties and medicinal uses of inorganic compounds belonging to the following classes	10
2	**Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity. **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance. **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.	10
3	**Gastrointestinal agents** **Acidifiers:** Ammonium chloride* and Dil. HCl **Antacid:** Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture **Cathartics:** Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite **Antimicrobials**: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations	10
4	**Miscellaneous compounds** **Expectorants:** Potassium iodide, Ammonium chloride*. **Emetics**: Copper sulphate*, Sodium potassium tartarate **Haematinics:** Ferrous sulphate*, Ferrous gluconate **Poison and Antidote:** Sodium thiosulphate*, Activated charcoal, Sodium nitrite333 **Astringents**: Zinc Sulphate, Potash Alum	8
5	**Radiopharmaceuticals**: Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I131, Storage conditions, precautions & pharmaceutical application of radioactive substances.	7

Practical

I **Limit tests for following ions**
Limit test for Chlorides and Sulphates
Modified limit test for Chlorides and Sulphates
Limit test for Iron
Limit test for Heavy metals
Limit test for Lead
Limit test for Arsenic
II **Identification test** Magnesium hydroxide Ferrous sulphate Sodium bicarbonate Calcium gluconate Copper sulphate
III **Test for purity**
Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide
IV **Preparation of inorganic pharmaceuticals**
Boric acid Potash alum Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: COMMUNICATION SKILLS
Subject Code: BP105TP

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Sr No	Course Contents	Total Hrs
1	**Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment	7
2	**Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style	7
3	**Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message	7
4	**Interview Skills:** Purpose of an interview, Do's and Dont's of an interview **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery	5
5	**Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion	4

Practical

Thefollowing learning modules are to be **conducted using Any Software English** language lab software

Basic communication covering the following topics

Meeting People
Asking Questions
Making Friends
What did you do?
Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)
Pronunciation and Nouns
Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech
Figures of Speech
Effective Communication
Writing Skills
Effective Writing
Interview Handling Skills
E-Mail etiquette
Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: REMEDIAL BIOLOGY Subject Code: BP106TP

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom

Objectives: Upon completion of the course, the student shall be able to

1. know the classification and salient features of five kingdoms of life
2. understand the basic components of anatomy & physiology of plant
3. know understand the basic components of anatomy & physiology animal with special reference to human

Sr No	Course Contents	Total Hrs
1	**Living world:** Definition and characters of living organisms Diversity in the living world Binomial nomenclature Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus, **Morphology of Flowering plants** Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed. General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones	7
2	**Body fluids and circulation** Composition of blood, blood groups, coagulation of blood Composition and functions of lymph Human circulatory system Structure of human heart and blood vessels Cardiac cycle, cardiac output and ECG **Digestion and Absorption** Human alimentary canal and digestive glands Role of digestive enzymes Digestion, absorption and assimilation of digested food **Breathing and respiration** Human respiratory system Mechanism of breathing and its regulation Exchange of gases, transport of gases and regulation of respiration Respiratory volumes	7
3	**Excretory products and their elimination** Modes of excretion Human excretory system- structure and function Urine formation Rennin angiotensin system **Neural control and coordination** Definition and classification of nervous system Structure of a neuron Generation and conduction of nerve impulse Structure of brain and spinal cord Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata **Chemical coordination and regulation** Endocrine glands and their secretions Functions of hormones secreted by endocrine glands **Human reproduction** Parts of female reproductive system	7

	Parts of male reproductive system Spermatogenesis and Oogenesis Menstrual cycle	
4	**Plants and mineral nutrition:** Essential mineral, macro and micronutrients Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation **Photosynthesis** Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.	5
5	**Plant respiration:**Respiration, glycolysis, fermentation (anaerobic). **Plant growth and development** Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators **Cell - The unit of life** Structure and functions of cell and cell organelles.Cell division **Tissues** Definition, types of tissues, location and functions.	4

Text Books

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

Practical

1. Introduction to experiments in biology a) Study of Microscope b)
Section cutting techniques c) Mounting and staining
d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root
Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: I

Subject Name: REMEDIAL MATHEMATICS
Subject Code: BP107TT

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Sr No	Course Contents	Total Hrs
1	**Partial fraction** Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics **Logarithms** Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems **Function***:* Real Valued function, Classification of real valued functions, **Limits and continuity** : Introduction , Limit of a function, Definition of limit of a function $(\in - \delta$ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1,$	6
2	**Matrices and Determinant:** Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving Pharmacokinetic equations	6
3	**Calculus: Differentiation** : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of *xn w.r.t*x,where *n* is any rational number, Derivative of *ex*,, Derivative of loge *x* , Derivative of *ax*,Derivative of trigonometric functions from first principles **(without Proof)**, Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application	6
4	**Analytical Geometry** **Introduction:** Signs of the Coordinates, Distance formula, **Straight Line** : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line **Integration:** Introduction, Definition, Standard formulae, Rules of integration , Method of	6

	substitution, Method of Partial fractions, Integration by parts, definite integrals, application	
5	**Differential Equations** : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations** **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**	6

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: II

Subject Name: Human Anatomy and Physiology II
Subject Code: BP201TP

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy

Objectives: Upon completion of the course student shall be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Sr No	Topics	% weightage
1.	**Nervous system:** Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid.structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts,reflex activity)	10
2.	**Digestive system** Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT **Energetics:** Formation and role of ATP, Creatinine Phosphate and BMR.	6
3.	**Respiratory system** Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods **Urinary system** Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine	10

	formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney	
4.	**Endocrine system** Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.	10
5.	**Reproductive system** Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition. **Introduction to genetics** Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance	9

Practical

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject**.**

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism
11. Determination of tidal volume and vital capacity
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens
13. Recording of basal mass index
14. Study of family planning devices and pregnancy diagnosis test
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A

6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkat

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: II

Subject Name: Pharmaceutical Organic Chemistry I
Subject Code: BP202TP

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

Sr No	Topics	% weightage
1.	**Classification, nomenclature and isomerism:** Classification of Organic Compounds Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds) Structural isomerisms in organic compounds	7
2.	**Alkanes*, Alkenes* and Conjugated dienes*:** SP hybridization in alkanes, Halogenation of alkanes, uses of paraffins, Stabilities of alkenes, SP hybridization in alkenes, E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation. Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement	10
3.	**Alkyl halides*:** SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform **Alcohols*-** Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol	10
4.	**Carbonyl compounds* (Aldehydes and ketones):** Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde,	10

	Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde	
5.	**Carboxylic acids*:** Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids ,amide and ester Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid **Aliphatic amines* -** Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine	8

Systematic qualitative analysis of unknown organic compounds like:

1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc
2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
3. Solubility test
4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides
5. Melting point/Boiling point of organic compounds
6. Identification of the unknown compound from the literature using melting point/ boiling point
7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point
8. Minimum 5 unknown organic compounds to be analysed systematically
9. Preparation of suitable solid derivatives from organic compounds
10. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: II

Subject Name: Pharmaceutical Engineering
Subject Code: BP203TP

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course the student shall be able to

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries

Sr No	Topics	% weightage
1.	**Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer. **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill. **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank	10
2.	**Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation	10
3.	**Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon	8

	blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier	
4.	**Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.	8
5.	**Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.	7

Recommended Books (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition

Practical:

1. Determination of radiation constant of brass, iron, unpainted and painted glass
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient by heat exchanger
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method
7. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier
8. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic andlogarithmic probability plots
9. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill
10. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment
11. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
12. To study the effect of time on the Rate of Crystallization.
13. To calculate the uniformity Index for given sample by using Double Cone Blender

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: II

Subject Name: Computer Applications in Pharmacy
Subject Code: BP204TP

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Sr No	Topics	% weightage
1.	**Number system**: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division **Concept of Information Systems and Software : I**nformation gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project	6
2.	**Web technologies**:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products. Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database	6
3.	**Application of computers in Pharmacy –** Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System	6
4.	**Bioinformatics:** Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery	6
5.	**Computers as data analysis in Preclinical development**: Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)	6

Practical List:

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools

4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended Books (Latest Editions)

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: II

Subject Name: Environmental Sciences
Subject Code: BP205TT

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature

Sr No	Topics	% weightage
1.	The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources: Natural resources and associated problems Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources	10
2.	Ecosystems: Concept of an ecosystem. Structure and function of an ecosystem. Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)	10
3.	Environmental Pollution: Air pollution; Water pollution; Soil pollution	10

Recommended Books (Latest Editions)

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: Pharmaceutical Organic Chemistry II
Subject Code: BP301TP

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. Write the structure, name and the type of isomerism of the organic compound
2. Write the reaction, name the reaction and orientation of reactions
3. Account for reactivity/stability of compounds,
4. Prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

Sr No	Topics	% weightage
1.	**Benzene and its derivatives:** • Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule • Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation. • Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction • Structure and uses of DDT, Saccharin, BHC and Chloramine	10
2.	**Phenols*:** Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols **Aromatic Amines*:** Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts **Aromatic Acids*:** Acidity, effect of substituents on acidity and important reactions of benzoic acid.	10
3.	**Fats and Oils:** • Fatty acids – reactions. • Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils. • Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.	10
4.	**Polynuclear hydrocarbons:**	8

	• Synthesis, reactions • Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives	
5.	**Cyclo alkanes*:** • Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only	7

Practical

Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- P-Iodo benzoic acid from P-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: PHYSICAL PHARMACEUTICS-I
Subject Code: BP302TP

Scope: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Sr No	Topics	% weightage
1.	**Solubility of drugs:** Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications	10
2.	**States of Matter and properties of matter:** State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols– inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism. **Physicochemical properties of drug molecules:** Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications	10
3.	**Surface and interfacial phenomenon:** Liquid interface, surface & interfacial tensions,surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.	8
4.	**Complexation and protein binding:** Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.	8
5.	**pH, buffers and Isotonic solutions:** Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.	7

Practical

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: BIOCHEMISTRY
Subject Code: BP303TP

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shell able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Sr No	Topics	% weightage
1.	**Biomolecules:** Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins. **Bioenergetics:** Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential. Energy rich compounds; classification; biological significances of ATP and cyclic AMP	8
2.	**Carbohydrate metabolism:** Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance Hormonal regulation of blood glucose level and Diabetes mellitus **Biological oxidation:** Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate level phosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers	10
3.	**Lipid metabolism:** β-Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid) Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.	10

	Amino acid metabolism: General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia) Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyperbilirubinemia and jaundice	
4.	**Nucleic acid metabolism and genetic information transfer** Biosynthesis of purine and pyrimidine nucleotides Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome Structure of DNA and RNA and their functions DNA replication (semi conservative model) Transcription or RNA synthesis Genetic code, Translation or Protein synthesis and inhibitors	10
5.	**Enzymes:** Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics (Michaelis plot, Line Weaver Burke plot) Enzyme inhibitors with examples Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions	7

Practical

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: PATHOPHYSIOLOGY
Subject Code: BP304TT

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Sr No	Topics	% weightage
1.	**Basic principles of Cell injury and Adaptation:** Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage),Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis, Electrolyte **Mechanism involved in the process of inflammation and repair:** Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis	10
2.	**Cardiovascular System:** Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis) **Respiratory system:**Asthma, Chronic obstructive airways diseases. **Renal system:**Acute and chronic renal failure	10
3.	**Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.	10
4.	**Gastrointestinal system:** Peptic Ulcer , Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout **Principles of cancer:** classification, etiology and pathogenesis of cancer	8
5.	**Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections **Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhea	7

Recommended Books (Latest Editions):

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore;1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey;
9. Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
10. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
11. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals:

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: PHARMACOGNOSY AND PHYTOCHEMISTRY I
Subject Code: BP305TP

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Course Learning Outcomes: Upon completion of the course, the student shall be able

1. to understand the techniques in the cultivation and production of crude drugs
2. to describe the crude drugs, their uses and chemical nature
3. to explain the evaluation techniques for the herbal drugs
4. to analyse the microscopic and morphological evaluation of crude drugs

Sr No	Topics	% weightage
1.	**Introduction to Pharmacognosy:** (a) Definition, history, scope and development of Pharmacognosy (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins). **Classification of drugs:** Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs **Quality control of Drugs of Natural Origin:** Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.	10
2.	**Cultivation, Collection, Processing and Storage of Drugs of Natural Origin:** Cultivation and Collection of drugs of natural origin Factors influencing cultivation of medicinal plants. Plant hormones and their applications. Polyploidy, mutation and hybridization with reference to medicinal plants **Conservation of Medicinal Plants**	10
3.	**Plant Tissue Culture:** Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance. Applications of plant tissue culture in pharmacognosy. Edible vaccines	7
4.	**Pharmacognosy in various systems of medicine:** Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine. **Introduction to secondary metabolites:** Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins	10
5.	Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs	8

	Plant Products: Fibers - Cotton, Jute, Hemp Hallucinogens, Teratogens, Natural allergens **Primary metabolites:** General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites: **Carbohydrates:** Acacia, Agar, Tragacanth, Honey, Starch, Sodium alginate, Pectin, Guar gum **Proteins and Enzymes :** Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin). **Lipids(Waxes, fats, fixed oils)** : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax **Marine Drugs:** Novel medicinal agents from marine sources	

Practical

1. Analysis of crude drugs by chemical tests: **(**i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and paliside ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions):

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. T.E. Wallis, Textbook of Pharmacognosy, 5th edition, CBS Publishers & Distributors, New Delhi, 2005
4. Mohammad Ali. Pharmacognosy, CBS Publishers & Distributors, New Delhi 2008
5. C.K. Kokate, Purohit, Gokhlae. Text book of Pharmacognosy, Gokhlae (2007), 37th Edition, Nirali Prakashan, Pune, 2007
6. R.D. Choudhary, Herbal Drug Industry Ist Edn, Eastern Publisher, New Delhi, 1996
7. SH.Ansari, Essentials of Pharmacognosy, IInd edition, Birla publications, New Delhi, 2007
8. C.K. Kokate, Practical Pharmacognosy, 5th edition, Vallabh Prakashan, New Delhi, 2016.
9. M.A. Iyengar, Anatomy of Crude Drugs, Manipal Press, Manipal, 2001.
10. Biren Shah & A. K. Seth, Textbook of Pharmacognosy & Phytochemistry, 2nd edition, Elsevier Publication, New Delhi, 2011.
11. Khandelwal K. R. Practical Pharmacognosy, 9th edition, Nirali Prakashan, Pune, 2009
12. Agrawal S.S., Herbal Drug Technology, 2nd edition, Orient Blackswan, New Delhi, 2012.
13. Vyas S. P. and Dixit V. K., Pharmaceutical Biotechnology, 1st edition, CBS Publisher & Distributors, New Delhi, 2016.
14. WHO: Quality Control Methods for Medicinal Plant Materials, World Health ORganisation, Geneva, 1988.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP401TT

SEMESTER: IV

Subject Name: Pharmaceutical Organic Chemistry III

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: Upon completion of the course the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Stereo isomerism** Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers Reactions of chiral molecules Racemic modification and resolution of racemic mixture. Asymmetric synthesis: partial and absolute	10
2.	Geometrical isomerism Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) Methods of determination of configuration of geometrical isomers. Conformational isomerism in Ethane, n-Butane and Cyclohexane. Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. Stereospecific and stereoselective reactions	10
3.	**Heterocyclic compounds:** Nomenclature and classification Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene	10
4.	Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives	8
5.	**Reactions of synthetic importance** Metal hydride reduction (NaBH4 and LiAlH4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement.	7

	Claisen-Schmidt condensation	

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry byMorrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP402TP
SEMESTER: IV
Subject Name: Medicinal Chemistry I

Scope: This subject is designed to impart fundamental knowledge on the structure chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Course Content:
Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selectiveclass of drugs as specified in the course and synthesis of drugs superscripted (*)

Sr No	Topics	% weightage
1.	**Introduction to Medicinal Chemistry** **History and development of medicinal chemistry** **Physicochemical properties in relation to biological action** Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism. **Drug metabolism** Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects	10
2.	**Drugs acting on Autonomic Nervous System** **Adrenergic Neurotransmitters:** Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution. **Sympathomimetic agents: SAR of Sympathomimetic agents** Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline. Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine. Agents with mixed mechanism: Ephedrine, Metaraminol. **Adrenergic Antagonists:** **Alpha adrenergic blockers:** Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide. **Beta adrenergic blockers:** SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.	10
3.	**Cholinergic neurotransmitters:**	10

	Biosynthesis and catabolism of acetylcholine. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution. **Parasympathomimetic agents: SAR of Parasympathomimetic agents** **Direct acting agents:** Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine. **Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):** Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion. **Cholinesterase reactivator:** Pralidoxime chloride. **Cholinergic Blocking agents: SAR of cholinolytic agents** **Solanaceous alkaloids and analogues:** Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*. **Synthetic cholinergic blocking agents:** Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.	
4.	**Drugs acting on Central Nervous System** **A. Sedatives and Hypnotics:** **Benzodiazepines:** SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem **Barbiturtes:** SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital **Miscelleneous:** Amides & imides: Glutethmide. Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol. Aldehyde & their derivatives: Triclofos sodium, Paraldehyde. **B. Antipsychotics** **Phenothiazeines:** SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride. **Ring Analogues of Phenothiazeines:** Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine. **Fluro buterophenones:** Haloperidol, Droperidol, Risperidone. **Beta amino ketones:** Molindone hydrochloride. **Benzamides:** Sulpieride. **C. Anticonvulsants:** SAR of Anticonvulsants**,** mechanism of anticonvulsant action **Barbiturates**: Phenobarbitone, Methabarbital. **Hydantoins:** Phenytoin*, Mephenytoin, Ethotoin **Oxazolidine diones:** Trimethadione, Paramethadione **Succinimides:** Phensuximide, Methsuximide, Ethosuximide* **Urea and monoacylureas**: Phenacemide, Carbamazepine* **Benzodiazepines**: Clonazepam **Miscellaneous:** Primidone, Valproic acid , Gabapentin, Felbamate	8
5.	**Drugs acting on Central Nervous System** **General anesthetics:** **Inhalation anesthetics:** Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. **Ultra short acting barbitutrates:** Methohexital sodium*, Thiamylal	7

	sodium, Thiopental sodium. **Dissociative anesthetics:** Ketamine hydrochloride.* **Narcotic and non-narcotic analgesics** **Morphine and related drugs:** SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate. **Narcotic antagonists:** Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride. **Anti-inflammatory agents:** Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.	

MEDICINAL CHEMISTRY – I (Practical)

I Preparation of drugs/ intermediates

1 1,3-pyrazole
2 1,3-oxazole
3 Benzimidazole
4 Benztriazole
5 2,3- diphenyl quinoxaline
6 Benzocaine
7 Phenytoin
8 Phenothiazine
9 Barbiturate

II Assay of drugs

1 Chlorpromazine
2 Phenobarbitone
3 Atropine
4 Ibuprofen
5 Aspirin
6 Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP403TP
SEMESTER: IV
Subject Name: Physical Pharmaceutics II

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon completion of the course the student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Course Content:

Sr No	Topics	% weightage
1.	**Colloidal dispersions:** Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization& protective action	7
2.	**Rheology:** Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers **Deformation of solids:** Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus	10
3.	**Coarse dispersion:** Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method	10
4.	**Micromeretics:** Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.	10
5.	**Drug stability:** Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents	10

	against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention	

PHYSICAL PHARMACEUTICS- II (Practical)

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of
1. single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP404TP
SEMESTER: IV
Subject Name: PHARMACOLOGY-I

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of the course the student shall be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Course Content:

Sr No	Topics	% weightage
1.	**General Pharmacology** **a.** Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and noncompetitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy. **b.** Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination	8
2.	**General Pharmacology** a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. b. Adverse drug reactions. c. Drug interactions (pharmacokinetic and pharmacodynamic) d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.	12
3.	**Pharmacology of drugs acting on peripheral nervous system** a. Organization and function of ANS. b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.	10

	c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics. d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). e. Local anesthetic agents. f. Drugs used in myasthenia gravis and glaucoma	
4.	**Pharmacology of drugs acting on central nervous system** a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine. b. General anesthetics and pre-anesthetics**.** c. Sedatives, hypnotics and centrally acting muscle relaxants. d. Anti-epileptics e. Alcohols and disulfiram	8
5.	**Pharmacology of drugs acting on central nervous system** a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens. b. Drugs used in Parkinsons disease and Alzheimer's disease. c. CNS stimulants and nootropics. d. Opioid analgesics and antagonists e. Drug addiction, drug abuse, tolerance and dependence.	7

PHYSICAL PHARMACEUTICS- II (Practical)

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs byMES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,.Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews PharmacologyPhysical Pharmaceutics by Ramasamy C, and Manavalan R.

6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP405TT
SEMESTER: IV
Subject Name: PHARMACEUTICAL JURISPRUDENCE

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India

Objectives: Upon completion of the course the student shall be able to

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Course Content:

Sr No	Topics	% weightage
1.	**Drugs and Cosmetics Act, 1940 and its rules 1945:** Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.	10
2.	**Drugs and Cosmetics Act, 1940 and its rules 1945.** Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors	10
3.	• **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and Penalties • **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.	10

	• **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties	
4.	• **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties • **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties • **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of EssentialMedicines (NLEM)	8
5.	• **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee • **Code of Pharmaceutical ethics** D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath • **Medical Termination of Pregnancy Act** • **Right to Information Act** • **Introduction to Intellectual Property Rights (IPR)**	7

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh 123
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-byM.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP501TT

SEMESTER: V

Subject Name: Medicinal Chemistry II

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Antihistaminic agents:** Histamine, receptors and their distribution in the human body **H1–antagonists:** Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium **H2-antagonists:** Cimetidine*, Famotidine, Ranitidin **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole **Anti-neoplastic agents:** **Alkylating agents:** Meclorethamine*, Cyclophosphamide, Melphalan Chlorambucil, Busulfan, Thiotepa **Antimetabolites:** Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine **Antibiotics:** Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin **Plant products:** Etoposide, Vinblastin sulphate, Vincristin sulphate **Miscellaneous:** Cisplatin, Mitotane	10
2.	**Anti-anginal**: **Vasodilators:** Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole **Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. **Diuretics:** Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide,	10

	Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride. Osmotic Diuretics: Mannitol **Anti-hypertensive Agents**: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide,Minoxidil, Reserpine, Hydralazine hydrochloride.	
3.	**Anti-arrhythmic Drugs**: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol. **Anti-hyperlipidemic agents**: Clofibrate, Lovastatin, Cholesteramine and Cholestipol **Coagulant & Anticoagulants**: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel **Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.	10
4.	**Drugs acting on Endocrine system** Nomenclature, Stereochemistry and metabolism of steroids **Sex hormones**: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol. **Drugs for erectile dysfunction:** Sildenafil, Tadalafil. **Oral contraceptives:** Mifepristone, Norgestril, Levonorgestrol **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone **Thyroid and antithyroid drugs**: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.	8
5.	**Antidiabetic agents:** Insulin and its preparations Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin. Thiazolidinediones: Pioglitazone, Rosiglitazone. Meglitinides: Repaglinide, Nateglinide. Glucosidase inhibitors: Acrabose, Voglibose. **Local Anesthetics:** SAR of Local anesthetics **Benzoic Acid derivatives**; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine. **Amino Benzoic acid derivatives**: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate. **Lidocaine/Anilide derivatives**: Lignocaine, Mepivacaine, Prilocaine, Etidocaine. **Miscellaneous**: Phenacaine, Diperodon, Dibucaine.*	7

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP502TP
SEMESTER: V
Subject Name: Pharmacology II

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition,emphasis on the basic concepts of bioassay.

Objectives: Upon completion of the course the student shall be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**Pharmacology of drugs acting on cardio vascular system** a. Introduction to hemodynamic and electrophysiology of heart. b. Drugs used in congestive heart failure c. Anti-hypertensive drugs. d. Anti-anginal drugs. e. Anti-arrhythmic drugs. f. Anti-hyperlipidemic drugs.	10
2.	**Pharmacology of drugs acting on cardio vascular system** a. Drug used in the therapy of shock. b. Hematinics, coagulants and anticoagulants. c. Fibrinolytics and anti-platelet drugs d. Plasma volume expanders **2. Pharmacology of drugs acting on urinary system** a. Diuretics b. Anti-diuretics.	10
3.	**Autocoids and related drugs** a. Introduction to autacoids and classification b. Histamine, 5-HT and their antagonists. c. Prostaglandins, Thromboxanes and Leukotrienes. d. Angiotensin, Bradykinin and Substance P. e. Non-steroidal anti-inflammatory agents f. Anti-gout drugs g. Antirheumatic drugs	10
4.	**Pharmacology of drugs acting on endocrine system** a. Basic concepts in endocrine pharmacology. b. Anterior Pituitary hormones- analogues and their inhibitors. c. Thyroid hormones- analogues and their inhibitors. d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.	8

	d. Insulin, Oral Hypoglycemic agents and glucagon. e. ACTH and corticosteroids.	
5.	**Pharmacology of drugs acting on endocrine system** a. Androgens and Anabolic steroids. b. Estrogens, progesterone and oral contraceptives. c. Drugs acting on the uterus **Bioassay** a. Principles and applications of bioassay. b.Types of bioassay c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT	7

Practical

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus
1. abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP503TP

SEMESTER: V

Subject Name: Pharmacognosy and Phytochemistry II

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine.

Objectives: Upon completion of the course the student shall be able to

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents
5.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**Metabolic pathways in higher plants and their determination** a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway. b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.	7
2.	General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites: **Alkaloids:** Vinca, Rauwolfia, Belladonna, Opium, **Phenylpropanoids and Flavonoids:** Lignans, Tea, Ruta **Steroids, Cardiac Glycosides & Triterpenoids**: Liquorice, Dioscorea, Digitalis **Volatile oils**: Mentha, Clove, Cinnamon, Fennel, Coriander, **Tannins:** Catechu, Pterocarpus **Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony **Glycosides:** Senna, Aloes, Bitter Almond **Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids	14
3.	Isolation, Identification and Analysis of Phytoconstituents a) Terpenoids: Menthol, Citral, Artemisin b) Glycosides: Glycyrhetinic acid & Rutin c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine d) Resins: Podophyllotoxin, Curcumin	6
4.	Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine	10

5.	**Basics of Phytochemistry** Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.	8

Practical List:

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
    a. Caffeine - from tea dust.
    b. Diosgenin from Dioscorea
    c. Atropine from Belladonna
    d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: **(**i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP504TP

SEMESTER: V

Subject Name: Pharmaceutical Microbiology

Scope: Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc...

Objectives: Upon completion of the course the student shall be able to

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterlization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes : Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy	10
2.	Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC). Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous,radiation and mechanical method of sterilization. Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. Sterility indicators.	10
3.	Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses. Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions. Evaluation of bactericidal & Bacteriostatic. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.	10
4.	Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.	8
5.	Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.	7

	Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.	

Practical List

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Recommended books: (Latest Edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP505TT

SEMESTER: V

Subject Name: Pharmaceutical Biotechnology

Scope:

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technologymakes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

Objectives: Upon completion of the course the student shall be able to

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences. b) Enzyme Biotechnology- Methods of enzyme immobilization and applications. c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries. d) Brief introduction to Protein Engineering. e) Use of microbes in industry. Production of Enzymes- General consideration -Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase. f) Basic principles of genetic engineering.	10
2.	a) Study of cloning vectors, restriction endonucleases and DNA ligase. b) Recombinant DNA technology. Application of genetic engineering in medicine. c) Application of r DNA technology and genetic engineering in the production of:i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin. d) Brief introduction to PCR	10
3.	Types of immunity- humoral immunity, cellular immunity a) Structure of Immunoglobulins b) Structure and Function of MHC c) Hypersensitivity reactions, Immune stimulation and Immune suppressions. d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine,antitoxins, serum-immune blood derivatives and other products relative to immunity. e) Storage conditions and stability of official vaccines	10

	f) Hybridoma technology- Production, Purification and Applications g) Blood products and Plasma Substituties.	
4.	a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting. b) Genetic organization of Eukaryotes and Prokaryotes c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons. d) Introduction to Microbial biotransformation and applications. **e)** Mutation: Types of mutation/mutants.	8
5.	a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring. b) Large scale production fermenter design and its various controls. c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.	7

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP506TP

SEMESTER: V

Subject Name: Contributor Personality Development Program

Scope: Improve the employability of students by giving them the right work ethic and thinking that employers are looking for.

- Build their confidence with which they can go into any job and contribute meaningfully.
- Improve their ability to engage better in the workplace and to be able to handle the challenges that come up there.
- Build their career-worthiness and help them develop into future-ready contributors with ability to navigate a career in a volatile, changing world.
- Widen their choices of career and success, so that they are able to open up more opportunities for themselves and take up unconventional career pathways.
- Enable them to recognize how they, as technical professionals, can participate and make a positive contribution to their communities and to their state.

Towards this goal, the Contributor Program has been designed to awaken and strengthen students from within, in terms of building positive self-esteem, increasing their confidence level and I-can attitude, improving their aspirations, giving them new methods of thinking, building their cognitive capacities, exposing them to the skills and practices associated with being contributors in the workplace (not mere employees).

The Program content is also designed to expose students to real-world workplace scenarios and sensitize them to some of the challenges faced in society around them, especially in the local communities around them and in their own state of Gujarat.

The Contributor Program syllabus has been evolved and fine-tuned over several years, (a) to address the changing need and contemporary challenges being faced by industry and what employers of today are looking for in the people they hire and (b) by working extensively with universities and students building an appreciation of their challenges and concerns. At the core, the program is guided by the higher ideas and principles of practical Vedanta in work.

Sr. No.	CO statement	Marks % weightage
Outcome of theory sessions		
CO-1	Students will be able to recognize & appreciate two alternative ideals of work – ideal of a "worker" and ideal of a "contributor". And why organizations of today expect people they employ to be contributors and not just workers.	10-12%
CO-2	Students will be able to recognize & appreciate alternative ways in which they could define themselves or "who am I" (their identity) – and which are positive identities that will lead to building intrinsic self-esteem and confidence in oneself; in contrast to identities that will lead to extrinsic self-esteem that makes them more dependent on their environment.	10-12%
CO-3	Students will be able to recognize & appreciate a "victim" stance as distinct from a "creator of destiny" stance in the way people approach challenges and situations; and how the latter frees individuals to take on challenges and open up opportunities.	10-12%
CO-4	Students will be able to differentiate between two alternative approaches to success - 'building one's engine of success' and 'chasing the fruits of success'; they also appreciate the payoffs/ consequences of both and which is more likely to lead to sustainable or lasting success in the long run.	10-12%
CO-5	Students will be able to recognize & appreciate different career models and their value; to help them make more informed career-related choices.	10-12%
CO-6	Students will be able to recognize & appreciate how one can expand the contribution possible in any role, thereby opening up an alternative way of career growth to them.	10-12%
Outcome of practical sessions		
CO-7	Students learn to re-interpret their life and college experiences to showcase their contribution affinities which are relevant for employers.	15%
CO-8	Students learn to apply contributor thinking to real-world or career relevant challenges.	15%

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	0	0	4	80	20	30	20

Sr No	Topics	% weightage
1	**The Contributor Work Ideal** In this topic, students explore what is their "ideal" of work - is the ideal to be a "worker" or to be a "contributor"? For example, an employee who has the ideal of a "worker" goes to work to pass time, earn a living, get benefits; in contrast to an employee with the ideal of a "contributor" who wants to make a difference, get things done well, create value for the company. This enables students to transform their expectation of themselves in work	1.5 hrs Classroom engagement (including self-discovery/ solutioning sessions)

2	**Identity & Self-esteem** In this topic, students engage with the question "who am I?" or on what basis do they define themselves. Is their identity defined by what others think of them (extrinsic self-esteem) or by what they think of themselves (intrinsic self-esteem)? Further, they discover positive identities that lead to intrinsic self-esteem, such as an I-can identity based on one's capacity and inner strength. This enables them to build confidence and self-esteem.	Same as above
3	**Become a Creator of one's destiny** In a "victim stance", we see the career environment as full of difficulties and hurdles. We feel powerless or blame our circumstances for not having many opportunities. This makes us fearful of uncertainty and makes us settle for jobs where we remain mediocre. In this topic, students discover the "creator of destiny stance" to challenges and situations. This stance frees them to try out new things, open up new possibilities, take on responsibility, see the opportunity hidden in their environment.	Same as above
4	**Achieving Sustainable Success** In this topic, students discover how to achieve sustainable or lasting success, by building one's "engine of success", making them success-worthy. Where their focus shifts to building one's "engine of success" rather than being on chasing the "fruits of success". This is important, because over a lifetime of work, all people go through ups and downs – where the fruits are not in their control. People who are focused on the fruits of success, fall prey to disappointment, loss in motivation, quitting too early, trying to find shortcuts – when fruits don't come. Whereas people focused on building their engine of success continue to contribute steadily, irrespective of whether fruits come or not. And with a strong engine of success, fruits come to them in time.	Same as above
5	**Career Development Models** In this topic, students explore a range of diverse "career development models" and the possibilities for contribution each opens up to them (e.g. start-up career model, change-maker career model, etc.). This opens their mind to different and even unconventional career models possible, beyond the usual (such as "stable large company career model" where one gets an engineering degree, then MBA, then get a job in a large company). This frees them from a herd mentality when making career choices.	Same as above
6	**Expanding contribution in every role** In this topic, students explore the many roles they can play in their life & discover the power they have to expand the contribution possible in any role. (E.g. role of student, role of manager, role of a project site engineer). So, the potential of a role is in the individual's hands. This opens their mind to an alternative way of career growth.	Same as above
7	**Finding Solutions** The market environment in which organizations are operating, is becoming increasingly dynamic and uncertain. So, employers are increasingly seeking out people who can innovate and figure out solutions in the face of any challenge (unlike in the past when it was the people who were most efficient and productive, who were valued by organizations). At the heart of innovation lies this way of thinking of "finding solutions" rather than "seeing problems or roadblocks". Students learn how to build this way of thinking, in this topic.	1.5 hrs Classroom engagement (including self-discovery/ solutioning sessions)
8	**Creating Value**	Same as above

	Companies are also looking for employees who do not just work hard, or work efficiently or productively - but those who will make a valuable difference to the fortunes of the company. This difference may come from innovation, but it may also come from focusing on the right things and identifying what really matters – both to the company and to the customers. In this topic, students learn how to build this capability.	
9	**Engaging deeply** The environment we live in is becoming increasingly complex because more and more things are getting interconnected, new fields are emerging, technologies are rapidly changing, capabilities and knowledge one is trained in will become fast obsolete. In such a scenario, the student's ability to quickly understand and master what is going on, dive deep, get involved in any area, rapidly learn new capabilities that a job demands, is important. Engaging deeply is a core way of thinking that can help them in this. In this topic, students learn how to engage deeply.	Same as above
10	**Enlightened self-interest & collaboration at work** The changing nature of work in organizations and in the global environment is increasingly demanding that people work more collaboratively towards shared goals and more sustainable goals. A key to working successfully when multiple stakeholders are involved is "thinking in enlightened self-interest". In this topic, students learn how to develop this way of thinking (going beyond "narrow self-interest").	Same as above
11	**Human-centered thinking & Empathy** In this topic, students explore a human-centric approach to work – where the ability to recognize and respond to other people (whether they are users or customers or team members) as a human being with human needs and difficulties, is essential. This is at the heart of user-centric design of products and solutions, at the heart of genuine customer-centricity in services, and of any successful interaction with other people.	Same as above
12	**Trust Conduct** The biggest currency in a sustainable career is "trust" i.e. being trusted by team members, bosses, and customers. When we are trusted, people listen to us, they are willing to give us the chance to grow, give us the space to make mistakes, and work seamlessly with each other without always having to "prove ourselves". In this topic, students learn how to demonstrate conduct that builds the trust of people.	Same as above

A. Basic reference for both students and teachers

1. Contributor Personality Program textbook cum workbook developed by Illumine
2. Web-based ActivGuide™ for self-exploration of rich media resources to vividly understand many of the ideas, watch role models, learn from industry people, get reference readings – that help them enrich the understanding they gained in the class published by Illumine Foundation

B. Advanced reference for teachers

1. On Contributors, Srinivas V.; Illumine Ideas, 2011
2. Enlightened Citizenship and Democracy; Swami Ranganathananda, Bharatiya Vidya Bhavan, 1989

3. Eternal Values for a Changing Society – Vol I-IV, Swami Ranganathananda; Bharatiya Vidya Bhavan
4. Karma Yoga, Swami Vivekananda; Advaita Ashrama
5. Vivekananda: His Call to the Nation, Swami Vivekananda; Advaita Ashrama
6. Six Pillars of Self Esteem, Nathaniel Branden; Bantam, 1995
7. Mindset: The New Psychology of Success, Carol S. Dweck; Random House Publishing Group, 2007
8. Lasting Contribution: How to Think, Plan, and Act to Accomplish Meaningful Work, Tad Waddington; Agate Publishing, 2007
9. Why not?: how to use everyday ingenuity to solve problems big and small, Barry Nalebuff, Ian Ayres; Harvard Business School Press, 2003
10. The value mindset: returning to the first principles of capitalist enterprise (Ch 8 & 9); Erik Stern, Mike Hutchinson; John Wiley and Sons, 2004
11. The Power of Full Engagement: Managing Energy, Not Time, is the Key to High Performance and Personal Renewal, Jim Loehr, Tony Schwartz; Simon and Schuster, 2003
12. Creating Shared Value, Michael E. Porter and Mark R. Kramer; Harvard Business Review; Jan/Feb2011, Vol. 89 Issue 1/2
13. The Speed of Trust: The One Thing That Changes Everything, Stephen M. R. Covey, Rebecca R. Merrill, Stephen R. Covey; Free Press, 2008
14. The Courage to Meet the Demands of Reality, Henry Cloud; HarperCollins, 2009
15. Responsibility at work: how leading professionals act (or don't act) responsibly, Howard Gardner; John Wiley & Sons, 2007

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP507TP

SEMESTER: V

Subject Name: Integrated Personality Development Course

Scope: IPDC aims to prepare students for the modern challenges they face in their daily lives. Promoting fortitude in the face of failures, unity amongst family discord, self-discipline amidst distractions, and many more priceless lessons. The course focuses on morality and character development at the core of student growth, to enable students to become self-aware, sincere, and successful in their many roles - as an ambitious student, reliable employee, caring family member, and considerate citizen.

Objectives: Upon completion of the course the student shall be able to

1. To provide students with a holistic value-based education that will enable them to be successful in their academic, professional, and social lives.
2. To give the students the tools to develop effective habits, promote personal growth, and improve their wellbeing, stability, and productivity.
3. To allow students to establish a stronger connection with their family through critical thinking and devolvement of qualities such as unity, forgiveness, empathy, and effective communication.
4. To provide students with soft skills that complement their hard skills, making them more marketable when entering the workforce.
5. To enhance awareness of India's glory and global values, and to create considerate citizens who strive for the betterment of their family, college, workforce, and nation.
6. To inspire students to strive for a higher sense of character by learning from role models who have lived principled, disciplined, and value-based lives.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
4	0	0	4	80	20	30	20

Course-Content :

Each lecture can be taken in a continuous two-hour session, or in two separate one-hour sessions. In addition to the core lectures, an induction and concluding lectures are recommended as shown in the below table.

Lecture No.	Module -Lecture	Lecture Description	% Weightage
Induction	The Need for Values	Students will learn about the need for values as part of their holistic development to become successful in their many roles - as ambitious students, reliable employees, caring family members, and considerate citizens.	2
1	**Remaking Yourself** Restructuring Yourself	Students learn how self-improvement enables them to secure a bright future for themselves. They will learn 6 powerful thought-processes that can develop their intellectual, physical, emotional, and spiritual quotients.	2
2	**Remaking Yourself** - Power of Habit	Students will undergo a study of how habits work, the habits of successful professionals, and the practical techniques that can be used to develop good habits in their life.	2

3	**Learning from Legends-** Tendulkar & Tata	Students will learn from the inspirational lives of India's two legends, Sachin Tendulkar and Ratan Tata. They will implement these lessons through relatable case studies.	2
4	**From House to Home-** Listening & Understanding	Active listening is an essential part of academic progress and communications. Students will learn to listen with their eyes, ears, mind, and heart.	2
5	**Facing Failures-** Welcoming Challenges	This lecture enables students to revisit the way in which they approach challenges. Through the study of successful figures such as Disney, Lincoln and Bachchan, students will learn to face difficulties through a positive perspective.	2
6	**Facing Failures-** Significance of Failures	Failure is a student's daily source of fear, negativity, and depression. Students will be given the constructive skills to understand failure as formative learning experiences.	2
7	**My India My Pride-** Glorious Past - Part 1	India's ancient Rishis, scholars, and intellectuals have made tremendous contributions to the world, they developed an advanced, sophisticated culture and civilization which began thousands of years ago. Students will learn the importance of studying India's glorious past so that they could develop a strong passion and pride for our nation.	2
8	**My India My Pride-** Glorious Past - Part 2	Our ancient concepts can be used to seek revolutionary ideas and to generate inspiration. Students will develop a deeper interest in India's Glorious Past – by appreciating the need to read about it, research it, write about it, and share it.	2
9	**Learning from Legends-** A.P.J. Abdul Kalam	Dr Kalam's inspirational life displayed legendary qualities which apply to students (1) Dare to Dream (2) Work Hard (3) Get Good Guidance (4) Humility (5) Use Your Talents for the Benefit of Others	2
10	**Soft Skills-** Networking & Leadership	Students are taught the means of building a professional network and developing a leadership attitude.	2
11	**Soft Skills-** Project Management	Students will learn the secrets of project management through the Akshardham case study. They will then practice these skills through an activity relevant to student life.	2
12	**Remaking Yourself-** Handling Social Media	Students will learn how social media can become addictive and they will imbibe simple methods to take back control.	2
13	**Facing Failures-** Power of Faith	Students will learn about the power and necessity of faith in our daily lives.	2
14	**From House to Home-** Bonding the Family	Students will understand the importance of strong family relationships. They will learn how to overcome the generation gap and connect with their family more.	2
15	**Selfless Service-** Seva	Students will learn that performing seva is beneficial to one's health, wellbeing, and happiness. It also benefits and inspires others.	2
16	**Remaking Yourself-** Begin with the End in Mind	Students will learn to visualize their future goals and will structure their lives through smart goals to give themselves direction and ultimately take them to where they want to go.	2

17	**Remaking Yourself-** Being Addiction-Free	Students will explore the detrimental effects of addictions on one's health, personal life, and family life. They will learn how to take control of their life by becoming addiction free.	2
18	**Selfless Service-** Case Study: Disaster Relief	Students will apply previous lessons of seva, to analyse the case study of the Bhuj earthquake relief work.	2
19	**Soft Skills-** Teamwork & Harmony	Students will learn the six steps of teamwork and harmony that are essential for students' professional and daily life.	2
20	**My India My Pride-** Present Scenario	To implement the transformation of India from a developing country into a developed country it is necessary to have a value-based citizen. Students will see how the transformation to a greater India relies on the vision and efforts of themselves as a youth.	2
21	**Learning from Legends-** Leading Without Leading	Students will explore a new approach to leadership, through humility.	2
22	**My India My Pride-** An Ideal Citizen - 1	Students will learn that to become value-based citizens, they must first develop good values in their lives. They start by exploring the values of responsibility and integrity.	2
23	**My India My Pride-** An Ideal Citizen - 2	Students will learn that by developing the values of loyalty, sincerity, and punctuality; they become indispensable and can leave a strong impression. They will start developing these values by trying to keep perfection in every small task and by looking at the bigger picture.	2
24	**Facing Failures** Timeless Wisdom for Daily Life	Students will learn the role wisdom plays in finding long-term stability. They will use ancient wisdom to solve their modern-day challenges.	2
25	**From House to Home-** Forgive & Forget	Students will understand the importance and benefits that forgiveness plays in their personal and professional life. They will learn to apply this knowledge in realistic situations.	2
26	**Remaking Yourself-** Stress Management	Students will learn to cope with current and future causes of stress.	2
27	**Remaking Yourself-** Better Health Better Future	A healthy body prevents disease and stress; increases positivity, productivity, and brainpower. Students will learn to maintain good health through regular exercise, healthy eating habits, and regular and sufficient sleep.	2
28	**Learning from Legends -** Words of Wisdom	A panel of learned and experienced mentors will personally answer practical questions that students face in their daily life.	2
29	**Soft Skills –** Financial Planning	Students will develop a variety of practical financial skills that prepare them to become financially stable throughout their future careers.	2
30	**Remaking Yourself** Impact of Company	Students will understand that the type of company that we keep, has a crucial role in determining who we are and who we will	2

		become. They will develop the ability to create a positive environment around them.	
Concluding	Life After IPDC	This concluding lecture encourages students to keep practising these priceless lessons and prepares them for the next steps in their lives.	2

COURSE MATERIAL / MAIN COURSE WORKBOOK -

1. IPDC Workbook-1 *(presented by B.A.P.S. Swaminarayan Sanstha)*

2. IPDC Workbook-2 *(presented by B.A.P.S. Swaminarayan Sanstha)*

IPDC REFERENCES –
These are the reference material for the IPDC lectures. This is not compulsory reading for the students as the essential information is contained in the workbooks.

Module No.	Module	References
1	Facing Failures	1. Thomas Edison's factory burns down, New York Times Archives, Page 1, 10/12/1914 2. Lincoln Financial Foundation, Abraham Lincoln's "Failures": Critiques, Forgotten Books, 2017 **3. J.K. Rowling Harvard Commencement Speech | Harvard University Commencement, 2008** 4. Born Again on the Mountain: A Story of Losing Everything and Finding It Back, Arunima Sinha, Penguin, 2014 5. Failing Forward: Turning Mistakes Into Stepping Stones for Success, John C. Maxwell, Thomas Nelson, 2007 6. Steve Jobs: The Exclusive Biography Paperback, Walter Isaacson, Abacus, 2015 7. Failing Forward: Turning Mistakes Into Stepping Stones for Success, John C. Maxwell, Thomas Nelson, 2007
2	Learning from Legends	1. Chase Your Dreams: My Autobiography, Sachin Tendulkar, Hachette India, 2017 2. Playing It My Way: My Autobiography, Sachin Tendulkar, Hodder & Stoughton, 2014 3. The Wit and Wisdom of Ratan Tata, Ratan Tata, Hay House, 2018 4. The Tata Group: From Torchbearers to Trailblazers, Shashank Shah, Penguin Portfolio, 2018 5. The Leader Who Had No Title, Robin Sharma, Jaico Publishing House, 2010 6. In the Joy of Others: A Life-Sketch of Pramukh Swami Maharaj, Mohanlal Patel and BAPS Sadhus, Swaminarayan Aksharpith, 2013
3	My India My Pride	1. Rishis, Mystics, and Heroes of India, Sadhu Mukundcharandas, Swaminarayan Aksharpith, 2011 2. Physics in Ancient India, Narayan Dongre, Shankar Nene, National Book Trust, 2016 3. The Rise of Civilization in India and Pakistan, Raymond Allchin, Bridget Allchin, Cambridge University Press, 1982 4. The Āryabhaṭīya of Āryabhaṭa: An Ancient Indian Work on Mathematics and Astronomy (1930), Walter Eugene Clark, University of Chicago Press, reprint, Kessinger Publishing, 2006

4	Remaking Yourself	1. Power of Habit, Charles Duhigg, Random House Trade Paperbacks, 2014 2. Change Your Habit, Change Your Life, Tom Corley, North Loop Books, 2016 3. The Seven Habits of Highly Effective People, Stephen Covey, Simon & Schuster, 2013 4. Seven Habits of Highly Effective Teens, Sean Covey, Simon & Schuster, 2012 5. Atomic Habits, James Clear, Random House, 2018 6. How a handful of tech companies control billions of minds every day, Tristan Harris, TED Talk, 2017
5	From House to Home	1. "What Makes a Good Life? Lessons from the Longest Study on Happiness", R. Waldinger, Ted Talks, 2015 **2. Long Walk To Freedom, Nelson Mandela, Back Bay Books, 1995** 3. Outliers, Malcolm Gladwell, Back Bay Books, 2011
6	Soft Skills	1. The 17 Indisputable Laws of Teamwork, John Maxwell, HarperCollins, 2013 2. Team of Teams: New Rules of Engagement for a Complex World, Stanley McChrystal, Portfolio, 2015 3. Predictably Irrational, Revised and Expanded Edition: The Hidden Forces That Shape Our Decisions, Dan Ariely, Harper Perennial, 2010
7	Selfless Service	1. Open: An Autobiography, Andre Agassi, Vintage, 10 August 2010 2. The Physiological Power of Altruism [online], James Hamblin, The Atlantic, December 30, 2015, https://www.theatlantic.com/health/archive/2015/12/altruism-for-a-better-body/422280/ [last accessed June 10, 2020] 3. TBI Blogs: From Entrepreneurs to Doorkeepers, Everybody Serves with Love & Warmth at This Ahmedabad Café [online], The People Place Project, The Better India, May 29, 2017, https://www.thebetterindia.com/102551/small-way-serve-ahmedabad-seva-cafe/, [last accessed June 10, 2020]

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP601TP

SEMESTER: VI

Subject Name: Medicinal Chemistry III

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course the student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**Antibiotics** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes **β-Lactam antibiotics:** Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams **Aminoglycosides:** Streptomycin, Neomycin, Kanamycin **Tetracyclines:** Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline	10
2.	**Antibiotics** Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes **Macrolide:** Erythromycin Clarithromycin, Azithromycin **Miscellaneous:** Chloramphenicol*, Clindamycin **Prodrugs:** Basic concepts and application of prodrugs design. **Antimalarials:** Etiology of malaria **Quinolines:** SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine. **Biguanides and dihydro triazines:** Cycloguanil pamoate, Proguanil. **Miscellaneous:** Pyrimethamine, Artesunete, Artemether, Atovoquone.	10
3.	**Anti-tubercular Agents** **Synthetic anti tubercular agents:** Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* **Anti tubercular antibiotics:** Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate **Urinary tract anti-infective agents** **Quinolones:** SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin,	10

	Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin **Miscellaneous:** Furazolidine, Nitrofurantoin*, Methanamine **Antiviral agents:** Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.	
4.	**Antifungal agents:** **Antifungal antibiotics:** Amphotericin-B, Nystatin, Natamycin, Griseofulvin **Synthetic Antifungal agents:** Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*. **Anti-protozoal Agents:** Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine. **Anthelmintics:** Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin. **Sulphonamides and Sulfones** Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine **Folate reductase inhibitors:** Trimethoprim*, Cotrimoxazole **Sulfones:** Dapsone*.	8
5.	**Introduction to Drug Design** Various approaches used in drug design. Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis Pharmacophore modeling and docking techniques. **Combinatorial Chemistry:** Concept and applications of Combinational chemistry: solid phase and solution phase synthesis.	7

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

Practical

I Preparation of drugs and intermediates

1. 1 Sulphanilamide
2. 2 7-Hydroxy, 4-methyl coumarin
3. 3 Chlorobutanol
4. 4 Triphenyl imidazole
5. 5 Tolbutamide
6. 6 Hexamine

II Assay of drugs

1. 1 Isonicotinic acid hydrazide
2. 2 Chloroquine
3. 3 Metronidazole
4. 4 Dapsone
5. 5 Chlorpheniramine maleate
6. 6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates byMicrowave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP602TP
SEMESTER: VI
Subject Name: Pharmacology III

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisoningsand
3. appreciate correlation of pharmacology with related medical sciences.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**Pharmacology of drugs acting on Respiratory system** a. Anti -asthmatic drugs b. Drugs used in the management of COPD c. Expectorants and antitussives d. Nasal decongestants e. Respiratory stimulants	10
2.	**Pharmacology of drugs acting on the Gastrointestinal Tract** a. Antiulcer agents. b. Drugs for constipation and diarrhoea. c. Appetite stimulants and suppressants. d. Digestants and carminatives. e. Emetics and anti-emetics.	
3.	**Chemotherapy** a. General principles of chemotherapy. b. Sulfonamides and cotrimoxazole. c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides	10
4.	**Chemotherapy** a. Antitubercular agents b. Antileprotic agents c. Antifungal agents d. Antiviral drugs e.Anthelmintics f. Antimalarial drugs g. Antiamoebic agents	10
5.	**Chemotherapy** l. Urinary tract infections and sexually transmitted diseases. m. Chemotherapy of malignancy	8
	Immunopharmacology a. Immunostimulants	

	b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars	
6	**Principles of toxicology** **a.** Definition and basic knowledge of acute, subacute and chronic toxicity. **b.** Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity **c.** General principles of treatment of poisoning **d.** Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning	7
7	**Chronopharmacology** a. Definition of rhythm and cycles. b. Biological clock and their significance leading to chronotherapy.	

Practical

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert, Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP603TP
SEMESTER: VI
Subject Name: Herbal Drug Technology

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**Herbs as raw materials** Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs Selection, identification and authentication of herbal materials Processing of herbal raw material **Biodynamic Agriculture** Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides. **Indian Systems of Medicine** a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.	11
2.	**Nutraceuticals** General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina **Herbal-Drug and Herb-Food Interactions:** General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.	7
3.	**Herbal Cosmetics** Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products. **Herbal excipients:** Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.	10

	Herbal formulations : Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes	
4.	**Evaluation of Drugs** WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs. **Patenting and Regulatory requirements of natural products:** a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem. **Regulatory Issues** - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs	10
5.	**General Introduction to Herbal Industry** Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India. **Schedule T – GoodManufacturing Practice of Indian systems of medicine** Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.	7

Practical

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in
7. Indian Medicine & Homeopathy)
8. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP604TT

SEMESTER: VI

Subject Name: Biopharmaceutics and Pharmacokintetics

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein

Objectives: Upon completion of the course the student shall be able to

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Introduction** **Biopharmaceutics To Absorption**; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs	10
2.	**Elimination:** Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs **Bioavailability and Bioequivalence:** Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.	10
3.	**Pharmacokinetics:** Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - KE ,t1/2,Vd,AUC,Ka, Clt and CLR- definitions methods of eliminations, understanding of their significance and Application	10
4.	***Multicompartment models:*** Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins	8
5.	**Nonlinear Pharmacokinetics:** a. Introduction, b. Factors causing Non-linearity. c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.	7

Recommended Books (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: ByMilo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, ByMilo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: ByMalcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, ByMack Publishing Company, Pennsylvnia

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP605TP
SEMESTER: VI
Subject Name: Industrial Pharmacy I

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of this course the student should be able to:

1. Know the various pharmaceutical dosage forms and their manufacturing Techniques
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**Preformulation Studies:** Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances. ***a. Physical properties:*** Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism ***b. Chemical Properties:*** Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant. Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.	7
2.	**Tablets:** a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling. b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating. c. Quality control tests: In process and finished product tests **Liquid orals:** Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia	10
3.	**Capsules:** a. ***Hard gelatin capsules:*** Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules. b. ***Soft gelatin capsules:*** Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications. **Pellets:** Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets	8
4.	**Parenteral Products:** a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity	10

	b. Production procedure, production facilities and controls, aseptic processing c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products. d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products. **Ophthalmic Preparations:** Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations	
5.	**Cosmetics:** Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens. **Pharmaceutical Aerosols:** Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. **Packaging Materials Science:** Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.	10

Practical

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Recommended Books (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. 6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5thedition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP701TP

SEMESTER: VII

Subject Name: Instrumental Methods of Analysis

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
2. Understand the chromatographic separation and analysis of drugs
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	6	80	20	80	20

Sr No	Topics	% weightage
1.	**UV Visible spectroscopy** Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications - Spectrophotometric titrations, Single component and multi component analysis **Fluorimetry** Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications	10
2.	**IR spectroscopy** Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications **Flame Photometry**-Principle, interferences, instrumentation and applications **Atomic absorption spectroscopy**- Principle, interferences, instrumentation and Applications **Nepheloturbidometry**- Principle, instrumentation and applications	10
3.	**Introduction to chromatography** **Adsorption and partition column chromatography**-Methodology, advantages, disadvantages and applications **Thin layer chromatography-** Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications **Paper chromatography**-Introduction, methodology, development techniques, advantages, disadvantages and applications	10

	Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications	
4.	**Gas chromatography -** Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications **High performance liquid chromatography (HPLC)-**Introduction, theory, instrumentation, advantages and applications	8
5.	**Ion exchange chromatography-** Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications **Gel chromatography-** Introduction, theory, instrumentation and applications **Affinity chromatography-** Introduction, theory, instrumentation and applications	7

Practical

1. Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2. Estimation of dextrose by colorimetry
3. Estimation of sulfanilamide by colorimetry
4. Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5. Assay of paracetamol by UV- Spectrophotometry
6. Estimation of quinine sulfate by fluorimetry
7. Study of quenching of fluorescence
8. Determination of sodium by flame photometry
9. Determination of potassium by flame photometry
10. Determination of chlorides and sulphates by nephelo turbidometry
11. Separation of amino acids by paper chromatography
12. Separation of sugars by thin layer chromatography
13. Separation of plant pigments by column chromatography
14. Demonstration experiment on HPLC
15. Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy byWilliam Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP702TT
SEMESTER: VII
Subject Name: Industrial Pharmacy II

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

Objectives: Upon completion of the course the student shall be able to

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Pilot plant scale up techniques:** General considerations – including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology	10
2.	**Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues	10
3.	**Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.	10
4.	**Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP	8
5.	**Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.	7

Recommended Books (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP703TT
SEMESTER: VII
Subject Name: Pharmacy Practice

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**a) Hospital and it's organization** Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions. **b) Hospital pharmacy and its organization** Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists. **c) Adverse drug reaction** Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. **d) Community Pharmacy** Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.	10
2.	**a) Drug distribution system in a hospital**	10

	Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs. **b) Hospital formulary** Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary. **c) Therapeutic drug monitoring** Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic DrugMonitoring, and Indian scenario for Therapeutic Drug Monitoring. **d) Medication adherence** Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. **e) Patient medication history interview** Need for the patient medication history interview, medication interview forms. **f) Community pharmacy management** Financial, materials, staff, and infrastructure requirements.	
3.	**Pharmacy and therapeutic committee** Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation. **b) Drug information services** Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information. **c) Patient counseling** Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist **d) Education and training program in the hospital** Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education. **e) Prescribed medication order and communication skills** Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.	10
4.	**a) Budget preparation and implementation** Budget preparation and implementation **b) Clinical Pharmacy** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. **c) Over the counter (OTC) sales** Introduction and sale of over the counter, and Rational use of common over the counter medications.	8
5.	**a) Drug store management and inventory control** Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure **b) Investigational use of drugs**	7

	Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee. **c) Interpretation of Clinical Laboratory Tests** Blood chemistry, hematology, and urinalysis	

Recommended Books (Latest Editions)

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills*, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy

Subject Code: BP704TT

SEMESTER: VII

Subject Name: NOVEL DRUG DELIVERY SYSTEMS

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course the student shall be able to

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	0	80	20	0	0

Sr No	Topics	% weightage
1.	**Controlled drug delivery systems**: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates.Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations **Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.	10
2.	**Microencapsulation:** Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications **Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems **Implantable Drug Delivery Systems:**Introduction, advantages and disadvantages, concept of implantsand osmotic pump	10
3.	**Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches **Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications **Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers	10
4.	**Targeted drug Delivery:** Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications	8
5.	**Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts **Intrauterine Drug Delivery Systems:** Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications	7

Recommended Books (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP705PP
SEMESTER: VII
Subject Name: Practice School

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
0	0	12	6	0	0	0	100

Guidelines:

In the VII semester, every candidate shall undergo practice school for a period of 150 hours during the semester. The student shall opt any one of the following activity for practice school:

- [+]Hospital training (Hospital having minimum 10 bed facilities)
- [+]Training in Drug store/ CHC/ PHC
- [+]Training in a R & D organization/ CRO/ Manufacturing organization/ QA & QC Laboratory/ Public testing laboratory/ Drug regulatory body
- [+]Successfully pass MOOCS course equivalent to 6 credits through SWAYAM Platform
- Detailed literature review on any technical topic (At least 50 references should be included in the report to be submitted)

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (about 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

The students can opt for Practice School and can perform the activities for Practice school after completion of Semester IV onwards (during the vacation/ official Holidays). Those who are doing Practice school during this period must complete the prescribed days or hours for practice School as per the guidelines. Institute should maintain documentation regarding Practice school for each student with requisite evidence.

[+] Certificate of training should be incorporated in the report.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP706TT
SEMESTER: VII
Subject Name: Quality Assurance

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course the student shall be able to

1. understand the cGMP aspects in a pharmaceutical industry
2. appreciate the importance of documentation
3. understand the scope of quality certifications applicable to pharmaceutical industries
4. understand the responsibilities of QA & QC departments.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Quality Assurance and Quality Management concepts:** Definition and concept of Quality control, Quality assurance and GMP **Total Quality Management (TQM):** Definition, elements, philosophies **ICH Guidelines**: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines **Quality by design (QbD)**: Definition, overview, elements of QbD program, tools **ISO 9000 & ISO14000**: Overview, Benefits, Elements, steps for registration **NABL accreditation** : Principles and procedures	10
2.	**Organization and personnel:** Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination. **Equipments and raw materials:** Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.	10
3.	**Quality Control:** Quality control test for containers, rubber closures and secondary packing materials. **Good Laboratory Practices:** General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities	10
4.	**Complaints:** Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. **Document maintenance in pharmaceutical industry:** Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records	8
5.	**Calibration and Validation:** Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation,	7

	types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation. **Warehousing:** Good warehousing practice, materials management	

Recommended Books (Latest Editions)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.
4. A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total QualityManagement – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP801TT
SEMESTER: VIII
Subject Name: Biostatistics and Research Methodology

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to

1. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
2. Know the various statistical techniques to solve statistical problems
3. Appreciate statistical techniques in solving the problems.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Introduction:** Statistics, Biostatistics, Frequency distribution **Measures of central tendency**: Mean, Median, Mode- Pharmaceutical examples **Measures of dispersion**: Dispersion, Range, standard deviation, Pharmaceutical Problems **Correlation**: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples	10
2.	**Regression:** Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution Poisson's distribution, properties – problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples **Parametric test**: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference	10
3.	**Non Parametric tests:** Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test **Introduction to Research:** Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism **Graphs:** Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph **Designing the methodology:** Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.	10
4.	Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression models	8

	Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach	
5.	**Design and Analysis of experiments:** **Factorial Design:** Definition, 22, 23design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques	7

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP802TT
SEMESTER: VIII
Subject Name: Social and Preventive Pharmacy

Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives: Upon completion of the course the student shall be able to

1. Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide
2. Have a critical way of thinking based on current healthcare development
3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Concept of health and disease:** Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. **Social and health education:** Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. **Sociology and health:** Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health **Hygiene and health:** personal hygiene and health care; avoidable habits	10
2.	**Preventive medicine:** General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse	10
3.	**National health programs, its objectives, functioning and outcome of the following:** HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme	10
4.	National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program	8
5.	Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.	7

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP803TT
SEMESTER: VIII
Subject Name: Pharma Marketing Management

Scope: The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Objectives: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Marketing:** Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior **Pharmaceutical market:** Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.	10
2.	**Product decision:** Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.	10
3.	**Promotion:** Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.	10
4.	**Pharmaceutical marketing channels:** Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management. **Professional sales representative (PSR):** Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.	10
5.	**Pricing:** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview	10

	of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). **Emerging concepts in marketing:** Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.	

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP804TT
SEMESTER: VIII
Subject Name: Pharmaceutical Regulatory science

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to:

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**New Drug Discovery and development** Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development	10
2.	**Regulatory Approval Process** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA. **Regulatory authorities and agencies** Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)	10
3.	**Registration of Indian drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.	10
4.	**Clinical trials** Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials	8
5.	**Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	7

Recommended Books: (Latest Editions)

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / SandyWeinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP805TT
SEMESTER: VIII
Subject Name: PHARMACOVIGILANCE

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives: *At completion of this paper it is expected that students will be able to (know, do, and appreciate):*

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Introduction to Pharmacovigilance** □ History and development of Pharmacovigilance □ Importance of safety monitoring of Medicine □ WHO international drug monitoring programme □ Pharmacovigilance Program of India(PvPI) **Introduction to adverse drug reactions** □ Definitions and classification of ADRs □ Detection and reporting □ Methods in Causality assessment □ Severity and seriousness assessment □ Predictability and preventability assessment □ Management of adverse drug reactions **Basic terminologies used in pharmacovigilance** □ Terminologies of adverse medication related events □ Regulatory terminologies	10
2.	**Drug and disease classification** □ Anatomical, therapeutic and chemical classification of drugs □ International classification of diseases	10

	□ Daily defined doses □ International Non proprietary Names for drugs **Drug dictionaries and coding in pharmacovigilance** □ WHO adverse reaction terminologies □ MedDRA and Standardised MedDRA queries □ WHO drug dictionary □ Eudravigilance medicinal product dictionary **Information resources in pharmacovigilance** □ Basic drug information resources □ Specialised resources for ADRs **Establishing pharmacovigilance programme** □ Establishing in a hospital □ Establishment & operation of drug safety department in industry □ Contract Research Organisations (CROs) □ Establishing a national programme	
3.	**Vaccine safety surveillance** □ Vaccine Pharmacovigilance □ Vaccination failure □ Adverse events following immunization **Pharmacovigilance methods** □ Passive surveillance – Spontaneous reports and case series □ Stimulated reporting □ Active surveillance – Sentinel sites, drug event monitoring and registries □ Comparative observational studies – Cross sectional study, case control study and cohort study □ Targeted clinical investigations **Communication in pharmacovigilance** □ Effective communication in Pharmacovigilance □ Communication in Drug Safety Crisis management □ Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media	10
4.	**Safety data generation** □ Pre clinical phase □ Clinical phase □ Post approval phase (PMS) **ICH Guidelines for Pharmacovigilance** □ Organization and objectives of ICH □ Expedited reporting □ Individual case safety reports □ Periodic safety update reports □ Post approval expedited reporting □ Pharmacovigilance planning □ Good clinical practice in pharmacovigilance studies	8
5.	**Pharmacogenomics of adverse drug reactions** □ Genetics related ADR with example focusing PK parameters. **Drug safety evaluation in special population** □ Paediatrics □ Pregnancy and lactation □ Geriatrics **CIOMS** □ CIOMS Working Groups □ CIOMS Form **CDSCO (India) and Pharmacovigilance** □ D&C Act and Schedule Y	7

	Differences in Indian and global pharmacovigilance requirements	

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP806TT
SEMESTER: VIII
Subject Name: Quality Control and standardization of Herbals

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines..

Objectives: Upon completion of the subject student shall be able to;
1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use	10
2.	**Quality assurance in herbal drug industry** of cGMP, GAP, GMP and GLP in traditional system of medicine. WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.	10
3.	EU and ICH guidelines for quality control of herbal drugs. Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines	10
4.	Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products. Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.	8
5.	Regulatory requirements for herbal medicines. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias. Role of chemical and biological markers in standardization of herbal products	7

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials,World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP807TT
SEMESTER: VIII
Subject Name: Computer Aided Drug Design

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand
- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	70	30	0	0

Sr No	Topics	% weightage
1.	**Introduction to Drug Discovery and Development** Stages of drug discovery and development **Lead discovery and Analog Based Drug Design** Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation. **Analog Based Drug Design:**Bioisosterism, Classification, Bioisosteric replacement. Any three case studies	10
2.	**Quantitative Structure Activity Relationship (QSAR)** SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.	10
3.	**Molecular Modeling and virtual screening techniques** **Virtual Screening techniques:** Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, **Molecular docking**: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.	10
4.	**Informatics & Methods in drug design** Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.	8
5.	**Molecular Modeling:** Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.	7

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.

3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" JohnWiley& Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP808TT
SEMESTER: VIII
Subject Name: Cell and Molecular Biology

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	a) Cell and Molecular Biology: Definitions theory and basics and Applications. b) Cell and Molecular Biology: History and Summation. c) Properties of cells and cell membrane. d) Prokaryotic versus Eukaryotic e) Cellular Reproduction f) Chemical Foundations – an Introduction and Reactions (Types)	10
2.	a) DNA and the Flow of Molecular Information b) DNA Functioning c) DNA and RNA d) Types of RNA e) Transcription and Translation	10
3.	a) Proteins: Defined **and** Amino Acids b) Protein Structure 173 c) Regularities in Protein Pathways d) Cellular Processes e) Positive Control and significance of Protein Synthesis	10
4.	a) Science of Genetics b) Transgenics and Genomic Analysis c) Cell Cycle analysis d) Mitosis and Meiosis e) Cellular Activities and Checkpoints	8

5.	a) Cell Signals: Introduction b) Receptors for Cell Signals c) Signaling Pathways: Overview d) Misregulation of Signaling Pathways e) Protein-Kinases: Functioning	7

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP809TT
SEMESTER: VIII
Subject Name: Cosmetic Science

Scope: To understand the classification of cosmetics and cosmeceutical products as per Indian and EU regulations. This subject deals with principles of formulation and the building blocks of skin care products, classification of sunscreens and sun protection factor, the role of herbs in cosmetics with their analytical methods, principles of cosmetic evaluation. The subject also includes about oily and dry skin, causes leading to dry skin, skin miniaturization as well as a basic understanding of the terms covering cosmetics.

Objectives: Upon completion of the course the student shall be able to
1. To know and explain about cosmetics, and related sciences, cosmeceuticals (cosmetics with skin, hair and oral care benefits) and personal care and hygiene products.
2. To demonstrate practical skills in the area of biology, formulation science and analytical techniques required to scientifically design and develop various cosmetic products.
3. To describe about basic cosmetic problems associated with skin, hair and oral care etc.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	Classification of cosmetic and cosmeceutical products Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs **Cosmetic excipients:** Surfactants, rheologymodifiers, humectants, emollients, preservatives. Classification and application **Skin:** Basic structure and function of skin. **Hair:** Basic structure of hair. Hair growth cycle. **Oral Cavity:** Common problem associated with teeth and gums**.**	10
2.	**Principles of formulation and building blocks of skin care products:** Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmecuticals. **Antiperspants & deodorants**- Actives & mechanism of action. **Principles of formulation and building blocks of Hair care products:** Conditioning shampoo, Hair conditioner,anti-dandruff shampoo. Hair oils. Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.	10
3.	Sun protection, Classification of Sunscreens and SPF. **Role of herbs in cosmetics:** Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove **Analytical cosmetics:** BIS specification and analytical methods for shampoo, skincream and toothpaste**.**	10

4.	Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties Soaps,and syndet bars. Evolution and skin benfits.	8
5.	Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants- Actives and mechanism of action	7

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) .Drugs and Cosmetic act/rules by govt. of India Publication
4) European Union regulation for cosmetics.
5) Poucher's Perfumes, Cosmetics and Soaps, Hilda Butler, 10th Edition, Kluwer Academic Publishers
6) Handbook of Cosmetic Science and Technology, 3rd Edition, André O. Barel, Marc Paye, Howard
7) Pulok K.Mukherjee. Quality Control Herbal Drugs Business Horizons; Reprint 2012 edition
8) Trease, G.E. and Evans, W.C. "Trease and Evans' Pharmacognosy" WB Saunders Co.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP810TT
SEMESTER: VIII
Subject Name: Experimental Pharmacology

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- ☐ Appreciate the applications of various commonly used laboratory animals.
- ☐ Appreciate and demonstrate the various screening methods used inpreclinical research
- ☐ Appreciate and demonstrate the importance of biostatistics and researchmethodology
- ☐ Design and execute a research hypothesis independently

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	Teaching Hrs
1.	**Laboratory Animals:** Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	7
2.	**Introduction to preclinical studies**: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study	3
3.	**Preclinical screening models** **Preclinical screening models for drugs acting on CNS** :- analgesic, antipyretic, anti-inflammatory, general anesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, nootropics anti Parkinsonism drugs, anti-Alzheimer drug **Preclinical screening models** for drugs acting on eye and local aesthetics	12
4.	**Preclinical screening models for drugs acting on ANS :** sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants	5
5.	**Preclinical screening models for drugs acting on CVS :-** antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants **Preclinical screening models** for antiulcer, antidiabetic, anticancer and antiasthmatic activities	13

6.	**Research methodology and Bio-statistics** Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students't' test and One-way ANOVA. Graphical representation of data	5

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-byM.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP811TT
SEMESTER: VIII
Subject Name: Advanced Instrumentation Techniques

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing

Objectives

Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**Nuclear Magnetic Resonance spectroscopy** Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications **Mass Spectrometry**- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications	10
2.	**Thermal Methods of Analysis**: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) **X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.	10
3.	**Calibration and validation-**as per ICH and USFDA guidelines **Calibration of following Instruments** Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC	10
4.	**Radio immune assay:**Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay **Extraction techniques**:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction	8
5.	**Hyphenated techniques**-LC-MS/MS, GC-MS/MS, HPTLC-MS.	5

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel

5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy byWilliam Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP812TT
SEMESTER: VIII
Subject Name: Dietary Supplements and Nutraceuticals

Scope: This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objectives
This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:
1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community. c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds	7
2.	Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin b) Sulfides: Diallyl sulfides, Allyl trisulfide. c) Polyphenolics: Reservetrol d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans g) Tocopherols h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.	15
3.	a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. b) Dietary fibres and complex carbohydrates as functional food ingredients..	7
4.	a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing. b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase,	10

	Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. c) Functional foods for chronic disease prevention	
5.	a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.	6

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP813PP
SEMESTER: VIII
Subject Name: Project Work

Guidelines:

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII or Minor research project at R & D organization/ CRO/ Manufacturing organization/QA & QC Laboratory/ Public testing laboratory/ Drug regulatory body/Hospital/ Community Pharmacy/ Help Centre or at Institute. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The students can perform the activities for project work after completion of Semester VI onwards (during the vacation/ official Holidays) but the credit of project work will be transferred in Semester VIII. Those who are doing Project work during this period must complete the prescribed days or hours for Project work as per the guidelines. Institute should maintain documentation regarding project Work for each student with requisite evidence.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP814TT
SEMESTER: VIII
Subject Name: Pharmaceutical Product Development

Scope: To understand the regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms. The subject also includes an advanced study of pharmaceutical excipients in pharmaceutical product development. It also covers optimization techniques to be used in pharmaceutical product development.

Objectives: Upon completion of the course the student shall be able to -

1. To know and explain about the basic concepts of product development and right selection of excipients for the conventional and novel formulation.
2. To describe Quality by design, Optimization technique and experimental design pharmaceutical product development for the conventional and novel formulation.
3. To explain the GRAS listing & inactive ingredient guide (IIG) limit for the excipients.
4. To discuss Regulatory requirement for Selection of packaging material and Quality control of various dosage form.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	Teaching Hrs
1.	Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms.	7
2.	An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories i. Solvents and solubilizers ii. Cyclodextrins and their applications iii. Non - ionic surfactants and their applications iv. Polyethylene glycols and sorbitol's v. Suspending and emulsifying agents vi. Semi solid excipients	10
3.	An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories i. Tablet and capsule excipients ii. Directly compressible vehicles iii. Coat materials iv. Excipients in parenteral and aerosols products v. Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications	10
4.	Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.	8

5.	Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.	7

References:

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B.Schwartz.
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman.
3. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
4. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill livingstone, Latest edition.
5. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005.
6. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
7. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York.
8. Bolton S. Optimization techniques. In: Pharmaceutical Statistics: Practical and Clinical Applications. 3rd ed. New York: Marcel Dekker, 1997

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP815TT
Semester: VIII
Subject Name: Epidemiology

Scope: This course introduces the student to the principles and basic methods of modem epidemiology. Epidemiology is defined as the study distribution and determinants of health-related states and events in defined populations and the application of this to study to solving public health problems. Presentation of epidemiologic data and basic measures of disease frequency are covered. Descriptive, analytical and interventional study designs are discussed in context to the health system with their corresponding analysis techniques. The concept of risk and its associated measures is also covered. It also covers the estimation and interpretation of odds ratio, attributable risk and their confidence intervals.

Objectives: Upon completion of this course, it is expected that students will be able to:

- To have a clear understanding of the definition and uses of epidemiology and appreciate its role in public health.
- To be able to identify the key sources of data and have the ability to draw appropriate inferences from them.
- To understand the concept and practical application of various measures such as: measures of disease frequency (prevalence and incidence), measures of effect (e.g. rate/risk ratios and rate/risk differences), and measures of public health impact (e.g. population attributable risk / fraction)
- To know the various types of epidemiological study designs and, understand their basic principles and the main analytic methods used in each specific design
- Ascertain causality between an exposure and an outcome

Teaching Scheme and examination scheme:

Teaching Scheme				**Evaluation Scheme**				**Total Marks**
Theory	**Tutorial**	**Practical**	**Total**	**Theory**		**Practical**		
				External	**Internal**	**External**	**Internal**	
3	**1**	**0**	**4**	**80**	**20**	**0**	**0**	**100**

Sr.	**Topic**	**Teaching Hrs**
1	Definition of Epidemiology, History and evolution of epidemiology. Aims and principles of Epidemiology Basic concepts and applications.	3
2	Sources of data and various methods of data collection Important aspects of data collection: Reliability and validity Sensitivity, specificity and predictive values.	10
3	Natural history of a disease and its application in disease control. Levels of prevention and modes of intervention. Bias, Confounding, & Effect Modification Causation & Risk	8
4	Epidemiological methods – Descriptive, Analytical & Experimental. Surveillance	4

5	Epidemiological study designs Overview of study designs Descriptive studies Ecological studies. Case control studies, cohort studies, randomized control trials.	6
6	Hybrid designs in epidemiology. Community based epidemiological studies.	3
7	Measuring disease occurrence. Measurement tools in Epidemiology – Rate, Ratio & Proportion Risk – frequency measures, morbidity frequency measures, mortality frequency measures, birth measures, measures of association, measures of public health impact.	8
8	Ethical and Professional Issues in Epidemiology.	3

Textbooks:

1. Epidemiology: Gordis, Leon Elsevier Saunders, latest edition.
2. Foundations of Epidemiology: Marit L. Bovbjerg, Kelly Johnson, Oregon State University

   Download for free at https://open.oregonstate.education/epidemiology/

3. Principles of Epidemiology in Public Health Practice, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Third Edition.
4. Basic Epidemiology: R. Bonita, R. Beaglehole, TKjellstrom, WHO, 2nd Edition.
5. Park's text book of Preventive and Social medicine: K. Park, M/s Banarasidas Bhanot publication, latest edition

Gujarat Technological University

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Home

TEACHING SCHEME / DETAIL SYALLBUS

MPHARM | 20 - Pharmaceutics | Sem | Academic Year | Subject Code | Enter Subject Name | Search

*L=lectures,T=tutorial,P=Practical,E=TheoryExternal,M=TheoryInternal,I=Practical Internal,V=Practical External,On Job Training(OJT) is equivalent to Practical

							Hours			Credit	Max Marks				
Exp.	Subcode	Branch code	Eff_from	SubjectName	Category	Sem /Year	L.	T.	P.	Total	E	M	I	V	Total
	MAT101T	20	2017-18	Modern Pharmaceutical Analytical Techniques		1	4	0	0	4	80	20	0	0	100
	MPH102T	20	2017-18	Drug Delivery System		1	4	0	0	4	80	20	0	0	100
	MPH103T	20	2017-18	Modern Pharmaceutics		1	4	0	0	4	80	20	0	0	100
	MPH104T	20	2017-18	Regulatory Affairs		1	4	0	0	4	80	20	0	0	100
	MPH105P	20	2017-18	Pharmaceutics Practical I		1	0	0	12	6	0	0	50	100	150
	MSA106P	20	2017-18	Seminar/Assignment		1	0	0	8	4	0	0	100	0	100
	MPH201T	20	2017-18	Molecular Pharmaceutics(Nano Tech and Targeted DDS)		2	4	0	0	4	80	20	0	0	100
	MPH202T	20	2017-18	Advanced Biopharmaceutics & Pharmacokinetics		2	4	0	0	4	80	20	0	0	100
	MPH203T	20	2017-18	Computer Aided Drug Delivery System		2	4	0	0	4	80	20	0	0	100
	MPH204T	20	2017-18	Cosmetic and Cosmeceuticals		2	4	0	0	4	80	20	0	0	100
	MPH205P	20	2017-18	Pharmaceutics Practical II		2	0	0	12	6	0	0	50	100	150
	MSA206P	20	2017-18	Seminar/Assignment		2	0	0	8	4	0	0	100	0	100
	MDP303P	20	2017-18	Discussion/ Presentation (Proposal Presentation)		3	2	0	0	2	0	50	0	0	50
	MJC302P	20	2017-18	Journal Club I		3	1	0	0	1	0	25	0	0	25
	MRM301T	20	2017-18	Research Methodology and Biostatistics*		3	4	0	0	4	80	20	0	0	100
	MRW304P	20	2017-18	Research Work - Dissertation Phase I		3	0	0	28	14	0	0	50	300	350
	MDP402P	20	2017-18	Discussion/ Presentation		4	3	0	0	3	0	75	0	0	75
	MDP402P	20	2018-19	Discussion/ Presentation		4	3	0	0	3	0	75	0	0	75
	MJC401P	20	2017-18	Journal Club II		4	1	0	0	1	0	25	0	0	25
	MJC401P	20	2018-19	Journal Club II		4	1	0	0	1	0	25	0	0	25
	MRW403P	20	2017-18	Research Work - Dissertation Phase II		4	0	0	32	16	0	0	0	400	400
	MRW404P	20	2018-19	Research Work - Dissertation Phase II		4	0	0	32	16	0	0	100	300	400

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: I

Subject Name: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
Subject Code: MAT101T

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc. .

Objectives: Upon completion of this course the student should be able to

1. Chemicals and Excipients
2. The analysis of various drugs in single and combination dosage forms
3. Theoretical and practical skills of the instruments

Sr No	Course Contents	Total Hrs
1	**UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UVVisible Spectroscopy **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy **Spectroflourimetry**: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications	11
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds,Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy	10
3	**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass Spectroscopy	10
4	**Chromatography**: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11
5	a. **Electrophoresis**: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing b. **X ray Crystallography**: Production of X rays, Different X ray diffraction methods, Bragg`s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction.	9

6	**Potentiometry**: Principle, thermal transitions and instrumentation (heat flux and power compensation anddesigns) working, Ion selective Electrodes and Application of potentiometry. **Thermal Analysis:** Polymer behavior, factors affecting and instrumentation, and working, application of TGA	9

REFERENCES:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICS

SEMESTER: I

Subject Name: DRUG DELIVERY SYSTEMS
Subject Code: MPH102T

SCOPE: This course is designed to impart knowledge on the area of advances in novel drug delivery systems

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering system
3. The formulation and evaluation of Novel drug delivery systems.

Sr.No	Course content	Total Hrs
1.	Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.	10
2.	Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals	10
3.	Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10
4.	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	6
5.	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation	10
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	8
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	6

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.

2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS:

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICS

SEMESTER: I

Subject Name: MODERN PHARMACEUTICS
Subject Code: MPH103T

SCOPE: Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The elements of preformulation studies.
2. The Active Pharmaceutical Ingredients and Generic drug Product development
3. Industrial Management and GMP Considerations
4. Optimization Techniques & Pilot Plant Scale Up Techniques
5. Stability Testing, sterilization process & packaging of dosage forms.

Sr.No	Course content	Total Hrs
1.	a. Preformation Concepts – Drug Excipient interactions – different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. b. Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation	10 10
2.	Validation : Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	10
3.	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.	10
4.	Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility	10
5.	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test	10

REFERENCES:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H.Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICS

SEMESTER: I

Subject Name: REGULATORY AFFAIRS
Subject Code: MPH104T

SCOPE: Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents : filing process of IND, NDA and ANDA

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. The Concepts of innovator and generic drugs, drug development process.
2. The Regulatory guidance's and guidelines for filing and approval Process
3. Preparation of Dossiers and their submission to regulatory agencies in different countries
4. Post approval regulatory requirements for actives and drug products
5. Submission of global documents in CTD/ eCTD formats
6. Clinical trials requirements for approvals for conducting clinical trials
7. Pharmacovigilence and process of monitoring in clinical trials.

Sr.No	Course content	Total Hrs
1.	a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	15
2.	CMC, post approval regulatory affairs. Regulation for combination Products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	15
3.	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	15
4.	Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	15

REFERENCES:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICS

SEMESTER: I

Subject Name: PHARMACEUTICS PRACTICALS - I
Subject Code: MPH105T

List of Practicals:

PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation
2. Formulation and evaluation of sustained release matrix tablets
3. Formulation and evaluation osmotically controlled DDS
4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
5. Formulation and evaluation of Muco adhesive tablets.
6. Formulation and evaluation of trans dermal patches.
7. To carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.
10. To study the effect of particle size on dissolution of a tablet.
11. To study the effect of binders on dissolution of a tablet.
12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
13. To perform stability testing of drug in liquid formulation.
14. To prepare and evaluate self-micro emulsifying drug delivery system (SMEDDS).
15. To perform calibration study of dissolution test apparatus.
16. To calculate standard deviation; perform Chi square test, students T-test and ANOVA test for given data.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: Molecular Pharmaceutics(Nano Tech and Targeted DDS)
Subject Code: MPH201T

Scope: This course is designed to impart knowledge on the area of advances in novel drug delivery systems

Objectives: Upon completion of the course student shall be able to understand

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of NTDS
3. The formulation and evaluation of novel drug delivery system

Sr.	Topic	Hr
1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	**12**
2.	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	**12**
3.	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, Preparation and application of Niosomes, Aquasomes, Phyotosomes, Electrosomes	**12**
4.	Pulmonary Drug Delivery Systems : Aerosols, propellents, ContainersTypes, preparation andevaluation, Intra Nasal Route Deliverysystems;Types,preparationandevaluation	**12**
5.	Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for genetherapy (inherited disorder andcancer). Gene expression systems (viral andnonviral genetransfer). Liposomal gene deliverysystems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisensemoleculesandaptamersasdrugs offuture	**12**

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded,Marcel Dekker,Inc.,NewYork,1992
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances,VallabhPrakashan,New Delhi,Firstedition 2002
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors,NewDelhi,Firstedition 1997 (reprint in2001).

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: Advanced Biopharmaceutics & Pharmacokinetics
Subject Code: MPH202T

Scope: This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives: Upon completion of the course student shall be able to understand

1. The basic concepts in biopharmaceutics and pharmacokinetics.
2. The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
3. The critical evaluation of biopharmaceutic studies involving drug product equivalency.
4. The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Sr.	Topic	Hr
1.	Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex.	**12**
2.	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.	**12**
3.	Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters	**12**

4.	Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative andabsolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution	**12**
5.	Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins andpeptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Genetherapies	**12**

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia,LeaandFebiger,1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal.,Vallab Prakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC,2ndedition,ConnecticutAppletonCenturyCrofts,1985
4. Textbook of Biopharmaceutics andPharmacokinetics, Dr. Shobha Rani R. Hiremath,PrismBook
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel DekkerInc.,New York,1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick.J,LeaandFebiger,Philadelphia,1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by MalcolmRowland and Thom~N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany,Pennsylvania1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition,revised andexpande byRobert. E. Notari, Marcel Dekker Inc,New YorkandBasel,1987
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.G Wagnerand M.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James.G.Boylan,MarcelDekkerInc,New York,1996
12. Basic Pharmacokinetics,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceuticalpress,RPS Publishing,2009
13. Absorption and Drug Development- Solubility, Permeability, and Charge State,AlexAvdeef,JohnWiley&Sons,Inc,2003

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: COMPUTER AIDED DRUG DEVELOPMENT
Subject Code: MPH203T

Scope: This course is designed to impart knowledge andskills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives: Upon completion of the course student shall be able to understand

1. History of Computers in Pharmaceutical Research and Development
2. Computational Modeling of Drug Disposition
3. Computers in Preclinical Development
4. Optimization Techniques in Pharmaceutical Formulation
5. Computers in Market Analysis
6. Computers in Clinical Development
7. Artificial Intelligence(AI) and Robotics
8. Computational fluiddynamics (CFD)

Sr.	Topic	Hr
1.	a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8guideline, Regulatory and industry views on QbD, Scientifically based QbD-examples of application	**12**
2.	Computational Modeling Of Drug Disposition: Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP,BBB-CholineTransporter	**12**
3.	Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	**12**
4.	a. Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitroin vivo correlation, Biowaiver considerations b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems	**12**

5.	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions	**12**

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins,2006,JohnWiley&Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris,Woodhead Publishing 3. Encyclopedia of Pharmaceutical Technology, Vol 1
3. James Swarbrick, James.G.Boylan,MarcelDekkerInc,New York,1996**.**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: COSMETICS AND COSMECEUTICALS
Subject Code: MPH204T

Scope: This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products

Objectives: Upon completion of the course student shall be able to understand

1. Key ingredients used in cosmetics and cosmeceuticals.
2. Key building blocks for various formulations.
3. Current technologies in the market
4. Various key ingredients and basic science to develop cosmetics and cosmeceuticals
5. Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy

Sr.	Topic	Hr
1.	Cosmetics – Regulatory : Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics., Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties	**12**
2.	Cosmetics - Biological aspects : Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm	**12**
3.	Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed asallergens in EU regulation Controversial ingredients: Parabens, formaldehyde liberators, dioxane	**12**
4.	Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, bodyodor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations	**12**
5.	Herbal Cosmetics : Herbal ingredients used in Hair care, skin care andoral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics	**12**

REFERENCES:

1. Harry'sCosmeticology.8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma,4th edition

4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach.3rdedition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmaceutics (20)

SEMESTER: II

Subject Name: PHARMACEUTICS PRACTICALS - II
Subject Code: MPH205P

1. To study the effect of temperature change , non solvent addition, incompatible polymer additionin microcapsules preparation
2. Preparation and evaluation of Alginatebeads
3. Formulation and evaluation of gelatin /albuminmicrospheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamolin animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cells tudies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-DesigninPharmaceuticalDevelopment
15. Computer Simulation sin Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: I

Subject Name: ADVANCED PHARMACOLOGY-I
Subject Code: MPL102T

Scope: The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved.

Objectives: Upon completion of this course the student should be able to

1. Discuss the pathophysiology and pharmacotherapy of certain diseases
2. Explain the mechanism of drug actions at cellular and molecular level
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Sr No	Course Contents	Total Hrs
1	**General Pharmacology** a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.	12
2	Neurotransmission a. General aspects and steps involved in neurotransmission. b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline). c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine]. d. Non adrenergic non cholinergic transmission (NANC). Cotransmission **Systemic Pharmacology** A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems **Autonomic Pharmacology** Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction	12
3	**Central nervous system Pharmacology** General and local anesthetics Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics	12
4	**Cardiovascular Pharmacology**	12

	Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet Drugs	
5	**Autocoid Pharmacology** The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonistsS	12

REFERENCES:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

SEMESTER: III

Subject Name: RESEARCH METHODOLOGY, BIOSTATISTICS AND IPR
Subject Code: MRM301T

Sr No	Course Contents	Total Hrs
1	**General Research Methodology** General Research Methodology: Research, objective, requirements, practical difficulties, Review of literature: Use of Library, books and journals-Medlines-Internet, and reprints of articles as a source for Literature survey. Selecting a problem and preparing Research proposals. The Research Report, Paper writing/ thesis writing, Different parts of the Research paper/Thesis Presentation oral/poster presentation) Importance, types, different skills, content, format of model, Poster, Gestures, eye contact, facial expressions, stage fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire. Sources for procurement research grants –National/ international agencies, Government and private bodies	12
2	**Experimental Design (15 hours)** Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design. Basic steps in experimental design. Screening Designs: Screening of factors, General properties for independent factor selected for experimental design, Fractional factorial design(FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design Optimization techniques and various method of optimization Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study	15

	Evolution of full and reduced mathematical models in experimental designs Central composite designs Taguchi and mixture design Application of experimental design in pharmacology for reduction of animal	
3	**Biostatistics** Definition, application, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test, Kruskal Wallis test, Mann Whitney U test), null hypothesis, P values, degree of freedom, interpretation of P values, post hoc tests for parametric and non-parametric data (Dunnett's test, Tukey's test, Dunn's test)	8
4	**Regulatory perspectives of Medical research** History of medical research (Nuremberg code, The declaration of Helsinki), initiation of ICH-GCP guidelines, advantages of ICH-GCP, core principles of ICH -GCP guidelines , Ethical Committee: Institutional Review Board, Ethical Guidelines by ICMR for Biomedical Research and Human Participants(ethical issues- informed consent process, confidentiality, payments, conflict of interest, vulnerable participants), Schedule Y, Preparation of clinical protocol, Investigator Brochure, Case Report Forms	10
5	**CPCSEA guidelines for laboratory animal facility** Objective and functions of IAEC, background and process of evolution of guidelines, statutory provisions regarding scientific experiments of animals, CPCSEA guidelines for animal experimentation and laboratory animal facility 2015, care and handling of animals, concept of 4 R, protocol preparation for Preclinical studies (Form B)	5
6	**IPR and Patents** Patents: Definition, Need for patenting, scope and importance of patents, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search and important websites, The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites. Copyrights and Trademark: Brief introduction to trademark protection and WTO patents, Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application	10

REFERENCES:

1. Research Methodology by C.R. Kothari
2. Compendium of CPCSEA 2018
3. Presentation skills - Michael Hallon- Indian Society for Institute education
4. Pharmaceutics Statistics by Sanford Bolton, Charles Bon
5. Patent laws , By P. Narayan. Eastern law house publications
6. Pharmaceutical Experimental Design By Gareth Lewis and Didier Mathieu
7. www. ipindia.nic.in, www.uspto.gov
8. www.cpcsea.nic.in
9. www.icmr.nic.in

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: I

Subject Name: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I
Subject Code: MPL103T

Scope: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes.

Objectives: Upon completion of this course the student should be able to

1. Appraise the regulations and ethical requirement for the usage of experimental animal
2. Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental Animals
3. Describe the various newer screening methods involved in the drug discovery process
4. Appreciate and correlate the preclinical data to humans

Sr No	Course Contents	Total Hrs
1	**Laboratory Animals** Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods	12
2	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System	12
3	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and laxatives	12
4	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods	12

5	**Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.** Iimmunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.	12

REFERENCES:

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: I

Subject Name: CELLULAR AND MOLECULAR PHARMACOLOGY
Subject Code: MPL104T

Scope: The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives: Upon completion of this course the student should be able to

1. Explain the receptor signal transduction processes
2. Explain the molecular pathways affected by drugs
3. Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process
4. Demonstrate molecular biology techniques as applicable for pharmacology

Sr No	Course Contents	Total Hrs
1	**Cell biology** Structure and functions of cell and its organelles, Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.	12
2	**Cell signaling** Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1, 4, 5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.	12
3	**Principles and applications of genomic and proteomic tools** DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.	12
4	**Pharmacogenomics:** Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics	12

	Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice	
5	a. **Cell culture techniques** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars	12

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: I

Subject Name: Pharmacology Practical I
Subject Code: MPL105P

List of Practicals:
PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.

5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: ADVANCED PHARMACOLOGY-II
Subject Code: MPL201T

Scope: The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved.

Objectives: Upon completion of this course the student should be able to

1. Explain the mechanism of drug actions at cellular and molecular Level
2. Discuss the Pathophysiology and pharmacotherapy of certain diseases
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

Sr No	Course Contents	Total Hrs
1	Endocrine Pharmacology Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation	12
2	Chemotherapy Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs	12
3	Chemotherapy Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemo therapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immuno suppressants and Immunostimulants	12
4	GIT Pharmacology Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs forconstipation and irritable bowel syndrome. Chronopharmacology Biological and circadian rhythms, applications of chronotherapyin various diseases like cardiovascular disease, diabetes, asthma and pepticulcer	12
5	Free radicals Pharmacology Generation of free radicals, role of free radicals inetiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus	12

REFERENCES:

1. The Pharmacological basis of therapeutics-Goodman andGillman's
2. Principles of Pharmacology. ThePathophysiologic basis of drug therapy by DavidE Golanetal.

3. Basic and Clinical Pharmacology byB.G -Katzung
4. Pharmacology by H.P.RangandM.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindaland Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolismfor Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
1. 10.A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava publishedbyAPC AvichalPublishingCompany.
2. 11.KD.Tripathi.EssentialsofMedicalPharmacology
3. 12.Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong,Wolters,Kluwer-LippincottWilliams&Wilkins Publishers

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
Subject Code: MPL202T

Scope: This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug &new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation

Objectives: Upon completion of this course the student should be able to

1. Explain the various types of toxicity studies
2. Appreciate the importance of ethical and regulatory requirements for toxicity studies
3. Demonstrate the practical skills required to conduct the preclinical toxicity studies

Sr No	Course Contents	Total Hrs
1	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice(GLP) History, concept and itsi mportance in drug development	12
2	Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicology studies	12
3	Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segmentII) Genotoxicity studies(Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12
4	IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay.Tier2-GI,renal and other studies	12
5	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternativemethodstoanimal toxicitytesting	12

REFERENCES:

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook.pdf
2. Schedule Y Guideline: drugs and cosmetics (secondamendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by RickNG.
4. Animal Models in Toxicology, 3rd Edition, Lower andBryan .
5. OECD test guidelines
6. Principles of toxicology by KarenE. Stine,ThomasM.Brown

7. Guidance for Industry M3(R2)Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: PRINCIPLES OF DRUG DISCOVERY
Subject Code: MPL203T

Scope: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives: Upon completion of this course the student should be able to

1. Explain the various stages of drug discovery
2. Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
3. Explain the various targets for drug discovery
4. Explain the various lead Seeking method and lead optimization
5. Appreciate the importance of the role of computer aided drug design in drug discovery**.**

Sr No	Course Contents	Total Hrs
1	An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.	12
2	Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. Protein structure Levels of protein structure, Domains, motifs, andfolds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction	12
3	Rational Drug Design Traditional vsrational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening	12
4	Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. Denovo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them	12
5	QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSARapproaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design	12

REFERENCES:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation.2006byTaylor and Francis Group, LLC
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American ChemicalSociety:Washington,DC,1999
7. J. Rick Turner. Newdrug development design, methodology and, analysis. JohnWiley&Sons,Inc.,New Jersey

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: CLINICAL RESEARCH AND PHARMACOVIGILANCE
Subject Code: MPL204T

Scope: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives: Upon completion of this course the student should be able to

1. Explain the regulatory requirements for conducting clinical trial
2. Demonstrate the types of clinical trial designs
3. Explain the responsibilities of key players involved in clinical trials
4. Execute safety monitoring, reporting and close-out activities
5. Explain the principles of Pharmacovigilance
6. Detect new adverse drug reactions and their assessment
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

Sr No	Course Contents	Total Hrs
1	Regulatory Perspectives of Clinical Trials: Origin and Principles of International Conference on Harmonization-Good Clinical Practice(ICH-GCP)guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant ScheduleY, ICMR Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process	10
2	Clinical Trials: Types and Design Experimental Study-RCT and Non RCT, Observation Study: Cohort,Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	10
3	Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drugreactions; Terminologies of ADR	10
4	Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance	10
5	Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary names	10

	for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	
6	Pharmacoepidemiology, pharmacoeconomics, safety pharmacology	10

REFERE**NCES:**

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry ofHealth;2001
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use.ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6;May1996
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, NewDelhi
4. Textbook of Clinical Trials edited by David Machin, Simon Dayand Sylvan Green, March 2005,JohnWileyandSons
5. Clinical Data Management edited by R K Rondels,S AVarley,C F Webbs. Second Edition,Jan2000,WileyPublications
6. Handbook of clinical Research. Julia Lloyd andAnnRaven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

Pharmacology

SEMESTER: II

Subject Name: Pharmacology Practical II
Subject Code: MPL205P

List of Practicals:

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable isolated tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable isolated tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable isolated tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable isolated tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted ratileum preparation.
12. Acuteoral toxicity studies as per OECD guidelines.
13. Acutedermal to toxicity studies as per OECD guidelines.
14. Repeated dose t toxicity studies - Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies.(2Nos.)
19. In-silico pharmacophorebased screening.
20. In-silico QSAR studies.
21. ADR reporting .

REFERENCES

1. Fundamentals of experimental Pharmacology-byM.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of in-vitro practical PharmacologybyIanKitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and AndrewB.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: QUALITY MANAGEMENT SYSTEMS
Subject Code: MQA102T

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives: Upon completion of this course the student should be able to

1. Understand the cGMP aspects in a pharmaceutical industry
2. To appreciate the importance of documentation
3. To understand the scope of quality certifications applicable to Pharmaceutical industries
4. To understand the responsibilities of QA & QC departments.

Sr No	Course Contents	Total Hrs
1	Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies. Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality.	12
2	Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.	12
3	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	12

4	Drug Stability: ICH guidelines for stability testing of drug substances and drug products. Study of ICH Q8, Quality by Design and Process development report Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12
5	Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	8
6	Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking.	4

REFERENCES:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield- Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: QUALITY CONTROL AND QUALITY ASSURANCE
Subject Code: MQA103T

Scope: This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives: Upon completion of this course the student should be able to

1. The importance of quality
2. ISO management systems
3. Tools for quality improvement
4. Analysis of issues in quality
5. Quality evaluation of pharmaceuticals
6. Stability testing of drug and drug substances
7. Statistical approaches for quality

Sr No	Course Contents	Total Hrs
1	Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.	12
3	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).	12
4	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing	12

	Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.	
5	Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.	12

REFERENCES:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
14. Packaging of Pharmaceuticals.
15. Schedule M and Schedule N.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER
Subject Code: MQA104T

Scope: This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives: Upon completion of this course the student should be able to

1. To understand the new product development process
2. To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
3. To elucidate necessary information to transfer technology of existing products between various manufacturing places

Sr No	Course Contents	Total Hrs
1	Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA	12
2	Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development	12
3	Pilot plant scale up: Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12
4	Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials. Quality control test: Containers, closures and secondary packing materials.	12
5	Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12

REFERENCES:

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febriger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: PHARMACEUTICAL QUALITY ASSURANCE
Subject Code: MQA105P

List of Practicals:

PART A:

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

PART B:

1. Case studies on
a. Total Quality Management
b. Six Sigma
c. Change Management/ Change control. Deviations,
d. Out of Specifications (OOS)
e. Out of Trend (OOT)
f. Corrective & Preventive Actions (CAPA)
g. Deviations
2. Development of Stability study protocol
3. Estimation of process capability
4. In process and finished product quality control tests for tablets, capsules,
5. parenterals and semisolid dosage forms.
6. Assay of raw materials as per official monographs
7. Testing of related and foreign substances in drugs and raw materials
8. To carry out pre formulation study for tablets, parenterals (2 experiment).
9. To study the effect of pH on the solubility of drugs, (1 experiment)
10. Quality control tests for Primary and secondary packaging materials
11. Accelerated stability studies (1 experiment)
12. Improved solubility of drugs using surfactant systems (1 experiment)
13. Improved solubility of drugs using co-solvency method (1 experiment)
14. Determination of Pka and Log p of drugs.

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: HAZARDS AND SAFETY MANAGEMENT
Subject Code: MQA201T

Scope: This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides theprinciplebased approach tosolvethe complex tribulations.

Objectives: Upon completion of this course the student should be able to

1. Understand about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the industry environment.
4. Ensure safety standards in pharmaceutical industry
5. Provide comprehensive knowledge on the safety management
6. Empower an ideas to clear mechanism and management in different kinds of hazard managements ystem
7. Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Sr No	Course Contents	Total Hrs
1	Multidisciplinary nature of environmental studies: Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b)Water resources; c) Mineral resources; d) Energy resources e)Land resources Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes	12
2	Air based hazards: Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system	12
3	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept	12
4	Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion electricity	12

	passivation, ventilation, and sprinkling, proofing, relief systems-relief valves ,flares, scrubbers	
5	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services	12

REFERENCES:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad– 380 013,India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL VALIDATION
Subject Code: MQA202T

Scope: The main purpose of the subject is to understand about validation and howit can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application .

Objectives: Upon completion of this course the student should be able to

1. The concepts of calibration, qualification and validation
2. The qualification of various equipments and instruments
3. Process validation of different dosage forms
4. Validation of analytical method for estimation of drugs
5. Cleaning validation of equipments employed in the manufacture of pharmaceuticals.

Sr No	Course Contents	Total Hrs
1	Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status Calibration Preventive Maintenance, Change management).	10
2	Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS	10
3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen	10
4	Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals andaerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation-A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP	10

5	Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place(CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital signature-21CFR Part11and GAMP	10
6	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications;International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices	10

REFERENCES:

1. B. T.Loftus &R. A.Nash, "Pharmaceutical Process Validation",Drugs and Pharm Sci. Series, Vol. 129,3rdEd.,MarcelDekkerInc.,N.Y.
2. The Theory &Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4. Validation of Aseptic Pharmaceutical Processes, 2ndEdition, by Carleton &Agalloco
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance inthe Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A.Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton(Ed.)and James Agalloco(Ed.),Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam,Y.C.Lee,Yue .Zhang, WileyI nterscience
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good ITPractice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: I

Subject Name: AUDITS AND REGULATORY COMPLIANCE
Subject Code: MQA203T

Scope: This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives: Upon completion of this course the student should be able to

1. To understand the importance of auditing
2. To understand the methodology of auditing
3. To carry out the audit process
4. To prepare the auditing report
5. To prepare the check list for auditing

Sr No	Course Contents	Total Hrs
1	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	Role of quality systems and audits in pharmaceutical manufacturing environment: cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries	12
3	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	12
4	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials	12
5	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	12

REFERENCES:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C
2. Pharmaceutical Manufacturing Handbook,Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications
3. Handbook of microbiological Quality control. Rosamund M.Baird, Norman A.Hodges,StephenP. Denyar.CRC Press.2000
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor andFrancis (2005).

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL MANUFACTURING TECHNOLOGY
Subject Code: MQA204T

Scope: This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives: Upon completion of this course the student should be able to

1. The common practice in the pharmaceutical industry developments, plant layout and production planning
2. Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology
3. Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing
4.

Sr No	Course Contents	Total Hrs
1	Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location Factors influencing. Plant layout: Factors influencing, Special provisions, Storage spacerequirements,sterile and asepticarea layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control	12
2	Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP &LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology:Principles, process, equipment	12
3	Non sterile manufacturing process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated),Capsules(Hard &Soft). Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying	12

	equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered	
4	Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material	12
5	Quality by design (QbD) and process analytical technology (PAT): Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD),QA,QC and GAMP. PAT guidance, standards and regulatory requirements	12

REFERENCES:

1. Lachman L,Lieberman HA,Kanig JL. The theory and practice of industrial rd pharmacy, 3 ed., Varghese Publishers, Mumbai 1991
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed.,B.I.PublicationsPvt. Ltd,Noida,2006
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosageforms: nd tabletsVol.I-III,2 ed.,CBS Publishers & distributors ,New Delhi, 2005
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4 Inc, New York,2005
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai
6. Indian Pharmacopoeia. Controller ofPublication.Delhi,1996
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London,2008
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc,USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor&Francis,1st Edition.UK
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009.Informa Healthcare USA Inc. New York
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey andSons,NewJersey,2008

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

PHARMACEUTICAL QUALITY ASSURANCE

SEMESTER: II

Subject Name: PHARMACEUTICAL QUALITY ASSURANCE
Subject Code: MQA205P

List of Practicals:

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air
5. Estimation of Chlorine in Work Environment
6. SamplingandanalysisofSO2 using Colorimetric method
7. Qualification of following Pharma equipment
   A) Autoclave
   B) .Hot air oven
   C) Powder Mixer (Dry)
   D) Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of atleast two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production
15. Check list for sterile production area
16. Check list for Water for injection
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT

Bachelor of Pharmacy

Semester - I w.e.f June 2012

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2210001	Unit Operation-I	4	0	3	7	80	20	80	20	200
2210002	Pharm Chem-I (Inorganic Chemistry)	4	0	3	7	80	20	80	20	200
2210003	Pharmaceutical Analysis-I	4	0	3	7	80	20	80	20	200
2210004	Human Anatomy Physiology - I	4	0	3	7	80	20	80	20	200
2210005	Basics of Computer Applications - I	2	0	3	5	80	20	80	20	200
	Total	**18**	**0**	**15**	**33**					

Semester - II w.e.f Dec 2012

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2220001	Physical Pharmacy	3	0	3	6	80	20	80	20	200
2220002	Pharmaceutical Chemistry-II (Physical Chemistry)	3	0	3	6	80	20	80	20	200
2220003	Pharmaceutical Analysis-II	4	0	3	7	80	20	80	20	200
2220004	Human Anatomy Physiology-II	4	0	3	7	80	20	80	20	200
2220005	Basics of computer application- II	0	0	3	3	0	0	80	20	100
1990001	Contributor Personality Development	4	0	0	4	80	20	0	0	100
2220006	Environmental Studies	3	0	0	3	80	20	0	0	100
	Total	**21**	**0**	**15**	**36**					

Semester - III w.e.f June 2013

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2230001	Dispensing Pharmacy I and Drug Store Management	3	0	3	6	80	20	80	20	200
2230002	Pharmaceutical Engineering	3	0	3	6	80	20	80	20	200
2230003	Pharmaceutical Chemistry-III (Biochemistry – I)	3	0	3	6	80	20	80	20	200
2230004	Pharmaceutical Chemistry-IV (Organic Chemistry – I)	3	0	3	6	80	20	80	20	200
2230005	Health Education & Community Health	3	0	0	3	80	20	0	0	100
2230006	Pharmacognosy-I	3	0	3	6	80	20	80	20	200
	Total	**18**	**0**	**15**	**33**					

Semester - IV w.e.f Dec 2013

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2240001	Unit Operations-II	3	0	3	6	80	20	80	20	200
2240002	Dispensing Pharmacy II and Pharma Industrial Management	3	0	3	6	80	20	80	20	200
2240003	Pharmaceutical Chemistry – V (Biochemistry – II)	3	0	3	6	80	20	80	20	200
2240004	Pharmaceutical Chemistry – VI (Organic Chemistry – II)	3	0	3	6	80	20	80	20	200
2240005	Basic Concepts of Pharmacology and Clinical Pharmacy Practice	3	0	0	3	80	20	0	0	100
2240006	Pharmacognosy-II	3	0	3	6	80	20	80	20	200
	Total	**18**	**0**	**15**	**33**					

Semester - V w.e.f June 2014

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2250001	Hospital and Community Pharmacy	3	0	0	3	80	20	0	0	100
2250002	Pharmaceutical Microbiology & Biotechnology – I	3	0	3	6	80	20	80	20	200
2250003	Pharmaceutical Analysis III	3	0	3	6	80	20	80	20	200
2250004	Pharmaceutical Chemistry – VII (Medicinal Chemistry - I)	3	0	3	6	80	20	80	20	200
2250005	Pharmacology and Pharmacotherapeutics–I	3	0	3	6	80	20	80	20	200
2250006	Pharmacognosy-III	3	0	3	6	80	20	80	20	200
	Total	**18**	**0**	**15**	**33**					

Semester - VI w.e.f Dec 2014

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2260001	Forensic Pharmacy	3	0	0	3	80	20	0	0	100
2260002	Pharmaceutical Microbiology & Biotechnology – II	3	0	3	6	80	20	80	20	200
2260003	Pharmaceutical Analysis IV	3	0	3	6	80	20	80	20	200
2260004	Pharmaceutical Chemistry – VIII (Medicinal Chemistry - II)	3	0	3	6	80	20	80	20	200
2260005	Pharmacology and Pharmacotherapeutics–II	3	0	3	6	80	20	80	20	200
2260006	Pharmacognosy-IV	3	0	3	6	80	20	80	20	200
	Total	**18**	**0**	**15**	**33**					

Semester - VII w.e.f June 2015

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2270001	Dosage form Design I	3	0	3	6	80	20	80	20	200
2270002	Pharmaceutical Technology I	3	0	3	6	80	20	80	20	200
2270003	Pharmaceutical Chemistry – IX (Medicinal Chemistry - III)	3	0	3	6	80	20	80	20	200
2270004	Pharmacology and Pharmacotherapeutics – III	3	0	3	6	80	20	80	20	200
2270005	Pharmacognosy-V	3	0	3	6	80	20	80	20	200
	Elective - I	3	0	0	3	80	20	0	0	100
	Total	**18**	**0**	**15**	**33**					

Subject code	Elective - I
2270006	Cyber Security
2270007	Environmental Toxicology and Green Audit
2270008	Nutraceuticals
2270009	Pharmaceutical Marketing Management
2270010	Pharmacovigilance
2270011	Herbal Cosmetics
2270012	Green Chemistry
2270013	Agronomy and Forestry of Medicinal Plants
2270014	Instrumental and Process Validation
2270015	Quality by Design (QbD) and Process Analytical Technology (PAT)
2270016	Innovations in Conventional Drug Delivery System
2270017	Disaster Management

Semester - VIII w.e.f Dec 2015

Subject Code	Subject Name	Teaching Scheme (Hours)			Credits	Theory		Practical		Total Marks
		Theory	Tutorial	Practical		External	Internal	External	Internal	
2280001	Dosage form Design II	3	0	3	6	80	20	80	20	200
2280002	Pharmaceutical Technology II	3	0	3	6	80	20	80	20	200
2280003	Pharmaceutical Chemistry – X (Medicinal Chemistry - III)	3	0	3	6	80	20	80	20	200
2280004	Pharmacology and Pharmacotherapeutics – IV	3	0	3	6	80	20	80	20	200
2280005	Pharmacognosy-VI	3	0	3	6	80	20	80	20	200
	Elective - II	3	0	0	3	80	20	0	0	100
	Total	**18**	**0**	**15**	**33**					

Subject code	Elective - II
2280006	Computer Applications in drug discovery
2280007	Pharmacy Practice
2280008	Bioavailability and Therapeatic Drug Monitoring
2280009	Food Analysis
2280010	Hospital Management and Medical Tourism
2280011	Drug Approval Process
2280012	Intellectual Property Rights and Patents
2280013	Medical Writing and coding
2280014	Commerce of herbs and Phytoconstitutents
2280015	Genetic engineering and gene therapy
2280016	Current advances in Novel Drug Delivery Systems
2280017	Elementary Mathematics

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM SEMESTER-I

UNIT OPERATION-I

Subject code: 2210001

Theory (4 Hours / Week; 4 Credits, 60 Hours)

Sr. No.	Course Contents	Hours
1.	**Size reduction** Objectives, importance and theory of size reduction. Factors affecting, energy requirements, mechanisms and methods (dry/wet grinding) of size reductions. Principle, material of construction, applications, advantages and disadvantages of various mills like cutter mill, hammer mill, roller mill, ball mill, fluid energy mill, colloid mill. Study of latest industrial mills used in manufacturing of various dosage forms and their application.	11
2.	**Size separation** Principles of size separation, screen and its standards as per pharmacopoeia, screening equipments including shaking & vibrating screens, gyratory screens, sedimentation type industrial separators etc. Methods of determining size distribution. Fluid classification methods like sedimentation and elutriation, Principle, material of construction, applications, advantages and disadvantages of cyclone separator, sedimentation tank, etc.	8
3.	**Mixing** Definition, objectives, mechanism and theory of mixing. Type of mixtures: liquid mixing, powder mixing, semi solids mixing. Principle, material of construction, applications, advantages and disadvantages of shaker mixer, propeller mixer, turbine mixer, paddle mixer, planetary mixer, double cone mixer, V mixer, sigma mixer and colloid mill, ultrasonic mixer, etc.	9
4.	**Crystallization** Objectives, crystal lattice, types of crystal, crystal form, size and habit, formation of crystals, super saturation theory, factors affecting crystallization process and crystal growth. Study of various types of crystallizers including Swenson walker, tanks, agitated & batch, circulating magma, vaccum and crystal crystallizer etc. Methods for prevention of caking of crystals. Brief study of spherical crystallization process. Numerical problems on crystal yield.	13
5.	**Extraction and leaching** Principle, theory and types of extraction. Solvents used for extraction, leaching and extraction equipments, small scale and large scale extraction methods, special extraction techniques-supercritical fluid extraction, applications in pharmaceutical industry.	8

6.	**Automated process control system** Process variables - temperature, pressure, vacuum, flow level and their measurements. Elements of automatic process control systems. Elements of computer aided manufacturing. Introduction to latest process control systems used in pharmaceutical industry.	7
7.	**Industrial hazards and safety precautions** Industrial hazards: mechanical, chemical, electrical, fire and dust hazards. Measures to prevent and combat the hazards. Accident records. Introduction to waste water system in industry.	4

UNIT OPERATION-I

Subject code: 22100P1

Practicals (3 hours/week, 4 credits, 45 hours)

Sr. No.	Course Contents
1	Study of various process parameters during size reduction by various mills.
2	Study of various techniques to determine particle size distribution.
3	Determination of degree of mixing of solid-liquid and solid-solid mixing by different mixing equipments.
4	Study the effect of various factors (rate of cooling, rate of agitation, seeding, solvent, etc.) on crystallization of different salts.
5	Study of liquid-liquid and solid-liquid extraction of various materials by different extraction techniques like maceration, percolation, infusion and decoction.
6	Demonstration of handling hazardous chemicals and safety precautions.

Books Recommended:

1. Elementary Chemical Engineering - Max S. Peters, Published by McGraw Hill Book Company, New York, 1954
2. Perry's Chemical Engineer's Handbook - Robert H Perry, Green D. W., Maloney J. O. 7th Edition, 1998, McGraw – Hill Inc., New York.
3. Tutorial Pharmacy by Cooper & Gunn, ed. S. J. Carter, CBS Publishers & Distributors, Delhi, 6th Edition, 2000.
4. Unit Operations of Chemical Engineering, 5th edition - McCabe, Smith & Harriott, McGraw – Hill Inc., New York.
5. Pharmaceutics: The Science of Dosage Form Design - M. E. Aulton.
6. The Theory & Practice of Industrial Pharmacy – Lachman L., Lieberman H.A. & Kanjig J. L., 3rd edition, 1990 Varghese Publishing House, Bombay.
7. Alfonso G. Remington: The Science & Practice of Pharmacy. Vol. I & II. Lippincott, Williams & Wilkins Philadelphia.
8. Online resources can also be accessed.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM SEMESTER-I
PHARM CHEM-I (INORGANIC CHEMISTRY)
SUBJECT CODE: 2210002
Theory (4 Hours / Week; 4 Credits, 60 Hours)

Sr. No.	Course Contents	Hours
1.	**Introduction** to Pharmaceutical Chemistry and pharmacopeia.	1
2.	**Impurities in Pharmaceuticals**: Sources of impurities, tests for purity and identity, limit tests for iron, arsenic, lead, heavy metals, chloride, sulphate.	5
3.	**An outline of method of preparation, uses, special tests if any, of the following class of inorganic pharmaceuticals included in the current pharmacopoeia:**	
3.1	**Acids and Bases**: Buffers, Waters	4
3.2	**Gastrointestinal agents**: Acidifying agents, Antacids, Protective and adsorbents, Cathartics.	7
3.3	**Major intra and extra-cellular electrolytes**: physiological ions, electrolytes used for replacement therapy, acids-base balance and combination therapy.	7
3.4	**Essential and trace elements**: Transition elements and their compounds of pharmaceutical importance: Iron and haematinics, mineral supplements.	6
3.5	**Topical agents**: Protective, Astringents and Anti-infectives.	5
3.6	**Gases and Vapors**: Oxygen, Anesthetics and Respiratory Stimulants.	2
3.7	**Dental products**: Dentifrices, Anti-caries agents.	3
3.8	Complexing and Chelating agents used in therapy.	2
3.9	**Miscellaneous agents**: Sclerosing agents, Expectorants, Emetics, poisons and Anti-dotes, Sedatives etc	7
3.10	**Pharmaceutical Aids used in pharmaceutical industry** : Anti-oxidants, preservatives, Filter aids, Adsorbents, Diluents,	6
3.11	**Inorganic Radio pharmaceuticals:** Nuclear radiopharmaceuticals, reactions, Nomenclature, Methods of obtaining their standards and units of activity, measurements of activity, clinical applications and dosage, hazards and precautions.	5

PHARM CHEM-I (INORGANIC CHEMISTRY)

Subject code: 22100P2

Practicals (3 hours/week, 3 credits, 45 hours)

Sr. No.	Course Contents
1.	The backgrounds and systematic qualitative analysis of Inorganic mixture of up to 4 radicals. Six mixtures to be analyzed, Preferably by semi-micro methods.
2.	All identification tests for pharmacopoeial inorganic pharmaceuticals and qualitative tests for cations and anions should be covered.
3.	Limit tests for Cl, SO_4, As, Heavy metals and Lead along with a few modifications.
4.	Volumetric Analysis of few important compounds covered in theory

Books Recommended:

1. Inorganic Medicinal and Pharmaceutical Chemistry : J. H. Block, E. B. Roche, T. O. Soine, C. O. Wilson, Varghese Publishing House, First Indian Reprint, 1986.
2. Bentley and Driver's Textbook of Pharmaceutical Chemistry: Revised by L. M. Atherden, Oxford University Press, 8th Ed. 1969.
3. The Indian Pharmacopoeia, Latest Edition, Controller of Publications, Delhi.
4. Practical Pharmaceutical Chemistry edited by A. H. Beckett, J. B. Stenlake, CBS Publishers, and First Indian edition 1987.
5. Vogel's Qualitative Inorganic Analysis Revised by G. Svehla, Longman Gr. Ltd., 7th Ed. 1996.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM SEMESTER-I

PHARMACEUTICAL ANALYSIS-I

Subject code: 2210003

Theory (4 Hours / Week; 4 Credits, 60 Hours)

Sr. No.	Course Contents	Hours
1.	**Basics of drugs and formulation analysis :** Weights, balances, importance of analysis, quality control and quality assurance, analytical methods (classification, validation parameters), requirements – chemicals (types, purification, checking purity), glass wares (types, calibration, cleaning), sampling techniques, sampling error minimization. Units of concentrations. Errors science, errors minimization.	6
2.	**Volumetric analysis (Titrimetric analysis)**	
2.1	**Acid-base titrations:** Relative strength and its effect on titration, common ion effect, pH, Henderson-Hesselbach equation, buffers, neutralization curve, acid bas indicators, theory of indicators, back titrations, biphasic titrations, pharmacopoeial applications, hydrolysis of salts, ionic products of water and law of mass action.	15
2.2	**Redox titrations :** Theory of redox titrations, redox indicators, types of redox titrations, iodometry, cerrimetry, mercury metry, diazotization nitrite titrations, 2,6-dichlorophenol indophenol titrations, titration curve and calculations of potentials during course of titrations.	12
2.3	**Argentometric or precipitation titrations :** Mohrs, Fajans and Volhard methods	6
2.4	**Nonaqueous titrations :** Nonaqueous solvents, titrants and indicators. Differentiating and leveling solvents.	5
2.5	**Complexometric titrations :** Theory of the titrations, titrant, indicators and pharmacopoeial applications.	6
2.6	**Miscellaneous titrations :** Karl-Fischer titrations, Kjeldahl method.	3
3.	**Gravimetric analysis :** Stability, solubility products, types of precipitations, precipitation techniques, pharmacopoeial applications	7

PHARMACEUTICAL ANALYSIS-I
B.PHARM SEMESTER-I
Subject code: 22100P3
Practicals (3 hours/week, 3 credits, 45 hours)

Sr. No.	Course Contents
1	Acid-base titrations Simple, back titrations, titrations of mixtures like $NaOH+Na_2CO_3$, borax + boric acid.
2	Redox titrations Simple, iodometry, cerrimetry, 2,6-dichlorophenol-indophenol titrations, mixtures like Fe+2 + Fe+3, oxalic acid + sodium oxalate
3	Complexometric titrations Replacement, back titrations
4	Nonaqueous titrations
5	Argentometric titrations
6	Gravimetric assay of one pharmacopoeial drug
7	Calibrations/cleaning of glasswares and checking precision and lower limit of quantitaiton of titrimetric methods.

Books recommended:

1. Pharmacopoeia: USP, B.P., I.P.
2. Practical Pharm. Chemistry, Vol. I – Backett, The athlone Press of University of London.
3. Fundamentals of Analytical Chemistry – Skoog, Harcourt College Publishers.
4. Quantitative chemical analysis – Vogel A. I., Pearson Education.
5. Text Book of Pharmaceutical Analsys – K. A. Connor, John Willey & Sons, New York.
6. Quantitative Chemical Analysis – Ayer by Harper & Row, New York.

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B. PHARM. SEMESTER-I

HUMAN ANATOMY PHYSIOLOGY

Subject code: 2210004

Theory (4 Hours / Week; 4 Credits, 60 Hours)

Sr. No.	Course Contents	Hours
1	**Introduction and Scope** of Anatomy and Physiology. Structural and functional organization of various organ systems. Homeostasis, Negative and positive feedback system. Transcellular, Extra-cellular and Intra-cellular fluids and their composition. Serosal cavities. Definitions of various terms used in Anatomy.	4
2	**Structure and function of cell** and its components with special emphasis on molecular structure of cell membrane, transporter mechanisms, mitochondria and nucleus. Cell cycle and its significance. Mechanism of protein synthesis by cell organelles	6
3	**Elementary tissues of the body:** Various elementary tissues and their subtypes with Characteristics, location and functions: epithelial tissue, muscular tissue, connective tissue and nervous tissue	4
4	**Osseous system:** Structure, Composition and function of skeleton. Histology of bone. Classification of joints and their function. Types of movements of joints. Brief introduction to disorders of bones and joints	5
5	**Muscular system:** Gross anatomy of skeletal muscles. Neuromuscular junction. Physiology of muscle contraction and its components. Properties of skeletal muscles. Brief introduction to muscle disorders.	7
6	**Haemopoietic system:** Introduction, composition, properties and functions of blood and its components. . Haemopoiesis Lifecycle and physiology of RBC. Blood groups and their significance. Hemostasis and fibrinolytic pathway. Types of Anemia. Brief information regarding disorders of blood.	9
7	**Lymph and lymphatic system:** Composition, formation, circulation and functions of lymph, Basic physiology and functions of spleen. Disorders of lymph and lymphatic system.	3
8	**Cardiovascular System:** Anatomy and physiology of the heart, Circulatory system including coronary circulation and pulmonary circulation. Properties of Cardiac muscle, Electrocardiogram (ECG), Blood pressure and its regulation, Basic understanding of cardiac cycle and heart sounds, cardiac output and factors affecting cardiac output. Renin Angiotensin Aldosterone system and its significance. Brief introduction to cardiovascular disorders like hypertension, atherosclerosis, angina pectoris, myocardial ischaemia and infarction, congestive cardiac failure and cardiac arrhythmias**.**	11

9	**Body defense Mechanisms and Immunity:** Basic principles of immunity, innate immunity, adaptive immunity, acquired immunity, immune interactions (cellular and humoral immunity).	5
10	**Digestive system**: Gross anatomy of the gastrointestinal tract. Structure and functions of various organs of alimentary canal and associated organs like liver, pancreas and gall bladder. Physiology of digestion and absorption at various parts of gastrointestinal tract including phases of gastric secretion. Brief overview of disorders of G. I. tract and associated organs.	6

HUMAN ANATOMY PHYSIOLOGY
Subject code: 22100P4
***Practical* (3 hours/week, 3 credits, 45 hours)**

Sr. No.	Course Contents
1	Study of the human skeleton with the help of charts and models, Study of joints with the help of charts
2	Digestive and Muscular System (Names, position, attachments and functions of various muscles) with the help of charts and models
3	Histology of elementary tissues and various organs of Cardiovascular, Digestive and Muscular System
4	Hematology experiments Use and Care of Microscope Study of Haemocytometry Hemoglobin estimation Total WBC count Total RBC count Differential WBC count Determination of clotting time and bleeding time of blood Erythrocyte Sedimentation Rate (ESR) Blood Groups, Effect of Osmosis on RBC
5	Study of the human cardiovascular (Heart, Arterial and Venous System), Circulatory system including arterial and venous system with special reference to the names and positions of main arteries and veins, Coronary circulation, Pulmonary circulation. Determination of pulse rate, blood pressure, listening to heart sounds. Demonstration of ECG
6	Amphibian experiments for study of properties of skeletal muscle using either demonstrations or computer simulated experiments

Books Recommended (Latest Editions):

1. William J. Larsen: Anatomy – Development, function, Clinical Correlations– Saunders (Elsevier Science)
2. Guyton A.C. and Hall J.E.: Textbook of Medical Physiology – 10th Edition– W. B. Saunders
3. Seeley R. R., Stephens T. D. and Tate P.: Anatomy and Physiology 2000– McGraw Hill Co.
4. Waugh A. and Grant A.: Ross and Wilson's Anatomy and Physiology in Health and illness — Churchill Livingstone
5. Sobotta. Atlas of Human Anatomy (2 Volumes) –Edited by Putz and R. Pabst, Lippincott, Williams and Wilkins
6. Anne M. R. Agur & Ming J. Lee: Grant's Atlas of Anatomy –Lippincott, Williams and Wilkins
7. Gosling T. A., Harris P. F., Whitmore I., William, Human Anatomy: Color Atlas and Text — Mosby
8. Bullock B.L. & Henze R.L., Focus on Pathophysiology –Lippincott
9. Martini F. Fundamentals of Anatomy and Physiology (Prentice Hall)
10. Goyal_R. K. & Mehta A. A._ Human Anatomy Physiology And Health Education, (B. S. Shah Prakashan)
11. West J. B. Best and Taylor's physiological Basis of Medical Practice (Williams and Wilkins, Baltimore)
12. Tortora G. J. and Anagnodokos, N. P. Principles of Anatomy and Physiology (Harper and Colling Publishers, New York)
13. Joshi Vijaya D. Preparatory Manual for Undergraduates Physiology (B.I. Churchill Livingstone) –
14. Chatterjee C. C. Human Physiology (Medical Allied Agency, Calcutta)
15. Goyal R. K. et al.: Practical Anatomy Physiology and Biochemistry (B.S. Shah Prakashan, Ahmedabad)
16. Garg K. et al. A Text Book of Histology (CBS Publishers, New Delhi)
17. Lesson C. R. et al.: Text Book of Histology (W.B.Saunders Company)

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM. SEMESTER - I
BASICS OF COMPUTER APPLICATIONS
Subject Code: 2210005
Theory (2 Hours / Week; 2 Credits)

Sr. No.	Course Content	Hours
1	**Computer Fundamentals** Definition, characteristics, history, computer terminology, computer organization, input & output devices, storage devices (including latest devices), classifications of computers (including current computer systems), application of computers in pharmacy, introduction to computer virus, problems associated with virus infection and its remedies.	**02**
2	**Operating Systems** Definition, functions of an operating system, types of operating systems and their characteristics, difference between operating system and application software. *Windows Operating Systems***:** Desktop, start-menu, components of control panel, accessories, components of my computer and my documents, recycle bin, printer and mouse settings, maximizing, minimizing, restoring and closing of windows, windows explorer, taskbar and its functions. Different file formats, various types of files, file extension, opening files by various programs	**05**
3	**Basics of MS Word and its applications** Word Essentials, Parts of MS Word screen, Typing and Editing, Finding and Replacing, Autocorrect and Auto text, Reusing Text and Graphics, use of spell-check & grammar, thesaurus and scientific symbols, viewing of document by various ways, Editing Tools, Text Formatting, Text Character, Formatting Paragraphs, Formatting and Sorting Lists, Page Design and Layout, Page Margins, Page Numbers, Columns, Working with Tables, Creating and formatting of tables and sorting, merging of data in tables etc., inserting, deleting and sizing of rows and columns in tables, Opening, Saving and Protecting Documents, Locating and Managing Documents, Printing.	**06**
4	**Basics of MS Excel and its applications** Introduction to EXCEL worksheet, calculations in EXCEL, preparation of templates for application in pharmaceutical chemistry, pharmaceutical technology, pharmacology and pharmacognosy (statistical treatment of data for Beers Lamberts curve, solution of problems based on physical chemistry, stability study, area under the curve, etc.) Special attention must be given to arithmetic expressions. Library functions such as logarithm, square root, sum, average, standard deviation, t-test, F-test, Chi-square test, ANOVA etc. Drawing graphs in EXCEL- line graph, histogram and pie-chart. Editing chart features such as annotation, labeling of axis, changing legends etc.	**06**
5	**MS PowerPoint** Creating and viewing a presentation, adding animations and managing slides etc.	**02**

6	**Internet and its applications** Internet – Basic terms, software and hardware requirement for internet, web browsers, internet tools, study of pharmaceutical web sites, online journals and search engines, searching through pharmaceutical databases, study of patent websites. Use of emails, mail merge and application of address book.	**05**
7	**Introduction to the following software** MS Paint, MS Access, Outlook, Adobe acrobat reader, Adobe Professional, Chemdraw, ISIS Draw, Nero Burning roam	**04**

BASICS OF COMPUTER APPLICATIONS

Subject Code: 22100P5

Practical (3 Hours / Week; 3 Credits)

Sr. No.	Course Contents
	Practical exercises should be based on theoretical topics. The practical should broadly cover the following:
1	Exercises on word processing to execute various commands in preparing and editing documents.
2	Preparation of documents and implementing various formatting parameters in MS Word.
3	Working with footnotes and endnotes, referencing documents
4	Working with auto-indexing, table and figure numbering
5	Preparing and editing worksheets in MS EXCEL, Inserting formulas for different functions in MS EXCEL like sum, average, standard deviation, logarithm, square root etc.
6	Drawing various charts using pharmaceutical experimental data
7	Preparation of power point presentation with animation
8	Working with internet browsing and using search engines
9	E-mailing using address book and applying mail merge
10	Surfing various pharmaceutical web sites, online journals and patent search

Recommended Books:

1. Taxali R.K., P.C. Software for Windows 98 made simple – 8th Edition – 2002 – Tata Mc, New Delhi.
2. WORD 2000, Guy Hart Davis, BPB Publications, New Delhi, 1999
3. MS Office: Step by Step, Joyce Cox, Prentice Hall of India, New Delhi, 2007
4. Accessing and Analysing Data with MS EXCEL, Cornell, Prentice Hall of India, New Delhi, 2007.
5. Manuals available with the software

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM SEMESTER-II

PHYSICAL PHARMACY

Subject code: 2220001

THEORY (3 Hours / Week; 3 Credits, 45 Hours)

Sr. No.	Course Contents	Hours
1.	**States of Matter:** Introduction, binding forces between molecules, states of matter-solids, liquids, gases, liquid crystals, glassy state, phase equilibrium and phase rule, condensed systems	5
2.	**Solubility and Distribution Phenomenon:** General principles, solvent-solute interactions, solubility of gases in liquids, solubility of liquids in liquids, solubility of solids in liquids, distribution of solutes between immiscible solvents.	6
3.	**Surface and Interfacial phenomenon:** Liquid interface, adsorption at liquid interfaces, adsorption at solid interface, applications of surface active agents, electrical properties of interfaces.	6
4.	**Complexation and protein binding** : Metal complexes, organic molecular complexes, protein binding, thermodynamic treatment of stability constants, applications of complexes in dosage forms.	5
5.	**Disperse systems:** a. Colloidal dispersions: Definition, types, properties of colloids, protective colloids, applications of colloids in pharmacy. b. Suspensions and Emulsions : Interfacial properties of suspended particles/globules, settling in suspensions, theory of sedimentation, effect of Brownian movement, sedimentation of flocculated particles, sedimentation parameters, wetting of particles, controlled flocculation, flocculation in structured vehicle, rheological considerations, emulsions ; types, theories, physical stability.	9
6.	**Micromeritics:** Particle size and distribution, methods for determining particle size, particle shape and surface area, methods for determining surface area, derived properties of powders,	6
7.	**Rheology :** a. Newtonian system, Non-Newtonian systems, thixotropy in formulation, determination of rheological properties, applications in pharmacy. b. Flow of Powders: Introduction, methods to determine, factors affecting powder flow, pharmacopeial specification of angle of repose, hausner's ratio, carr's index.	8

B.PHARM SEMESTER-II
PHYSICAL PHARMACY
Subject code: 22200P1
PACTICAL (3 Hours / Week; 3 Credits, 45 Hours)

Practical related to following topics should be covered:

Sr. No.	Course Contents	Hours
1.	Solubility of solids.	**45**
2.	Determination of phenol water coefficient.	
3.	Preparation of thymol salol eutectic system.	
4.	Preparation of ternary phase system with one pair of partially miscible liquid.	
5.	Determination of latent heat, vapor pressure, critical point.	
6.	To find out the distribution coefficient of given solid.	
7.	Determination of surface / interfacial tension, HLB value and CMC of surfactants	
8.	Determination of particle size and size distribution of powders by different methods.	
9.	Determination of derived properties of powder	
10.	Determination of particle shape and surface area	
11.	Determination of viscosity of Newtonian and Non-newtonian systems	
12.	Effect of temperature on viscosity of liquids.	
13.	Effect of particle size, porosity, moisture, lubricants, glidants on flow property of powder.	
14.	Studies on different types of complexes and determination of their stability constants	
15.	Determination of sedimentation parameters for suspensions and emulsions.	

Books Recommended (Latest Editions):

1. Martin's Physical pharmacy by Patrick J. Sinko, 5th edition, Lippincott Williams & Wilkins, New York, 2006.
2. Pharmaceutics: The Science of Dosage Form Design, 2nd edition, Aulton, Michael E., Chrchill Livingstone, London, 2002.
3. Remington: The Science and Practice of Pharmacy, Vol-I & II, 20th edition, Gennaro, Alfonso R.,Lippincott Williams & Wilkins, New York, 2002.
4. Physicochemical Principles of Pharmacy, 3rd edition, Florence, A. T. Atwood, D. Macmillan Press Ltd., London 1998.
5. Pharmaceutical Dosage Forms and Drug Delivery Systems, Ansel, Howard. C., Allen, Loyd V., Popovich, Nicholas G. Lippincott Williams & Wilkins, New York, 2002.
6. Cooper and Gunn's Tutorial Pharmacy, ed. Carter, S. J., 6th edition, CBS Publishers & Distributors, Delhi, 2000.
7. Bentley's textbook of Pharmaceutics by E. A. Rawlins

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM SEMESTER-II

PHARMACEUTICAL CHEMISTRY-II (PHYSICAL CHEMISTRY)

Subject Code: 2220002

THEORY (3 Hours /Week; 3 Credits, 45 Hours)

Sr. No.	Course Contents	Hours
1.	**The liquid state:** Physical properties surface tension, parachor, viscosity, refractive index, optical rotation, dipole moment of chemical constituents.	7
2.	**Solutions:** Ideal and real solutions, solutions of gases in liquids, colligative properties, partition co-efficient, conductance and its measurement, Debye-Huckel theory.	8
3.	**Thermodynamics:** Basic principles, First, Second and third laws, Zeroth Law, absolute temperature scale, thermo chemical equations, phase equilibria and phase rule, One and two component systems.	9
4.	**Adsorption:** Basic principles, Freundlich and Gibbs adsorption isotherms, Langmuir theory of adsorption.	4
5.	**Photochemistry:** Basic principles, Consequence of light adsorption, Jablonski diagram, Lambert-Beer Law, Quantum efficiency.	6
6.	**Chemical kinetics:** Zero, first and second orders reactions, complex reaction, theories of reaction kinetics, characteristics of homogeneous and heterogeneous catalysts, acid-base enzyme catalysis.	11

B.PHARM SEMESTER-II
PHARMACEUTICAL CHEMISTRY-II (PHYSICAL CHEMISTRY)
Subject Code: 22200P2
PRACTICAL (3 Hours / Week; 3 Credits, 45 Hours)

Sr. No.	Course Contents	Hours
1.	Experiments on surface tension and viscosity, partition coefficient, adsorption, order of reaction (First and Second), refractive index and molar refraction should be covered.	**45**

Books Recommended (Latest Editions):

1. Text book of Physical Chemistry: Samuel Glasstone, Macmillan India Limited, 2nd Ed. 1995.
2. Elements of Physical Chemistry; Peter Atkins, Julio de paula, Oxford University Press, 4th Ed. 2007.
3. Essentials of Physical Chemistry: Arun Bahl, B.S. Bahl, G.D. Tuli, S Chand & Co Ltd, 26th Ed. 2009.
4. Schaum's Outline of Theory and Problems of Physical Chemistry: Clyde R. Metz, Tata McGraw-Hill Publishing Company Ltd., New Delhi. 2nd Ed. 2004.
5. Physical Chemistry: Keith J. Laidler, John H. Meiser, CBS Publishers & Distributors, New Delhi. 2nd Ed. 2006.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM SEMESTER-II

PHARMACEUTICAL ANALYSIS-II

Subject Code: 2220003

THEORY (4 Hours / Week; 4 Credits, 60 Hours)

Sr. No.	Course Contents	Hours
1.	**Basics of instrumental analytical methods:** Advantages, limitations, validation,signal to noise ratio.	4
2.	Chromatography: Classification, theories, retention mechanism, separation efficiency, methodology an pharmacopoeial applications of column, paper and thin layer chromatography.	15
3.	**Electroanalytical methods:** Basics of electroanalytical methods	4
3.1	**Conductometry:** Conductances, factors affecting conductance, Kohlrausch law, conductivity cells, applications	6
3.2	**Potentio and pH metric methods:** Standard reduction potentials, various electrodes, electrodes and cell potential, applications of potentiometry and pH metry.	8
3.3	**Polarography, amperometry, biamperometry:** Basics of current flow in polarography, dropping mercury electrode, diffusion current, half wave potential, modifications like pulsed and differential pulse polarography, stripping voltametry, biamperometric titrations, amperometric titrations.	11
4	**Calorimetry:** Types, thermogravimetric analysis, differential scanning calorimetry, differential thermal analysis, melting point, etc. and their applications	5
5	**Polarimetry:** Polarimeter, qualitative and quantitative applications	3
6.	**Extraction techniques :** Simple extraction, multiple extractions, separation of drugs in multicomponent system. Effect of pH on extractability of drugs, continuous extractions.	3
7.	**Miscellaneous methods:** Oxygen combustion flask method, gasometric method, etc.	1

B.PHARM SEMESTER-II
PHARMACEUTICAL ANALYSIS-II
Subject Code: 22200P3
PRACTICAL (3 hours/week, 3 credits, 45 hours)

Sr. No.	Course Contents	Hours
	Quantitative analysis of different compounds involving following techniques:	**45**
1	Conductometry	
2	Potentiometry	
3	pH metry	
4	Polarimetry	
5	Column chromatography	
6	Thin layer chromatography	
7	Paper chromatography	
8	Polarography, amperometry and biamperometry	

Books recommended (Latest Editions):

1. Pharmacopoeia: IP, BP, USP.
2. Practical Pharm. Chemistry, Vol. I – Backett, The athlone Press of University of London.
3. Fundamentals of Analytical Chemistry – Skoog, Harcourt College Publishers.
4. Quantitative chemical analysis – Vogel A. I., Pearson Education.
5. Text Book of Pharmaceutical Analysis – K. A. Connor, John Willey & Sons, New York.
6. Textbook of Pharmaceutical Analysis – J. W. Munson, Marcel Dekker Inc., New York.

Gujarat Technological University

B. PHARM SEMESTER-II

HUMAN ANATOMY AND PHYSIOLOGY

Subject Code: 2220004

THEORY (4 Hours/Week, 4 Credits, 60 Hours)

Sr. No.	Course Contents	Hours
1	**Respiratory System:** Anatomy and physiology of various organs of respiratory system, pulmonary ventilation and factors affecting it, lung volumes and capacities, gas laws in relation to exchanges of oxygen and carbon dioxide, external and internal respiration including transport of gases in the blood, control and regulation of respiration, voice production, brief outline of hypoxia, asthma, COPD, emphysema, chronic bronchitis, pneumonia, tuberculosis, pulmonary oedema, sudden infant death syndrome, severe acute respiratory syndrome.	**8**
2	**Nervous system:** Organization and functions of nervous system, parts of Neuron, structural and functional classification of neurons, Neuroglia, Myelination, Gray and white matter, Graded potential, Resting membrane potential, Generation and propagation of Nerve action potential, Signal transmission at synapses, Post synaptic potentials (EPSP,IPSP) and their summation, Brief overview of various types of neurotransmitter, Overview of nervous disorders like multiple sclerosis, epilepsy.	**5**
	Anatomy of spinal cord (External, Internal), Protective structures of Spinal cord and nerves, names and functions of spinal nerves, physiology of spinal cord, sensory and motor tracts, reflexes and reflex arcs, brief outline of meningitis and poliomyelitis	**5**
	Major parts and protective coverings of brain, blood brain barrier, CSF, medulla oblongata, pons, midbrain, reticular formation, cerebellum, thalamus, Epithalumus, subthalamus, hypothalamus, cerebral cortex, lobes of cerebrum, cerebral white matter, basal nuclei, limbic system, sensory, motor and association areas of cerebral cortex, brain waves, cranial nerves names and functions, brief outline of cerebrovascular accident, transient ischemic attack, Alzheimer's disease, Dementia, Encephalitis, Attention Deficit Hyperactivity Disorder	**8**
	Comparison of somatic and autonomic nervous system, Anatomy of autonomic motor pathways (preganglionic neurons, autonomic ganglia, postganglionic neurons, enteric neurons), Synthesis, release and removal of neurotransmitters (e.g. Acetylcholine, Nor adrenaline), Physiology of the ANS, comparisons of sympathetic and parasympathetic divisions of ANS.	**4**
3	**Special Senses: Basics** Sensory modalities, Process of sensation, sensory receptors, somatic sensation, somatic sensory and motor pathways, Brief outline of Parkinson's disease, Amyotropic lateral sclerosis. Olfactory receptors, physiology of olfaction, Anatomy of taste buds and papillae, physiology of gustation, Accessory structures of eyes, anatomy of eyeball, image	**6**

	formation, refraction abnormalities, photo receptors and physiology of vision. Anatomy of ear, physiology of hearing and equilibrium. Brief outline of cataract, glaucoma, deafness, meniere's disease, otitis media.	
4	**Urinary System**: Anatomy of kidney, nephron, functions of renal system, glomerular filtration, tubular reabsorption and tubular secretion and their regulation, formation of urine, ureter, urinary bladder, urethra, brief outline of renal calculi, urinary tract infection, glomerular disease, renal failure, acid base balances and imbalances.	**8**
5	**Endocrine System:** Hormone, its type, endocrine glands (pituitary gland, thyroid, parathyroid, adrenals, Pancreas, testes and ovary), their secretion, regulation of secretion, functions and disorders (brief outline of pituitary gland, thyroid gland, adrenal gland, pancreatic islet disorders, definitions of gynecomastia, hirsutism).	**8**
6	**Reproductive System:** Gross Anatomy of male reproductive system and their functions, sperm and spermatogenesis, Accessory sex glands. Gross Anatomy of Female reproductive system and their functions, Ovum and Oogenesis, Physiology of Menstruation, Family planning, various contraceptive methods, Medical termination of pregnancy (Abortion), brief outline of erectile dysfunction (Impotence), Premenstrual syndrome, Male and female infertility, endometriosis, Benign prostatic hyperplasia.	**8**

B. PHARM. SEMESTER-II
HUMAN ANATOMY AND PHYSIOLOGY
Subject Code: 22200P4
PRACTICAL (3 Hours/Week, 3 Credits, 45 Hours)

Sr. No.	Course Contents	Hours
1	Biochemical analysis of urine: physical characteristics, normal constituents	**3**
2	Biochemical analysis of urine: abnormal constituents	**3**
3	Identify the constituents of urine in unknown sample.	**3**
4	Study anatomy of Respiratory system using charts and models	**3**
5	Study anatomy of Nervous system using charts and models	**3**
6	Study anatomy of Ear and Eye using charts and models	**3**
7	Study anatomy of Urinary system using charts and models	**3**
8	Study anatomy of Male & Female reproductive system using charts & models	**3**
9	Study histology and functions of various organs of Respiratory system and nervous system using slides	**3**
10	Study histology and functions of various organs of slides urinary system and male and female reproductive system using slides.	**3**
11	Study of various contraceptive techniques using charts	**3**
HUMAN EXPERIMENTS		
12	Determination of body temperature and study of learning and memory (Short term and long term)	**3**
13	Determination of lung function a. Determination of lung volumes and vital capacity using Spirometer / Flowmeter b. Determination of breath holding time	**3**
14	Determination of vision acuity a. Near Point and near response b. Determination of Stereoscopic vision c. Dominance of the eye	**3**
15	Determination of other special senses a. Temperature sensations b. Sensation of taste c. Sensation of smell	**3**

Books Recommended (Latest Editions):

1. Tortora Gerard. J. and Derrickson Bryan. Principles of Anatomy and Physiology (International Student Edition 13th edition- Wiley)
2. Guyton A.C. and Hall J.E. : Textbook of Medical Physiology – 10th Edition– W. B. Saunders
3. Waugh A. and Grant A.: Ross and Wilson's Anatomy and Physiology in Health illness – – Churchill Livingstone
4. Chatterjee C. C. Human Physiology (Medical Allied Agency, Calcutta)
5. West, J. B. Best and Taylor's physiological Basis of Medical Practice (Williams and Wilkins, Baltimore)
6. Martini, F. Fundamentals of Anatomy and Physiology (Prentice Hall)
7. Goyal_R. K. & Mehta A.A._ Human Anatomy Physiology and Health Education, (B. S. Shah Prakashan)
8. Garg K. et al. A Text Book of Histology (CBS Publishers, New Delhi)
9. Sobotta : Atlas of Human Anatomy (2 Volumes) –Edited by Putz and R. Pabst,

Lippincott, Williams and Wilkins
10. Anne M. R. Agur & Ming J. Lee: Grant's Atlas of Anatomy –Lippincott, Williams and Wilkins
11. Gosling T.A., Harris P.F., Whitmore I., William, Human Anatomy: Color Atlas and Text - Mosby
12. Joshi Vijaya D. Preparatory Manual for Undergraduates Physiology (B.I. Churchill Livingstone)
13. Textbook of practical Physiology C.L.Ghai (Jaypee Brothers Medical publishers)
14. Goyal R.K. et al.: Practical Anatomy Physiology and Biochemistry (B. S. Shah Prakashan, Ahmedabad)

GUJARAT TECHNOLOGICAL UNIVERSITY

Subject Name: Environmental Studies
Subject Code: 2220006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Contents:

Sr. No.	Topics	Teaching Hrs.	Module Weightage
UNIT I: ENVIRONMENT AND NATURAL SYSTEMS			
1	**Introduction to Environment and Environmental Studies**: Definition and Components of Environment, Relationship between the different components of Environment, Man and Environment relationship, Impact of technology on Environment, Environmental Degradation, Multidisciplinary nature of the Environment studies, its scope and importance in the present day Education System	4	6%
2	**Ecology and Ecosystems:** Introduction: Ecology- Objectives and Classification , Concept of an ecosystem- structure and functions of ecosystem Components of ecosystem- Producers, Consumers, Decomposers Bio-Geo- Chemical Cycles- Hydrologic Cycle, Carbon cycle, Energy Flow in Ecosystem, Food Chains, Food webs ,Ecological Pyramids Major Ecosystems: Forest Ecosystem, Grassland Ecosystem, Desert Ecosystem, Aquatic Ecosystem, Estuarine Ecosystem.	10	11%
3	**Natural Resources:** **a.** Renewable and Nonrenewable resources, exploitation and conservation, Role of individual in conservation of natural resources. b. Water resources: Water sources- Surface and Ground water sources, Indian and Global scenario. c. Land as a resource, social issues d. Forest resources: Definition and Classification of Forests Ecological and Economic importance and benefits of forest, Indian scenario, Deforestation: causes and effects, remedial measures. e. Food resources: Sources of food, Global and Indian food demand scenario, Limits of food production, Environmental effects of Agriculture.	8	14%
UNIT II: HUMAN POPULATION AND ENVIRONMENTAL POLLUTION			
4	**Human Population and Environment:**	4	8%

	Population Growth, World and Indian scenario, Population and Environmental Degradation, Malthusian theory, Optimum theory, Population explosion – Causes, Effects and Control. **Urbanization**: Urban population growth and Environmental problems		
5	**Environmental pollution:** **Types of Environmental Pollution:** **a) Water Pollution:** Introduction – Water Quality Standards, Sources of Water Pollution: Industrial ,Agricultural, Municipal; Classification of water pollutants, Effects of water pollutants, Eutrophication **b)** Marine pollution- **c) Air Pollution:** Composition of air, Structure of atmosphere, Ambient Air Quality Standards, Classification of air pollutants, Sources of common air pollutants like PM, SO_2, NO_X, Natural & Anthropogenic Sources, Effects of common air pollutants **d) Land Pollution:** Land uses ,Land degradation: causes, effects and control, soil erosion **e) Noise Pollution:** Introduction, Sound and Noise, Noise measurements, Causes and Effects **f) Thermal Pollution**: Causes and effects **g) Role of individual in the prevention of pollution**	14	22 %
UNIT III: ENERGY AND GLOBAL ENVIRONMENTAL ISSUES			
6	**Global Environmental Issues:** Climate Change, Global Warming and Green House Effect, Acid Rain, Depletion of Ozone layer	3	17 %

Reference Books:

1. Textbook of Environmental Studies for Undergraduate Courses by Erach Bharucha Second edition,2013 Publisher: Universities Press (India) Private Ltd, Hyderabad.
2. Basics of Environmental Studies by Prof Dr N S Varandani ,2013 Publisher: LAP -Lambert Academic Publishing , Germany
3. Environmental Studies by Anindita Basak ,2009 Publisher: Drling Kindersley(India)Pvt. Ltd Pearson
4. Textbook of Environmental Studies by Deeksha Dave & S S Kateva , Cengage Publishers.
5. Environmental Sciences by Daniel B Botkin & Edward A Keller Publisher: John Wiley & Sons.
6. Environmental Studies by R. Rajagopalan, Oxford University Press
7. Environmental Studies by Benny Joseph, TMH publishers
8. Environmental Studies by Dr. Suresh K Dhameja, 2007 Published by : S K Kataria & Sons New Delhi
9. Basics of Environmental Studies by U K Khare, 2011 Published by Tata McGraw Hill

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: Dispensing Pharmacy I and Drug Store Management
Subject Code: 2230001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	Definition and scope.	1
2	**The prescription**: Handling of prescription, source of errors in prescription, care required in dispensing procedures including labelling at dispensed products.	2
3	**Dispensing techniques**: Compounding and dispensing procedures, packaging, storage and stability of medicines, labelling of dispensed product.	2
4	**Pharmaceutical calculations**: Posology: Introduction to imperial and metric system, avoirdupois and apothecaries system of weights and measures. Calculation of doses for infants, adults and elderly patients, enlarging and reducing recipes, percentage solutions, allegation, alcohol dilution, proof spirit, isotonic solutions, displacement value etc.	10
5	Principles involved and procedures adopted in dispensing of • Liquid Products – Oral and external solutions, Mixtures and Emulsions. Liniments, lotions etc. • Solid Products – Powders, Lozenges, Pastilles, Tablet triturates etc • Ophthalmic- Eye drops, Eye lotions, Eye ointments, Contact lens solutions etc. • Oral unit dosage forms, inhalations etc.	15
	Drug Store Management	
6	**Drugs store Management and inventory control:** • Organization of drugs store, Types of materials stocked, storage conditions • purchase and inventory control principles, purchase procedures, purchase order, procurement and stocking. • Quality control of drugs in hospitals.	8
7	**Retail and whole sale drugs store**: Organization and structure of retail and whole sale drug store, types of drug stores and design, maintenance of drug store, dispensing of proprietary products, maintenance of records of retail and wholesale.	7

Practical – 22300P1

1.	Introduction to Latin to English translation, imperial, metric system, avoirdupois and apothecaries system of weights and measures.
2.	To prepare and dispense aromatic waters (e.g. chloroform and camphor), elixirs (e.g. Phenobarbitone elixirs BPC)
3.	To prepare and dispense gargles (e.g. Potassium chloride and phenol gargle) Mouth washes (e.g. Compound sodium chloride, mouth wash B.P.) Thorat paints (e.g. Mandel's paints) Douches (e.g. boric acid, potassium permanganate) Ear Drops (e.g. Sodium bicarbonate, Chloramphenicol)
4.	To prepare and dispense Mixtures Containing; diffusible, indiffusiable solid with volatile oil, precipitate forming liquid, slightly soluble liquid and pediatric Kaolin Mixture as per BP'88)
5.	To prepare and dispense emulsion (liquid paraffin emulsion, emulsion with fixed oil, volatile oil, resinous liquids, soap emulsion, emulsion based enema, w/o type emulsion etc.)
6.	To prepare and dispense lotions (e.g. salicylic acid Calamine and precipitate Sulphur), liniments (e.g turpentine liniment, white liniment)
7.	To prepare and dispense Eutectic powder, aspirin powder, dispensing of potent drug in powders, Compound Rhubarb Powder, Compound Sodium Bicarbonate powder, Compound zinc Oxide-salicylic acid dusting powder, Zinc starch And talc Dusting Powder.
8.	To prepare and dispense Insufflations (Camphor –Menthol Insufflations etc) and Kaolin Poultices B.PC
9.	To prepare and dispense effervescent granules (Sodium phosphate effervescent granules, antacid effervescent granules etc.)
10.	To prepare and dispense tablet triturates and lozenges.

References Books:

1. Pharmaceutical Practice – by Diana M. Collett and Michale E. Aulton, ELBS Publishers.
2. Dispensing for pharmaceutical by Cooper and Gunn by S.J. Carter, CBS Publishers
3. Pharmaceutical Calculations by Mitchell J. Stocklosa and Howard C. Ansel, B. I. Waverly Pvt. Ltd., New Delhi.
4. Pharmaceutical Dosage forms and Drug delivery systems by Howard C. Ansel, Lippincott Williams and Wilkins.
5. Pharmaceutical Practice, Edited by A.J. Winfield and R.M.E. Richards.
6. Bentley's Textbook of pharmaceutics, E A Rawlins.
7. Remington: The Science and Practice of Pharmacy, Latest Edition, by Mack Publishing Company.
8. Management by James A.F. Stoner.
9. Statistics for Management by Richard I. Levin.
10. Personnel Management by Arun Monappa.
11. Business Organisation and Office Management by Santhosh Bushan.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: Pharmaceutical Engineering
Subject Code: 2230002

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Introduction:** Pharma engineering and its significance, unit operations and unit processes. Unit systems, SI unit, CgS unit, gas constant and conversion of units. Physical quantities, dimensions and units, dimensional equations, dimensional analysis and dimensionless groups. Different types of graphical representation.	2
2	**Stoichiometry:** General principles, material balance-tie substances, chemical reactions and molal units, rate process, steady, unsteady and equilibrium state, laws of combining weights, applications of gas laws, energy balance, fuels and combustion,etc.,Mathematical problems.	9
3	**Fluid flow:** Types of steady flow, Reynold number & its significance, types of pressure, viscosity, concept of boundary layers, total energy balance and total mechanical energy balance, losses in mechanical energy of fluids, basic equations of fluid flow, valves, flow meters, manometers. Mathematical problems.	10
4	**Material handling systems:** Solid handling- storage, conveyers, vacuum & pneumatic conveying. Liquid handling- storage, pumps Gases- Fans, blowers and compressors. Colour coding of Pipelines, use of forklifts and pallets, store design in pharmaceutical industries.	8
5	**Heat transfer:** Modes of heat transfer. Conduction- Fourier's law, resistances in series and parallel, use of mean area and mean temperature difference. Convection-Concept of film, overall coefficient, heat transfer by forced convection in laminar and turbulent flow, condensing vapours, evaluation of individual film coefficients. Radiation-Black body, absorptivity & emmisivity. Heating of fluids, steam as heating medium, properties and uses of steam, steam traps, study of steam table. Heat exchange equipments-Heat exchangers, condensers, boilers, extended surface scraped and surface equipments etc. applications of heat transfer in industrial processes. Mathematical problems.	10

6	**Mass Transfer:** Principle, streams in mass-transfer operations, solid/fluid and fluid/fluid mass transfer, influence of mass transfer on unit operations.	3
7	**Materials of Pharmaceutical Plant Construction:** General study of composition, corrosion resistance, properties, factors affecting the selection of material of pharmaceutical plant construction with special reference to stainless steel and glass. Corrosion-types, causes, theories of corrosion and its prevention.	3

Practical – 22300P2

1.	To demonstrate unit systems and conversion of units.
2.	To demonstrate stoichiometry and tie substances in chemical reactions
3.	To measure pressure of gas and other fluids using different manometers (U-tube manometer, inclined manometer etc)
4.	Study of various flow meters (orifice meter, venturi meter, rotameter) and ejector pump.
5.	Experiment on Reynolds number
6.	Determination of overall heat transfer coefficient.
7.	Demonstration of corrosion resistance of various materials.
8.	Practical related to topics in pharmaceutical engineering theory should be carried out.
9	Introduction to engineering drawing – Demonstration of orthographic and isometric projections, preparation of sheets based on orthographic projections.

References Books:

1. Elementary Chemical Engineering - Max S. Peters, Published by McGraw Hill Book Company, New York, 1954.
2. Perry's Chemical Engineer's Handbook - Robert H Perry, Green D.W., Maloney J.O.7th Edition, 1998, McGraw – Hill Inc., New York.
3. Tutorial Pharmacy by Cooper & Gunn, ed. S.J.Carter, CBS Publishers & Distributors, Delhi, 6th Edition, 2000.
4. Unit Operations of Chemical Engineering, 5th edition - McCabe, Smith & Harriott, McGraw – Hill Inc., New York.
5. Pharmaceutical Engineering – K.Sambamurthy, 2002 NAI (P) Ltd., Delhi.
6. Pharmaceutics : The Science of Dosage Form Design - M.E. Aulton.
7. The Theory & Practice of Industrial Pharmacy – Lachman L., Lieberman H.A. & Kanjig J.L., 3rd edition, 1990 Varghese Publishing House, Bombay.
8. Alfonso G. Remington: The Science & Practice of Pharmacy. Vol. I & II. Lippincott, Williams & Wilkins Philadelphia.
9. Pharmaceutics I (Pharmaceutical Engineering), Jani G. K., B. S. Shah Prakashan, Ahmedabad.
10. Pharmaceutical Engineering : Principles and Practice, Subramanyam C.V.S., Thimma J, Suresh S.S. et. al., 2002, Vallabh Prakashan, Delhi.
11. A Textbook of Engineering Drawing Vol. I and II, P.J.Shah,6th Edition, 2003, Ahmedabad
12. Engineering Drawing, 34th edition, N.D.Bhatt Charutar Publishing House, 1994

13. Engineering Drawing & Graphic Technology, 13th edition by Thomas E. French, Charles J. Vierch, Rebot J. Foster, McGraw Hill International Edition, New Delhi, 1972
14. Introduction to Chemical Engineering by Walter L. Badger & Julius T. Banchero, Mc graw Hill International edition, New Delhi, 1955

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: Pharmaceutical Chemistry-III (Biochemistry – I)
Subject Code: 2230003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Sr. No.	Course contents	Proposed Hours
1	Biochemical Organization of the cell and Transport Processes Across cell Membrane.	04
2	Introduction to Carbohydrates, Lipids	08
3	**a. Carbohydrate Metabolism:** Conversion of Polysaccharides to Glucose-1-Phosphate. Glycolysis and Fermentation and their Regulation, Gluconeogenesis, Glycogenesis and Glycogenolysis, Metabolism of Galactose and Fructose. Role of Sugar Nucleosides in Biosynthesis and Pentose-Phosphate Pathway. **b. The Citric Acid Cycle:** Significance, Reaction and Energetic of the Cycle, Amphibolic Role of the Cycle and Glyoxalic Acid Cycle, Uric Acid Cycle **c. Role of Hormones in Maintenance of Blood Sugar Level.**	15
4	**Lipid metabolism**: oxidation of fatty acids, beta-oxidation and energetic, alpha-oxidation, omega-oxidations, biosynthesis of ketone bodies and their utilization, biosynthesis of saturated and unsaturated fatty acids, control of lipid metabolism and metabolism of cholesterol.	07
5	**Enzymes:** Nomenclature, Enzyme Kinetics and its Mechanism of action, Mechanism of Inhibition, Enzymes and Iso-Enzymes in Clinical Diagnosis.	05
6	**Co-Enzymes:** Vitamins as Co-Enzymes and their Significance. Metals as Co-Enzymes and their Significance.	03
7	**Water and mineral metabolism: brief introduction**	03

PRACTICAL – 22300P3

1.	To perform the identification for carbohydrates (Glucose, Maltose, Lactose, Sucrose, Fructose etc…..)
2.	Detection and identification of lipids (Glycerol, Cholesterol, Oleic Acid, Stearic Acid etc…..).
3.	To determine the Acid value and Saponification value of the given fixed oil.
4.	To determine the Iodine value of the given fixed oil.
5.	To estimate glucose in urine by Benedict's method.
6.	To determine glucose content in blood by folin Wu method.
7.	To estimate the total cholesterol in plasma.
8.	To perform biochemical analysis of flour and potato.

9.	To perform biochemical analysis of cheese or milk or bread.
10.	To perform biochemical analysis of (i) gastric juice and (ii) estimation of total acidity in gastric juice.
11.	To perform the estimation of pepsin in gastric juice.
12.	To perform the Gastric juice analysis.
13.	To perform estimation of diastase in urine.
14.	To determine the achromic point and chromic period of salivary amylase.
15.	To estimate acidity and ammonia in Uria.

References Books:

1. E. E. Conn and P. K. Stumpf, Outlines of biochemistry, John Wiley and Sons, New York.
2. A. L. Lehninger, Principles of biochemistry, CBS Publishers and Distributors.
3. R. K. Murray, D. K. Granner, P. A. Mayes. V.W. Rodwell, Harpers Biochemistry, Prentice hall International Inc. latest edn.
4. S. C. Rastogi, Biochemistry, Tata McGraw Hill New delhi, Latest edn.
5. M.Cohn, K.S. Roth, Biochemistry and Disease. William and Wilkins co. Baltimore, Latest edn.

6. U.Satyanarayan, Biochemistry, Books and allied (P) ltd. Calcutta, latest edn.
7. G. F. Zubay, W. W. Parson, D. E. Vance, Principles of Biochemistry, WCB Publishers, England, latest edn.
8. S. Ramkrishnan, K. G. Prasannan, R. Rajan. Textbook of medical Biochemistry, Orient Longman Madras, Latest edn.
9. S.K. Sawhney, Randir Singh Eds, Introductory practical Biochemistry, Narosa Publishing house New Delhi.
10. D. T. Plummer, An Introduction to Practical Biochemistry, Tata McGraw Hill New Delhi.
11. J. Jayaraman, Laboratory manual in Biochemistry, Wiley eastern Ltd. New Delhi

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: Pharmaceutical Chemistry-IV (Organic Chemistry – I)
Subject Code: 2230004

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr. No	Course content	Proposed Hours
1	**Structure and Properties :** Introduction to organic chemistry, quantitative analysis of elements, determination of molecular weight and molecular formula, Atomic structure, atomic orbitals, molecular orbital theory, molecular orbitals, bonding and antibonding orbitals.	08
2	**Chemical bonding and Properties :** Introduction, covalent bond, hybridization and hybrid orbitals, intermolecular and intramolecular forces, bond dissociation energy, electronegativity, polarity of bonds, polarity of molecules, resonance, hyperconjugation	08
3	**Reactive intermediates of carbon:** Carbocation, carbanion, free radical, carbenes, nitrenes, reaction involving these intermediates	04
4	**Structure, properties, nomenclature, preparation and reactions of the following class of functional groups** • Alkanes, alkenes, alkynes, dienes, alkyl halides, alcohols, ethers, • Benzene, • Polynuclear aromatic compounds, [naphthalene, anthracene.	25

PRACTICAL – 22300P4

1.	Introduction to safe working in organic chemistry laboratory.
2.	Systemic qualitative analysis of organic compounds and preparation of their derivatives {Various examples of organic compounds include, Acidic: Oxalic acid, succinic acid, tartaric acid, citric acid, benzoic acid, salicylic acid, cinnamic acid, p-nitrobenzoic acid, acetyl salicylic acid, Phthalic acid etc; Strong acidic Amphoteric: p-aminobenzoic acid, o-aminobenzoic acid, sulphanilic acid etc.; Weak acidic amphoteric: Sulphanilamide etc.; Phenolic: α-napthol, β-napthol, Phenol, Resorcinol, Catechol, o/m/p-nitrophenol, o/m/p-cresol etc.; Basic: Aniline, N-methyl aniline, N,N-dimethyl aniline, o/m/p-anisidine, o/m/p toluidine, o/m/p chloroanline, diphenyl amine, o/m/p-nitroaniline etc.; Neutral: Isopropyl alcohol, tert. Butyl alcohol, Acetophenone, benzophenone, acetaldehyde, benzaldehyde, m-dinitrobenzene, nitrobenzene, o/m/p/-nitrotoluene, acetanilide, benzanilide, benzamide, acetamide, urea, thiourea, naphthalene, anthracene, chlorobenzene, bromobenzene, ethylacetate, benzyl alcohol, methanol, ethanol, diethyl

	ether, toluene etc.; * Salt: Sodium benzoate, Sodium salicylate}:
2.1	Preliminary test for given organic compounds. (3)
2.2	Nature identification of given organic compounds (Category: Salts, Acidics, Strong acidic amphoterics, Phenolics, Weak acidic amphoterics, Basics, Neutrals* (6)
2.3	Element detection for given organic compounds(3)
2.4	Oxidizability and bromination test for selected category(3)
2.5	Functional group test for following functional groups: • Carboxylic acids and phenols. (3) • Basic compounds and amino carboxylic acids. (3) • Aldehyde, ketone, ester, ether, alcohol, amide, acetamido, halogenated and non-halogenated hydrocarbon and nitro compounds (including nitrocarboxylic acid and nitro phenol) (6) • Melting point and Boiling point determination of given organic compound (3) • Derivatization of functional groups for above selected functional groups(6)
2.6	Identification of given unknown organic compounds for above compounds (9)

Reference Books:

1. Organic Chemistry, Robert T. Morrison and Robert N. Boyd, 6th Ed., Pearson Education, 2002.
2. Organic Chemistry, G. Marc Loudon, 4th Ed., Oxford University Press, 2004.
3. Organic Chemistry, Vol I and II by I. L. Finar, 6th Ed., Pearson Education, 2000.
4. Advanced Organic Chemistry, Jerry March, 4th Ed., Wiley India, 2007.
5. Vogel's textbook of practical organic chemistry, 5th Edition, Pearson Education Ltd., 2005
6. "Experimental Organic Chemistry" L. M. Harwood, L. J. Moody, J. M. Percy, 2nd Edition, Blackwell Science, 2005.
7. Techniques and Experiment of Organic Chemistry, Addison Ault, 6th Edition, University Science Books, 1998.
8. Introduction to Organic Laboratory Techniques, A Microscale Approach, Donald L. Pavia, Gary M. Lampman, George S. Kriz, 3rd Edition, Harcourt College Pub., 4th Edition, 2007.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name: Health Education & Community Health
Subject Code: 2230005

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Contents	Total Hrs
	Health Education	
1	Concept of health: Definitions of health, Dimensions of health, determinants of health, indicators of health.	4
2	Health care of the community: concept of health care, health system (levels of health care – primary, secondary and tertiary), elements and principles of primary health care, health for all, national strategy for HFA / 2000.	3
3	Nutrition and health- Classification of foods , proteins- functions, sources, requirements & diseases, Fats – classification, sources, functions, fats and diseases, requirements, Carbohydrates, dietary fibres Vitamins- functions, sources, deficiency, requirement, Minerals and trace elements – source, functions, deficiency, requirements , Nutritional requirements - Recommended Daily Allowance , food guide pyramid	10
4	Occupational Health- health of the worker, occupational hazards and diseases, measures for health protection of workers, medical measures for prevention of occupational diseases	4
5	Concept of disease concept of causation, natural history of disease (Prepathogenesis and pathogenesis phase, agent factors, host factors, environmental factors, risk factors, risk groups, spectrum of disease, iceberg of disease), concepts of disease control, concepts of prevention Mode of intervention. List of communicable and non-communicable diseases.	4
6	Communicable diseases : Brief outline, their causative agents, modes of transmission, symptoms and prevention- Respiratory infections (Chicken pox, measles, influenza, diphtheria, whooping cough, SARS, tuberculosis) , Intestinal infections (poliomyelitis, helminthiasis, Hepatitis, Cholera, Typhoid, Amoebisas, Food poisoning), Arthropod borne infections (Dengue, Malaria, Filariasis), Zoonoses (Rabies, Plague), Surface infections (Trachoma, Tetanus, Leprosy, Syphyllis, Gonorrhoea and AIDS). Hospital acquired infections	12
7	Principles of Epidemiology and it's methods- Definition, Aims, approach, epidemiologic methods (Observational, experimental), uses of epidemiology.	5
8	Demography – concepts and importance, Demography cycle	1

9	First Aid: Emergency treatment of shock, snake bites, burns, poisoning, Fractures and resuscitation methods.	2

References Books:

1. Textbook of Preventive and Social Medicine by K. Park. 20th Edition
2. Health Education and Community Pharmacy by P. C. Dandiya, Z. Y. K. Zafer, Afifa Zafer 2005 onwards
3. Basics of Education and Community Pharmacy by Dr. R. K. Goyal 4th edition

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: III

Subject Name:Pharmacognosy-I
Subject Code: 2230006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	Definition, history, scope and development of Pharmacognosy.	2
2	**Sources of drugs:** Plant, Animal, Marine, Mineral and Biotechnology	3
3	Introduction to plant parts and tissue. a) Definition and function of leaf, stem, root, flower, fruit and seed. Classification of modification leaf, stem, root b) Definition, classification and functions of plant tissues. c) Classification and identification non-living cell contents d) Microscopic difference between mono cot and dicot leaf, stem and root	5
4	**Classification of drugs:** Alphabetical, Morphological, Taxonomical, Chemical and Pharmacological. Role of chemotaxonomy in classification.	3
5	Cultivation, collection, processing and storage of crude drugs **a.** Factors influencing cultivation of medicinal plants. **b.** Types of soils and fertilizers of common use. **c.** Plant hormones and their applications. **d.** Polyploidy, Mutation and Hybridization with reference to medicinal plants. **e.** Poly Houses/Green Houses for cultivation.	7
6	An introduction to active constituents of drugs and their classification, properties and chemical tests.	4
7	Evaluation of crude drugs by organoleptic, microscopic (including quantitative microscopy), physical, chemical, biological and other methods. Adulteration of crude drugs. WHO guidelines for evaluation of Herbal drugs.	6
8	**Carbohydrates and derived products:** Definition, classification, physico-chemical properties, general methods of preparation, sources and systematic Pharmacognostic study of following drugs. • **Monosaccharide:** Honey • **Polysaccharides:** Starch, Dextrin • **Gums and Mucilage:** Agar, Isabgol, Guar gum, Acacia, Tragacanth, Sodium Alginate, Stercuila • **Carbohydrate derivatives:** Chitin and Pectin	6
9	**Lipids:** Definition, classification, physico-chemical properties,	9

	general methods of preparation, sources and systematic Pharmacognostic study of following drugs. • **Fixed oil:** Castor oil, Olive oil, Hydnocarpus oil, Seasame oil, Linseed oil, Mustard oil, Rape seed oil, Rice bran oil, Cod liver oil, Shark liver oil, Karanj oil • **Fat:** Lard, Cocoa butter, Kokum butter • **Wax:** Beeswax, Wool fat.	

Practical

Sr No	Course Contents
1	Use, Care and types of Microscopes, Techniques in microscopy.
2	Microscopy of plant tissues and their components.
3	Microscopy of monocot and dicot leaf, stem, root.
4	Study of chromosomes in Onion Cells (Polyploidy).
5	Microscopy of cell contents: Starch grains, Calcium oxalate crystals and Phloem fibres.
6	Quantitative microscopy (Determination of leaf constants).
7	Phytochemical Screening: General chemical test for primary and secondary metabolites
8	Carbohydrates: Study of crude drugs for morphology and chemical test for saccharides, gum and mucilage. Isolation of Potato starch. Microscopy of Maize, wheat, potato and rice starch.
9	Lipid: Study of crude drugs for morphology, chemical test, study of acid value, Iodine value and saponification value.

References Books:

1. Botany: A. C. Dutta, Calcutta Oxford University Press, New Delhi, 6th Revised Edition, 2010.
2. College botany Vol-I-III, Ganguly H.C., Das K.S., and Dutta C., New Central Book Agency [P] Lt., 2006.
3. Cultivation and Utilization of Medicinal Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989.
4. Supplement to Cultivation and Utilization of Medicinal Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi,
5. A Text book of Pharmacognosy: C. S. Shah, J. S. Quadry, B. S. Shah Prakashan, Ahmadabad. 15th Edition, 2009.
6. Textbook of Pharmacognosy: T. E. Wallis, CBS Publishers and Distributors, New Delhi, 5th Edition, reprinted, 2009.
7. Pharmacognosy: C. K. Kokate, A. P. Purohit, S. B. Gokhale, NiraliPrakashan Pune, 42nd edition, 2008.
8. Pharmacognosy: V. E. Tyler, L. R. Brady, J. E. Habbers, Lea and Febiger Philadelphia, 9th Edition, 1988.
9. Trease and Evans Pharmacognosy. 16h Edition, William Charles Evans, W. Saunders, Edinburg London New York Philadelphia St. Louis Sydney Toronto 2009.
10. Essentials of Pharmacognosy by Ansari S. H., Birla Publications Pvt. Ltd., 4th Edition, 2011.
11. Pharmacognosy of Powdered crude drugs - M. A. Lyenger (Manipal Power Press)
12. Practical Pharmacognosy, Technique and Experiment by C. K. Kokate and S. B. Gokhale, NiraliPrakashan, Pune, 8th edition, 2005.

13. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals. Dr. Pulok K. Mukherjee. Business Horizons Pharmaceutical Publishers; 2002
14. The Practical Evaluation of Phytopharmaceutics by Brain K. R. and Turner R. D., Wrigth-Scientechnics Bristol.
15. Malati G Chanhan& A. P. G Pillai, Microscopic profile of powdered drugs used in Indian system of medicine, Volume I, Bark drugs 2005, Institute of Ayurvedic medicinal plant science, Gujarat Ayurved unit Jamnagar; CPTA
16. Malati G Chauhan& A. P. G Pillai, "Microscopic profile of powdered drugs used in Indian systems of Medicine, Leaf Drugs, Vol. 2, 2007, Institute of P.G Teaching & Research in Ayurveda, Gujarat Ayurved University, Jamnagar.
17. Malati G Chauhan& A. P. G Pillai, " Microscopic profile of Drugs used in Indian system of Medicine, Seed drugs, Volume- 3, part- 1, 2011; Publisher: Prof Malati G Chauhan, P.G T- S.F C cell, I.P. G T. & R.A, Gujarat Ayurved University, Jamnagar,

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: IV

Subject Name: Unit Operations-II
Subject Code: 2240001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Filtration:** Theory and mechanism of filtration process, Types of filtration, factors influencing filtration, filter aids, filter media, industrial filter including filter press, filter leaf, rotary filter, edge filter, cartridge filters, membrane filters, mathematical problems on filtration, optimum cleaning cycle in batch filters, applications in pharmacy.	8
2	**Centrifugation:** Principle and theory of centrifugation, industrial centrifuges including perforated basket centrifuge, sedimentation type centrifuge, continuous centrifuges, etc., applications in pharmacy.	4
3	**Drying:** Theory and mechanism of drying, moisture content, loss on drying, rate of drying & time of drying calculations, classification of dryers, factors affecting selection of dryers, dryers used in pharmaceutical including drum dryer, spray dryer, fluidised bed dryer, tray dryer, tunnel dryer, rotary dryer vacuum dryer, Microwave, Radiant heat dryer (Infra Red), Mathematical problems on drying, applications in pharmacy.	9
4	**Distillation:** Raoult's law and its limitation, Henry's Law, Phase diagram, volatility & relative volatility, General parts of distillator, simple steam and flash distillation, batch and continuous distillation, rectification distillation columns and their efficiency, McCabe Thiele method for calculation of number of theoretical plates, azeotropic, molecular & steam distillation, mathematical problems, applications in pharmacy.	8
5	**Evaporation:** Basic concept of phase equilibria, factors affecting evaporation, heat transfer in evaporators, Duhring's Rule and Raoult's law, evaporators including natural circulation, forced circulation & film	8

	evaporators, single effect and multiple effect evaporators, mathematical problems, applications in pharmacy.	
6	**Humidity, Ventilation and Air Conditioning Systems (HVAC):** Basic concepts & definitions, measurement of humidity, psychometric charts, theory and calculations of humidification processes, humidity control, applications of humidity, equipment for humidification and dehumidification operations. Types of refrigeration cycles, air conditioning, applications in pharmacy. Design of HVAC systems.	8

Practical – 22400P1

1	Study of filtration process and various factors affecting it.
2	Demonstration of centrifuge.
3	Study of rate of drying curve and various parameters related to it.
4	Demonstration of various dryers.
5	Study of various distillation processes.
6	Comparison of efficiency of different columns used in distillation process.
7	Study of evaporation process and various factors affecting it.
8	Determination of humidity and related parameters using DBT/WBT and dew point method.
9	Demonstration of sling psychrometer, dial type and digital humidity measuring instruments.

Note: Any other practical related to theory topic can be carried out.

References Books:

1. Elementary Chemical Engineering - Max S. Peters,Published by McGraw Hill Book Company, New York, 1954
2. Perry's Chemical Engineer's Handbook - Robert H Perry, Green D.W., Maloney J.O.7th Edition, 1998, McGraw – Hill Inc., New York.
3. Tutorial Pharmacy by Cooper & Gunn, ed. S.J.Carter, CBS Publishers & Distributors, Delhi, 6th Edition, 2000.
4. Unit Operations of Chemical Engineering, 5th edition – McCabe, Smith & Harriott, McGraw – Hill Inc., New York.
5. Pharmaceutical Engineering – K.Sambamurthy, 2002 NAI (P) Ltd., Delhi.
6. Pharmaceutics: The Science of Dosage Form Design - M.E. Aulton.
7. The Theory & Practice of Industrial Pharmacy – Lachman L.,Lieberman H.A. & Kanjig J.L., 3rd edition, 1990 Varghese Publishing House, Bombay.
8. Alfonso G. Remington: The Science & Practice of Pharmacy. Vol.I & II. Lippincott, Williams & Wilkins Philadelphia.
9. Introduction to Chemical Engineering by Walter L. Badger & Julius T. Banchero, Mcgraw Hill International edition, New Delhi, 1955.
10. Pharmaceutical Engineering (Principles and Practices) by C.V.S. Subrahmanyam, Vallabh prakashan, Delhi 110034.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: IV

Subject Name: Dispensing Pharmacy II and Pharma Industrial Management
Subject Code: 2240002

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Principles involved and procedures adopted in dispensing of** • Semisolid Products – Ointment, Creams, Gels, Pastes • Suppositories – Bases, Dispensing, Displacement value etc.	8
2	**Incompatibilities** • Physical, chemical and therapeutic incompatibilities observed in prescriptions of dispensed products • Identification and correction of incompatibilities. • Inorganic incompatibilities including incompatibility of metals and their salts, non metals, acids, alkalis. Organic incompatibilities: purine bases, alkaloids, ammonium compounds, carbohydrates, glycosides, anesthetics, surface active agents.	14
	Pharma Industrial Management	
3	**Concept of Management** Administrative management: Planning, Organizing, Staffing, Directing and Controlling. Entrepreneurship Development and Operative Management, Personnel, Materials, Production, Financial Marketing, Time/Space Margin / Morale. Principles of Management Co-ordination, Communication, Motivation, Decision-Making, Leadership, Innovation, Creativity, Delegation of Authority / Responsibility, Record keeping.	12
4	**Pharmaceutical marketing** Functions, buying, selling, transportation, storage, finance, insurance, feedback, information, channels of distribution, wholesale, retail departmental store, multiple shops and mail order business.	7
5	**Salesmanship** Principles of sales promotion, advertising, ethics of sales merchandising.	4

Practical – 22400P2

1.	Practicals may be designed to solve a Physical incompatibilities(e.g. inmiciability, insolubility and liquidification)
2.	Practicals may be designed to solve Chemical incompatibilities of alkaloidal salt with alkali substance, soluble iodides, Tannins and salicylates, Iron, CO2.
3.	Chemical incompatibilities of soluble salicylates with alkali, acid and ferric salt.
4.	Incompatibility of potassium chlorate with oxidizable substances and incompatibility causing evolution of gas (e.g. borex with sodium bicarbonate and glycerine, bismuth subnitrate with sodium bicarbonate)
5.	To prepare and dispense Pastes (e.g. Zinc Gelatin Paste, Compound zinc oxide Paste, Zinc and Salicyclic acid Paste, Compound aluminium Paste etc.)
6.	To prepare and dispense jellies (e.g. Sodium Alginate, Zinc gelatin jelly and Lubricating jelly).
7.	To prepare and dispense suppositories (Tannic acid suppositories, Phenol suppositories, Icthamol suppositories with Cocoa Butter, Cocoa Butter suppositories containing insoluble solid (boric acid), Cocoa Butter suppositories containing soluble solid (chloral hydrate)
8.	To prepare and dispense Glycerol – gelatin suppositories with macrogols base (Suppository of Eucalyptus Oil, Zinc Oxide – Glycerogelatin suppository, Soap-Glycerin Suppository etc).

References Books:

1. Pharmaceutical Practice – by Diana M. Collett and Michale E. Aulton, ELBS Publishers.
2. Dispensing for pharmaceutical by Cooper and Gunn by S.J. Carter, CBS Publishers.
3. Pharmaceutical Calculations by Mitchell J. Stocklosa and Howard C. Ansel, B. I. Waverly Pvt. Ltd., New Delhi.
4. Pharmaceutical Dosage forms and Drug delivery systems by Howard C. Ansel, Lippincott Williams and Wilkins.
5. Pharmaceutical Practice, Edited by A.J. Winfield and R.M.E. Richards.
6. Bentley's Textbook of pharmaceutics, E A Rawlins.
7. Remington: The Science and Practice of Pharmacy, Latest Edition, by Mack Publishing Company.
8. Management by James A.F. Stoner.
9. Statistics for Management by Richard I. Levin.
10. Personnel Management by Arun Monappa.
11. Business Organisation and Office Management by Santhosh Bushan.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: IV

Subject Name: Pharmaceutical Chemistry – V (Biochemistry – II)
Subject Code: 2240003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr. No.	Course contents	Proposed Hours
1	Detailed chemistry of Proteins and nucleic acid	08
2.	Metabolism of ammonia and nitrogen containing monomers: nitrogen balance, biosynthesis of amino acids, catabolism of amino acids, conversion of amino acids to specialized products. Assimilation of ammonia, urea cycle. Metabolic disorders of urea cycle, metabolism of sulphur containing amino acids, porphyrin biosynthesis, formation of bile pigments, hyperbilirubinemia, purine biosynthesis, purine nucleotide interconversion, pyridine biosynthesis.	12
3.	Biosynthesis of nucleic acids. Brief introduction of genetic organization of the mammalian genome, alteration and rearrangement of genetic material, biosynthesis of DNA and its replication, DNA repair mechanism, biosynthesis of RNA	05
4.	Genetic code and protein synthesis: genetic code, components of protein synthesis and inhibition of protein synthesis. Brief account of genetic engineering and polymerase chain reactions	05
5.	Regulation of gene expression	02
6.	The Concept of free energy, Determination of Change in free energy from Equilibrium Constant and Reduction Potential, Bioenergetics, Production of ATP and its Biological Significance	02
7.	Biological oxidation, enzymes and co-enzymes involved in oxidation reduction and its control. The respiratory chain, its role in energy capture and its control, energetic of oxidative phosphorylation, inhibitors of respiratory chain and oxidative phosphorylation, mechanism of oxidative phosphorylation	08
8.	Techniques used in biochemistry: spectrophotometry, centrifugation, electrophoresis, chromatography, extraction and purification of proteins and nucleic acids	03

PRACTICAL – 22400P3

1	Identification of various proteins (Gelatine, Casein, Albumin etc….)
2	Identification of various proteins (Peptone, Creatinine etc….)
3	To identify substances of physiological importance (Protein, Lactic Acid, HCl etc...).
4	To identify substances of physiological importance (Bile, Blood, Creatinine, Urea, Acetone, NaCl etc….)
5	To perform the tests for normal inorganic and organic constituent of urine.
6	To perform the qualitative analysis for pathological (abnormal) constituents in urine.
7	To estimate Creatinine in blood by colorimetric analysis.
8	To estimate total proteins in plasma by biuret method.
9	To perform the estimation of urea in blood by diacetyl method.
10	To perform estimation of chloride and phosphate in urine.
11	To determine titratable acidity and ammonia in urine.
12	To perform the estimation of Calcium and Magnesium in urine.
13	To perform biochemical analysis of bile.
14	Separation of Amino Acids (Proline, Glutamate, Aspartate, Glycine, Alanine etc…) by Paper Chromatography.
15	Separation of Amino Acids (Proline, Glutamate, Aspartate, Glycine, Alanine etc…) Thin Layer Chromatography (TLC).
16	To estimate calcium in serum.
17	Colourimetirc analysis of Bilirubin and cholesterol in plasma.
18	Estimation of uric acid in urine.

Books recommended:

1. E. E. Conn and P. K. Stumpf, Outlines of biochemistry, John Wiley and Sons, New York.
2. A. L. Lehninger, Principles of biochemistry, CBS publishers and distributors.
3. R. K. Murray, D. K. Granner, P. A. Mayes. V.W. Rodwell, Harpers biochemistry, Prentice hall international Inc. latest edn.
4. M.Cohn, K.S. Roth, Biochemistry and disease. William and Wilkins co. Baltimore, Latest edn.
5. U.Satyanarayan, Biochemistry, Books and allied (P) ltd. Calcutta, latest edn.
6. G. F. Zubay, W. W. Parson, D. E. Vance, Principles of Biochemistry, WCB publishers, England, latest edn.
7. S.K. Sawhney, Randir Singh Eds, Introductory practical biochemistry, Narosa publishing house New Delhi.
8. D. T. Plummer, An introduction to practical biochemistry, Tata McGraw Hill New Delhi.
9. J. Jayaraman, Laboratory manual in biochemistry, Wiley eastern Ltd. New Delhi.
10. G. T. Mills, G. Leaf Practical Biochemistry, John Smith and Son Ltd.
11. Alan H. Gowenlock, Janet R. Mcmurray, Donald M. McLauchlan, Varley's Practical clinical biochemistry, Heinemann professional publishing.
12. P. G. Tikekar, Practical Biochemistry.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: IV

Subject Name: Pharmaceutical Chemistry – VI (Organic Chemistry – II)
Subject Code: 2240004

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Sr. No.	Course contents	Proposed Hours
1	**Stereochemistry:** • Chirality • Optical activity (dextro and leavo rotation concept) • Stereoisomerism • Enantiomers, Diastereomers, Mesomers with physical, chemical and biological properties of the same. • Geometrical isomers and its nomenclature. Physical and chemical properties of the same • Racemic mixture and its resolution methods. • Specification of configuration: Relative configuration (L and D), Absolute configuration (R and S) (CIP Rules) • Axial Chirality: Stereochemistry of Allene, spiran and Biphenyl. • Conformational isomers: Alkanes and Cyclohexane	08
2	**Structure, properties, nomenclature, preparation and reactions of following class of functional groups** • amines, • phenols, • aldehydes and ketones, • carboxylic acids and their derivatives.	22
3	**Unsaturated carbonyl compounds, Nucleophilic aromatic substitution**	02
4	**Heterocyclic compounds: Chemistry, preparation and properties of** • Furan, thiophene, pyrrol and pyridine • Pyrrazole, imidazole, oxazole, isoxazole and thiazole • Pyrazine, pyridazine and pyrimidine • Quinoline, isoquinoline and indole	10
5	**Introduction, principles and applications of:** • nanochemistry, • microwave synthesis and • green chemistry.	03

PRACTICAL – 22400P4

1.	Qualitative analysis of unknown organic compound according to the following list of organic compounds : 1.1 – Identification and characterization of given unknown organic compound (Salts/Acids/Strong acidic Amphoterics) 1.2 – Identification and characterization of given unknown organic compound (Phenolics/Basics) 1.3 – Identification and characterization of given unknown organic compound (Neutrals) 1.4 – Identification and characterization of given unknown organic compound (Salts/Acids/Strong acidic Amphoterics/Phenolic/Basics Neutrals) 1.5 – Identification and characterization of given unknown organic compound (Salts/Acids/Strong acidic Amphoterics/Phenolic/Basics/Neutrals) List of organic compounds: a. **Salts:** Sodium benzoate, Sodium salicylate etc. b. **Acidics:** Benzoic acid, Salicylic acid, Cinnamic acid, Acetyl salicylic acid, Phthalic acid etc. c. **Strong acidic Amphoterics:** p-Aminobenzoic acid, o-Aminobenzoic acid, Sulphanilic acid etc. d. **Weak acidic Amphoterics**: Sulphanilamide etc. e. **Phenolics**: o/m/p-nitrophenol, alpha/beta-naphthol, o/m/p-cresol etc. f. **Basics**: Anliine, N-Methyl aniline, N,N-Dimethyl aniline, o/m/p-Anisidine, o/m/p-Nitroaniline, p-Chloroaniline, o/m/p toluidine etc. g. **Neutrals**:Acetophenone, Benzaldehyde, m-Dinitrobenzene, Nitrobenzene, Chlorobenzene, Bromobenzene, Acetanilide, Benzamide, Anthracene, Napthalene, Benzophenone isopropyl alcohol, tert butyl alcohol etc.	15
2	Introduction and detailed demonstration to various synthetic techniques and apparatus used therein: 2.1 Heating and cooling methods, distillation, reaction work-up, filtration and extraction. 2.2 Purification and identification	06
3	3.1 Synthesis and purification of selected organic compounds: 1. Synthesis of p-nitroacetanilide from acetanilide (Nitration) 2. Synthesis of p-bromoacetanilide from acetanlide (Halogenation) 3. Synthesis of p-nitroanline from p-nitroacetanlide (Hydrolysis) 4. Synthesis of P-bromoanline from p-bromoacetanlide (Hydrolysis) 5. Synthesis of benzil from benzoin (Oxidation) 6. Synthesis of benzylidene acetophenone (Chalcone) from acetophenone and benzaldehyde (Condensation reaction) 7. Synthesis of Magnesone-II from p-nitroaniline (Diazotization). Monitoring progress of reaction by Thin Layer Chromatography (TLC) with the help of any one of above selected reaction**.**	21
4	Introduction to the use of stereomodels	03

Reference Books:

1. Organic Chemistry, Robert T. Morrison and Robert N. Boyd, 6th Ed., Pearson Education, 2002.
2. Organic Chemistry, G. Marc Loudon, 4th Ed., Oxford University Press, 2004.
3. Organic Chemistry, Vol I and II by I. L. Finar, 6th Ed., Pearson Education, 2000.
4. Advanced Organic Chemistry, Jerry March, 4th Ed., Wiley India, 2007.
5. Vogel's textbook of practical organic chemistry, 5th Edition, Pearson Education Ltd., 2005
6. "Experimental Organic Chemistry" L. M. Harwood, L. J. Moody, J. M. Percy, 2nd Edition, Blackwell Science, 2005.
7. Techniques and Experiment of Organic Chemistry, Addison Ault, 6th Edition, University Science Books, 1998.
8. Introduction to Organic Laboratory Techniques, A Microscale Approach, Donald L. Pavia, Gary M. Lampman, George S. Kriz, 3rd Edition, Harcourt College Pub., 4th Edition, 2007.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: IV

Subject Name:Basic Concepts of Pharmacology and Clinical Pharmacy Practice
Subject Code: 2240005

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Theory

Sr No	Course Contents	Total Hrs
1	Define following terms: Pharmacy, Pharmacology, Clinical pharmacy, Clinical Pharmacology, Pharmacokinetics, Pharmacodynamics, Pharmacoepidemiology, Pharmacoeconomics, Pharmacogenomics, Therapeutics, Toxicology, Chemotherapy, Pharmacopoiea, Drug, Medicine, Poison, Drug tolerance, Tahcyphylaxis. Introduction and scope of pharmacology and clinical pharmacy, Nature and sources of drugs, Drug nomenclature, Routes of drug administration.	4
2	Pharmacokinetics: (A) Biological membrane, mechanism of drug transportation, Absorption, factors affecting absorption, Distribution, volume of distribution, redistribution, penetration into brain, passage across placenta, plasma protein binding, tissue storage,Metabolism/biotransformation, Phase-I and Phase-II reactions, microsomal enzymes and their induction, Excretion, mechanism of renal excretion, enterohepatic circulation. (B) Area under curve (for single dose and repeated dose), Bioavilability and bioequivalence, Plasma half life and Clearance, Loading dose and maintenance dose, Therapeutic drug monitoring (TDM) and its significance.	12
3	Pharmacodynamics: Principle of drug action, Target of drug action– receptors, ion channels, enzymes, transport proteins, Introduction to various types of receptor- ligand gated ion channel, G-protein coupled receptor, kinase linked receptor, nuclear recetor, Introduction to various types of ion channels- open channels and gated channels, Dose response relationship, Agonist and antagonist, Combined effects of drugs (potentiation, addition, synergism and antagonism), Drug antagonism	9
4	Modification in effects of drugs with special reference to Children, elders and pregnancy.	4

5	Drug interaction: Classify drug interaction based on mechanisms (pharmacokinetic types and pharmacodynamic types), drug food interaction.	3
6	Adverse drug reactions: Brief outline on followings terminology related to adverse effects-side effects, overdose effects, secondary effects, toxic effects, intolerance, drug allergy, iatrogenic effects, mutagenicity, teratogenicity, carcinogenicity, photosensitivity, drug withdrawal reactions, drug dependence Classify ADR as per Rawlins-thompson system, Pharmacovigilance and epidemiological methods in ADR detection, Medication errors and adverse drug events.	7
7	Patient counselling, communication skills for effective counselling, steps for patient counselling, Medication adherence and non-adherence, determinants of medication non-adherence, Drug information and poison information.	4
8	Concept of essential medicines and rational drugs use, essential medicines list, Standard Treatment Guidelines, Drug and Therapeutics Committee	2

References Books:

1. Clinical pharmacy and therapeutics . Roger Walker and Cate Whittlesea
2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics..
3. Rang, H.P. & Dale, M.M. Pharmacology.
4. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. The pharmacological Basis of therapeutics.
5. Katzung, B.G. Basic and clinical pharmacology. Latest edition.
6. K.D. Tripathi. Essentials of Medical Pharmacology.
7. G. Parathsarthee, K. Nyfort-Hansen and M. C. Nahata. A textbook of clinical pharmacy practice.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: IV

Subject Name: Pharmacognosy-II

Subject Code: 2240006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Volatile Oils:** Definition, classification, physico-chemical properties, general methods for isolation, source, cultivation, collection, commercial varieties and systematic pharmacognostic study of volatile oils containing drugs • **Alcohol:** Coriander, Geranium, Sandal wood • **Esters and Alcohol:** Rose, Mentha • **Aldehyde:** Cinnamon, Cassia, Lemon peel, Orange peel, Lemon grass, Eucalyptus, Cumin • **Ketone:** Caraway, Dill • **Phenol:** Clove, Tulsi, Ajowan • **Ether:** Star Anise, Fennel, Nutmeg, Cardamom **Others:** Gaultheria, Valerian, Vaj, Vetiver, Nagarmotha, Garlic, Saffron, Vanilla	25
2	**Resins:** Definition, classification, Physico-chemical properties, general methods for isolation, source, cultivation, collection, commercial varieties and their systematic pharmacognostic study of following drugs • **Acid resin:** Colophony • **Resin Alcohol & Phenols:** Balsam, Cannabis • **Ester Resin:** Benzoin • **Oleo gum resin:** Asafoetida, Myrrh, Guggul, Salaiguggul • **Oleo-resin:** Ginger, Turmeric • **Glyco-resin:** Kaladana, Podophyllum, Nishoth **Other:** Vidang, Capsicum	13
3	**Tannins:** Definition, classification, Physico-chemical properties, general methods for isolation, source, cultivation, collection, commercial varieties and their systematic pharmacognostic study • **Hydrolysable:** Amla, Harde, Behda, Galls • **Condensed:** Pale catechu, Black catechu, Ashoka, Bael, Pterocarpus	7

Practical – 22400P6

1	Demonstration of methods for isolation of volatile oil from crude drugs.
2	Study the Morphology of Volatile oil containing following drugs. Perform Microscopy (TS and Powder) and TLC of underlined drugs • Leaf drugs: Mentha, Eucalyptus, Lemon grass, Gaultheria, Tulsi, Basil, Geranium, Rosemary, Thyme • Bark and Peel: Cinnamon (Ceylon and Chinese), Orange peel, Lemon peel, Star anise • Umbelliferous fruits: Fennel, Coriander, Dill, Ajowan, Caraway, Cumin • Flower drugs: Clove and Rose • Seed and wood: Cardamom, Nutmeg, Sandal wood • Rhizome: Vaj, Valerian, Nagarmoth, Garlic
3	Study of Morphology and Microscopy (TS and powder drugs) of Amla, Ashoka Pale catechu, Black catechu, Galls, Harde, Behda, Bael, Pterocarpus
4	Isolation of oleoresin, identification (Chemical test) and study of Morphology and Microscopy (TS and powder drugs) from Colophony, Balsam, Benzoin, Myrrh, Asafoetida, Guggul, Ginger, Turmeric, Vidang, Kaladana
5	Isolation of tannins from crude drugs and extract. Removal of tannin from drugs and extract. Tests for tannins
6	Isolation of Thymol / Eugenol / Menthol

References Books:

1. Cultivation and Utilization of Aromatic Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989
2. Cultivation and Utilization of Medicinal Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989
3. Supplement to Cultivation and Utilization of Medicinal Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi,
4. Supplement to Cultivation and Utilization of Aromatic Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi
5. A Text book of Pharmacognosy: C. S. Shah, J. S. Quadry, B. S. Shah Prakashan, Ahmadabad. 15th Edition, 2009.
6. Textbook of Pharmacognosy: T. E. Wallis, CBS Publishers and Distributors, New Delhi, 5th Edition, reprinted, 2009.
7. Pharmacognosy: C. K. Kokate, A. P. Purohit, S. B. Gokhale, Nirali Prakashan Pune, 42nd edition, 2008.
8. Trease and Evans Pharmacognosy. 16h Edition, William Charles Evans, W. Saunders, Edinburg London New York Philadelphia St. Louis Sydney Toronto 2009.
9. Essentials of Pharmacognosy by Ansari S. H., Birla Publications Pvt. Ltd., 4th Edition, 2011.
10. Pharmacognosy of Powdered crude drugs - M.A. Lyenger. (Manipal Power Press)
11. Practical Pharmacognosy, Technique and Experiment by C. K. Kokate and S. B. Gokhale, Nirali Prakashan, Pune, 8th edition, 2005
12. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals. Dr. Pulok K. Mukherjee. Business Horizons Pharmaceutical Publishers; 2002
13. The Practical Evaluation of Phytopharmaceutics by Brain K. R. and Turner R. D., Wrigth-Scientechnics Bristol.

14. Malati G Chanhan & A. P.G Pillai, Microscopic profile of powdered drugs used in Indian system of medicine, Volume I, Bark drugs 2005, Institute of Ayurvedic medicinal plant science, Gujarat Ayurved unit Jamnagar; CPTA.
15. Malati G Chauhan & A.P.G Pillai, "Microscopic profile of powdered drugs used in Indian systems of Medicine, Leaf Drugs, Vol 2, 2007, Institute of P.G Teaching & Reaearch in Ayurveda, Gujarat Ayurved University, Jamnagar
16. Malati G Chauhan & A.P.G Pillai, " Microscopic profile of Drugs used in Indian system of Medicine, seed drugs, Volume- 3, part- 1, 2011; Publisher: Prof Malati G Chauhan, P.G T- S.F C cell, I.P. G T. & R.A, Gujarat Ayurved University, Jamnagar

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: V

Subject Name: Hospital and Community Pharmacy
Subject Code: 2250001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Theory

Sr No	Course Contents	Total Hrs
1	Organization and structure: Organization of a hospital, organization & personnel of hospital pharmacy, responsibilities of a hospital pharmacist, pharmacy procedural manual, Budget preparation and Implementation, Pharmacy and Therapeutic Committee, Hospital Formulary and its contents, preparation and revision of hospital formulary.	8
2	Drug distribution systems in hospitals: a) Dispensing of drugs to out-patients. b) Dispensing of drugs to in-patients. c) Dispensing of controlled drugs. d) Pre-packaging and labeling. e) Drug charges and charging policy. f) Central Sterile Supply Unit and their Management. g) Surgical supplies and health accessories	8
3	Duties and responsibilities of hospital pharmacist	2
4	Hospital formulary: Format and appearance of the formulary, distribution of the formulary, keeping the formulary currentuse of nonformulary drugs, the legal basis of the formulary system,anti-substitution laws and formulary, Preparation of the formulary, formulary Vs. drug catalogue or list, selection of guiding for admission or deletion of drug, conteins, prescription writing, format, size, loose leaf Vs bound publication, formulary drug listing service preparation, categorizing and indexing, sample pharmacologic index, text, specialty formulary	6
5	Nuclear pharmacy: Introduction to Radio-pharmaceuticals, radio-active half life, Units of radio-activity Production of radio-pharmaceuticals, methods of isotopic tagging, preparation of radio-isotopes in laboratory using radiation dosimetry, radio-isotope generators, permissible radiation dose level, radiation hazards and their prevention, specifications for radio-active laboratory.	5
6	Records and Reports: Prescription filling, drug profile, patient medication profile, annual report.	3
7	Patient counseling and Patient Compliance: Role of pharmacist in community health care and education.	3
8	Drugs Information Services: Sources of Information on drugs,	6

	disease, treatment schedules, procurement of information, computerized services (e.g. MEDLINE, MEDLAR etc.), retrieval of information, medication error, safe use of medicine, drug Information center, pharmacist as a information specialist.	
9	Use of computer in hospital: Terminology, program criteria, managing computer system, development of ASHP technical assistant bulletin on hospital drug distribution and control, impact of the computer in dispensing time, model computer regulations.	4

References Books:

1. Merchant and Quadry, Text book of hospital pharmacy
2. Hassan, Hospital pharmacy (Lee and Febiger)
3. R K Parikh, Hospital Pharmacy
4. Parmar N S Health education and community pharmacy

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: V

Subject Name: Pharmaceutical Microbiology & Biotechnology – I
Subject Code: 2250002

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	Introduction and Scope of Microbiology	2
2	General microbiology: a) Microscopy • Light Microscopy (Bright Field, Dark field & Phase contrast, Fluorescent, Differential interference) • Electron Microscopy (SEM & TEM) b) General Structure • Prokaryotic and Eukaryotic Cell c) Brief over view of 3 kingdom Classification system d) Structure and Taxonomy of Actinomycetes, Bacteria, Spirochetes, Rickettsia and Viruses, fungus with emphasis on pathogenic and pharmacological importance. e) Identification of microbes • Staining Techniques f) Nutritional requirements • Nutrition requirements, Growth curve • Introduction to various nutritional media, • Cultivation and Isolation of bacteria, virus and fungus. g) Bacterial count techniques	19
3	Control of microbes in pharmaceutical industry **a. <u>Disinfection:</u>** • Classification, mode of actions and Factor affecting Disinfection • Dynamics of Disinfection • Evaluation of Disinfection **b. <u>Sterilization:</u>** • Introduction, significance, sensitivity of microorganisms, • Detailed methods for sterilization processes. • Sterilization control and sterility assurance.	14
4	Introduction of DNA & RNA, details of Genetic code and protein synthesis Introduction and scope of Biotechnology	06
5	Immobilization of Enzymes: • Techniques of immobilization	04

	• Factors affecting enzyme kinetics • Applications	

PRACTICAL – 22500P2

1.	Introduction to Pharmaceutical Microbiology practical
2.	Preparation of Various Media
3.	Sub culturing of Common Bacteria (Aerobic and Anaerobic)
4.	Staining of Microorganism (Monochrome staining, Gram staining, acid fast staining etc)
5.	Methods of Isolation
6.	Study of Sterilization and Their Validation
7.	Viable Counts and total counts by various methods
8.	Evaluation of the disinfectants
9.	Maintenance and preservation of pure culture

References Books:

1. Textbook of Microbiology by Tortora.
2. Pharmaceutical Microbiology, sixth edn, edited by W. B. Hugo and A. D. Rusell Blackwell science.
3. Principles of Microbiology, Ronald M. Atlas. Second edn. W. C. Brown Publishers.
4. Bergeys manual of Systematic Bacteriology, Williams and Wilkins- A Waverly company.
5. Disinfection, Sterilization and Preservation. Fourth edn, Symour S. Black. Lea and Febiger Philadelphia, London.
6. Industrial Microbiology. Fourth edn, Prescott and Dunn. CBS Publishers and Distributors.
7. Principles of Fermentation Tehchnology. Second edn. P. F. Stanbury, A.Whiteshaker and S. J. Hall Aditya Books Pvt Ltd. New Delhi.
8. Microbiology, Pelczar/Chan Kreig Tata McGraw Hill edn.
9. Industrial Microbiology L.E. Casida, Jr. New age International Publishers.
10. Fundamental Principles of Bacteriology. A. J. Sale, Tata McGraw Hill Publishing Company Ltd.
11. Fundamentals of Microbiology by Forbischer.
12. Bentleys Text book of Pharamceutics.
13. Dispensing Pharmacy by Cooper and Gunn, Twelfth edn.
14. Remington Pharmaceutical Scicence, Latest edn.
15. Microbiology by Ronald Atlas.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: V

Subject Name: Pharmaceutical Analysis III
Subject Code: 2250003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	Fundamentals of Spectroscopy: Classification of spectra i.e. line, band, continuous spectra / absorption, emission spectra; Wave properties of electromagnetic radiation; Particle/photon properties of electromagnetic radiation; Electromagnetic spectrum.	03
2	UV-VIS Spectroscopy: Theory; Beer and Lambert's law - limitations and deviations from the law; Terminologies associated with absorption measurements; Types of transitions; Factors affecting spectral characteristics (structural and nonstructural); Effect of conjugation; Wood ward Fieser rule; Photometric titrations; Instrumentation, applications (in analysis of organic compounds and inorganic complexes), advantages and limitations of UV Visible spectroscopy; Quantitative analysis of binary mixtures of absorbing substances by simultaneous equation method; Calibration of UV Visible Spectrophotometer as per Pharmacopoeia.	10
3	Fluorescence Spectroscopy: Introduction: luminescence, photoluminescence; Theory of Fluorescence and Phosphorescence; Jablonski diagram; Factors affecting fluorescence intensity (structural and nonstructural); Instrumentation, applications, advantages and limitations of fluorescence spectroscopy	04
4	IR Spectroscopy: Theory of absorption of Infrared radiation by molecules; Molecular vibrations; Factors influencing vibrational frequencies; Calculation of vibrational frequencies (Hooke's law); Sample handling techniques; Instrumentation (Dispersion and FTIR spectrometer) and applications of IR Spectroscopy; Calibration of IR Spectrophotometer as per Pharmacopoeia.	07
5	Atomic Spectroscopy: Basics of atomic spectroscopy; Principle of atomic absorption and atomic emission spectroscopy; Interferences in atomic spectroscopy; Factors affecting atomic spectroscopy like solvents, buffers, other ions, etc; Flame Photometry; Atomic emission spectroscopy with plasma and electrical discharge sources; Instrumentation (including radiation sources like hollow cathode	05

	lamp), applications, advantages and limitations of atomic absorption and atomic emission spectroscopy.	
6	Mass Spectrometry: Theory; Ionization techniques, Ion separating techniques; Different types of ions and their significance in mass spectra, Fragmentation rules and rearrangements; Instrumentation and applications of mass spectrometry	06
7	Nuclear Magnetic Resonance spectroscopy: Fundamental Principles - nuclear spin, magnetic moment; Proton NMR spectroscopy - theory, chemical shift and factors affecting chemical shift, spin- spin coupling, coupling constant, relaxation process, Instrumentation and applications of PMR; Brief overview of C13 NMR.	07
8	Structure elucidation by joint application of UV, IR, NMR and Mass spectrometry	03

Note:
Examples based on assays & structure elucidation shall be covered at concerned subtopics in each of the above chapters

Practical – 22500P3

Sr. No.	Content
1	Calibration of UV spectrophotometer
2	Calibration of IR spectrophotometer
3	To determine % purity of paracetamol by UV Spectrophotometry
4	Determination of λmax, A(1cm1%), Detection-Quantitation Limit and preparation of calibration curve (Verification of Beer's law) for any drug by UV-visible spectrophotometer.
5	To determine % purity of Metformin by UV Spectrophotometry
6	Effect of pH and solvent on the UV spectrum of given compound
7	To determine excitation and emission wavelength of drug by spectrofluorimetry
8	Assay of quinine sulphate by spectrofluorimetry
9	To determine effect of Quenching on fluorescence of quinine sulphate by fluorimetry
10	Assay of sulpha drugs by colorimetry
11	To determine %purity of paracetamol by colorimetry
12	To determine isosbetic point of indicator by UV Spectrophotometry
13	To determine dissociation constant of indicators by UV spectrophotometry
14	Content Uniformity of any drug as per Pharmacopoeia.
15	Identification of API by IR spectrum.
16	To interpret multiplication of signals of various compound by NMR
17	Workshop on structure elucidation of simple organic compounds using UV, IR, NMR, and Mass
18	To determine % purity of Paracetamol and Diclofenac Sodium Combination as per IP'96
19	Simultaneous estimation of Paracetamol & Ibuprofen/any other combination by simultaneous equation method

References Books:

1. Principles of Instrumental Analysis Skoog, Holler, Nieman, 5th edition.
2. Instrumental Methods of Analysis, H.H. Willard, L.L. Meritt, J.A. Dean and F.A. Settle Wadsworath, New York
3. Pharmaceutical Analysis: Modern methods Part A, Part B, James W. Munson.
4. Vogel's Text Book of Quantitative Chemical Analysis, G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by), Longman, London
5. A Textbook of Pharmaceutical Analysis. Connors K.A.
6. Practical Pharmaceutical chemistry, part 1&2, A.H. Beckett and J.B. Stenlake, the athlone press, London.
7. Pharmacopoeia of India, Govt. of India, Ministry of Health.
8. British Pharmacopoeia, ministry of health and social welfare, UK.
9. The United States Pharmacopeia–National Formulary (USP–NF)

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: V

Subject Name: Pharmaceutical Chemistry – VII (Medicinal Chemistry – I)
Subject Code: 2250004

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	An introduction to the subject of medicinal chemistry: History and development of medicinal chemistry, Drug therapy	02
2	Physiochemical properties of drug molecules influencing biological activity a) Solubility, Partition coefficient, Hydrogen bonding, Complexation, Ionization, Redox potential, Surface activity and protein binding b) Stereochemical features of drugs: geometric and optical isomers, Bioisosterism.	08
3	Introduction, history, classification, mechanism of action, adverse effects, therapeutic uses, structure activity relationship (SAR) and synthetic procedures of selected drugs and recent developments of following categories to be covered. (Synthesis of drugs mentioned in each category)	
	1) Drugs acting on respiratory tract • Antiasthmatics • Expectorants • Antitussive agents • Respiratory stimulants • Mucolytics • Decongestants	06
	2) Drugs acting on gastrointestinal tract • Antacids • Antisecretary (Synthesis: Ranitidine) • Proton pump inhibitors (Synthesis: Omeprazole) • Antiemetics • Antidiarrheals • Laxatives • Prokinetics • Antispasmodics and drug modifying intestinal motility • Drugs for irritable bowel syndrome	7
	3) Autocoids: a) Histamines and Histamine receptors, Antihistaminics:H_1antagonists (Synthesis:	08

	diphenhydramine, tripelenamine, chlorcylclizine, chlorpheniramine, promethazine, cyproheptadiene, cetrizine) H_2 antagonists b) Eicosanoids: history and discovery, eicosanoids biosynthesis, drug action mediated by eicosanoids, eicosanoids approved for human clinical use	
	4) Diagnostic agents: Radiopharmaceuticals, Radiological contrast media (Synthesis: diphenoxylate, diatrizoic acid)	02
	5) Drugs acting on ANS **a) Parasympathomimetic agents:** SAR- Parasympathomimetics (Synthesis: Neostigmine, Dicyclomine HCl) **b) Parasymatholytic agents:** SAR:- Muscarinic antagonists **c) Sympathomimetic agents:** SAR:- β-Phenylethanolamine class (Synthesis: Adrenaline, Salbutamol and Ephedrine) **d) Smpatholytic agents:** (Synthesis:- Propranolol and atenolol) **e) Neuromuscular blocking agents and ganglionic blockers**	12

Practical – 22500P4

Sr. No.	Content	No. of practical hours
A	**Separation and qualitative analysis of Organic binary mixtures containing having salt, acidic, phenolic, amphoteric, basic and neutral nature (Solid + Solid (Solid), Solid + Solid (Eutectic)) with derivative preparations.** **1. Salts (sodium benzoate, Sodium salicylate etc.)** **2. Acids (Benzoic acid, salicylic acid, cinnamic acid, acetyl salicylic acid etc.)** **3. Phenols (α-Naphthol, β-Naphthol, o/m/p-nitrophenol etc.)** **4. Strong acidic amphoteric (P-amino benzoic acid, o-amino benzoic acid, sulphanilic acid etc.) and weak acidic amphoteric (Sulphanilamide etc.)** **5. Bases (α-Naphthylamine, p-anisidine, diphenyl amine, o/m/p-nitroaniline etc.)** **6. Neutrals (Benzophenone, m-dinitrobenzene, acetanilide, benzamide, naphthalene etc.)**	30
1	Separation and qualitative analysis of organic binary mixture	
2	Separation and qualitative analysis of organic binary mixture	
3	Separation and qualitative analysis of organic binary mixture	
4	Separation and qualitative analysis of organic binary mixture	
5	Separation and qualitative analysis of organic binary mixture	
6	Separation and qualitative analysis of organic binary mixture	
7	Separation and qualitative analysis of organic binary mixture	

8	Separation and qualitative analysis of organic binary mixture	
9	Separation and qualitative analysis of organic binary mixture	
10	Separation and qualitative analysis of organic binary mixture	
B	**Synthesis of some organic compounds including some heterocyclic compounds:**	12
11	Benzimidazole from o-phenylenediamine	
12	2-phenylindole from phenyl hydrazine	
13	Methyl orange from sulphanilic acid	
14	9,10dihydroanthracene-9,10-endo-α,β-succinic anhydride from anthracene (Diels-Alder Reaction)	
15	Workshops on stereo models using some selected drugs	3

References Books:

1. Textbook of organic medicinal and pharmaceutical chemistry, J. N. Delagado and W. A. R. Remers, edn, Wilson and Giswolds , J. Lippincott Co. Philadelphia
2. Principles of medicinal chemistry, W. C. Foye, Lea and febiger, Philadelphia
3. Burgers Medicinal chemistry, John Wiley and sons, H. E. Wolff, edn, New York
4. Strategies for organic drug synthesis and design, Daniel Lednicer, John Wiley and Sons USA
5. B Fundamentals of drug metabolism and disposition. . N. Ladu, H. G. Mandel and E. L. Way.William and Willkins co. Baltimore
6. Organic chemistry Vol. I and Vol. II. I. L. Finar. ELBS/Longman, London
7. Vogels Text books practical organic chemistry, ELBS/Longman, London
8. Practical organic chemistry, Mann and Saunders, Orient Longman, UK
9. The systematic identification of organic compounds, Shriner, Hermann, Morill, Curtin and Fusion. John Wiley and Sons

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: V

Subject Name: Pharmacology and Pharmacotherapeutics–I
Subject Code: 2250005

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Pharmacology of Peripheral and Autonomic Nervous system**	
	Neurohumoral transmission (autonomic and somatic)- organization and function, co-transmission	03
	Cholinergic system and drugs- cholinergic transmission,receptors, Parasympathomimetics, anticholinesterases, anticholinesterase poisoning, Parasympatholytics, drugs acting on autonomicganglia (stimulants and blockers)	06
	Adrenergic system abd drugs- adrenergic transmission, direct, indirect and mixed Sympathomimetics, Sympatholytics, Neuron blocking agents	06
	Skeletal muscle relaxants (peripherally, directly and centrally acting) – classification, mechanism of actions, actions and uses, difference between competitive and non-competitive blockers, difference between centrally and peripherally acting muscle relaxants.	03
	Local anaesthetics- classification, mechanism of actions, local and systemic actions, adverse effects, uses and techniques of local anaesthesia	02
2	**Autacoids**	
	Histamine- pharmacological actions, pathophysiological actions, Histamine releasers, antihistaminics	03
	5-HT- pharmacological and pathophysiological actions, 5-HT antagonists, drug therapy of migraine	03
	Prostanglandins and leukotrienes- actions, pathophysiological role, uses, Platelet activating factor, bradykinin., angiotensin	02
3	**Pharmacology of following class of drugs**	
	Laxatives- classification, mechanism of action, details of each class, and antidiarrhoeal drugs- oral rehydration, drug therapy- specific and non-specific, details of each class of drugs	03
	Emetics and antiemetics- classification, uses, contraindications	02
	Antitussive agents and Expectorants- classification , individual drugs	02
4	**Definition, epidemiology, etiology, pathophysiology, signs and symptoms, diagnosis, complications, treatment and management of following diseases/conditions:**	
	Bronchial asthma, COPD	3
	Peptic Ulcer Disease, Gastro Esophageal Reflux Disorder (GERD)	2
	Inflammatory Bowel Disease	2

	Hepatitis	2
	Glaucoma	1

Practical – 22500P5

Sr. No.	Content
1	Introduction to experimental pharmacology, commonly used instruments in experimental pharmacology
2	Legal regulations for the use of experimental animals, common laboratory animals , Euthanasia of laboratory animals, anesthetics used in animal studies
3	Some common and standard techniques for drug administration (intravenous injection, intra gastric administration) and collection of blood samples
4	Preparation of different solutions for experiments. Drug dilutions, use of molar and W/V solutions in experimental pharmacology
	To study the effects of various agonists (pD_2) and antagonist (pA_2) using isolated preparations.
5	To record the concentration response curve (CRC) of acetylcholine using rat ileum/chicken preparation.
6	To study the effect of atropine on concentration response curve (CRC) of acetylcholine using rat/chicken ileum preparation.
7	To record the concentration response curve (CRC) of Histamine on guinea pig/chicken ileum
8	To study the effect of mepyramine on concentration response curve (CRC) of Histamine using guinea pig /chicken ileum preparation
	Demonstration Experiments :-To study the effects of autonomic drugs on rabbits eye
9	Demonstration Experiments :-To study the effect of hepatic microsomal enzyme inhibitors and inducers on pentobarbitone sleeping time
10	Case studies (questions based on history, etiology, symptoms, investigations, medication, adverse effects, drug interactions, pharmacists' advice)
11	To evaluate case study of Bronchial asthma / COPD (minimum 3 cases)
12	To evaluate case study of Peptic ulcer disease (minimum 3 cases)
13	a. To evaluate case study of Hepatitis (minimum 2 cases) b. To evaluate case study of Cough (minimum 2 cases)
14	a. To evaluate case study of Glaucoma (1 case) b. To evaluate case study of Organophosphorus poisoning (1 case) c. To evaluate case study of Myasthenia gravis (1 case)
15	a. To evaluate case study of diarrhoea and constipation (minimum 2 cases) b. To evaluate case study of emesis (minimum 2 cases)

References Books:

1. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
2. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.
3. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.

4. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
5. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
6. R.K.Goyal. Practicals in Pharmacology: B.S. Shah Prakashan, Ahmedabad.
7. Clinical pharmacy and therapeutics . Roger Walker and Cate Whittlesea
8. Textbook of therapeutics. Drug and disease management. Eric T Herfindal Dick R Gourley

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: V

Subject Name:Pharmacognosy-III
Subject Code: 2250006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Glycosides:** Definition, classification, Physico-chemical properties, general methods for isolation, biological sources, agronomy (cultivation, collection), commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following drugs: a) **Saponins:** Liquorice, Ginseng, Dioscorea, Arjun, Aritha, Achyranthus, Brahmi, Gokhru, Methi, Satavari, Dhamaso, Gymnema, Sarsaparilla, senega b) **Cardioactive Sterols:** Digitalis, Squill, Strophanthus, Thevetia, Nerium c) **Anthraquinone cathartics:** Aloe, Senna, Rhubarb, Cascara, *Cassia fistula, Cassia tora*, Majith d) **Bitter glycosides:** Gentian, Picrorrhiza, Chirata, Kalmegh, Quassia e) **Coumarins:** Psoralea, Ajmoda, Bhangro, Calophyllum f) **Cyanogenetic glycosides:** Almond, Linseed, Prunus g) **Isothiocyanate glycosides:** Mustard, Black mustard h) **Flavanoids:** *Ruta graveolens*, Butea, Bhilama i) **i. Others:** Salix	35
2	**Plant tissue culture:** Introduction, basic requirements, types of culture, nutritional requirements, laboratory requirements and applications	10

Practical – 22500P6

1. General methods for isolation and chemical tests of different glycoside containing drugs.
2. Study of Morphology, Microscopy and TLC of crude drugs: (T.S., Powder and TLC of underlined drugs):

a. **Anthraquinone:** Majith, Senna, Aloe, Rhubarb, *Cassia fistula, Cassia tora*

b. Cardioactive Sterols: Digitalis (Powder), Squill, Thevetia, Nerium (leaf)

c. **Saponins glycosides:** Liquorice, Achyranthus, Satavar, Ginseng, Dhamaso, Brahmi, Methi, Dioscorea, Sarsaparilla, senega

d. **Bitter glycosides:** Gentian, Chirata, Kalmegh, Quassia

e. **Coumarins:** Psoralea, Ajmoda, Bhangro

f. **Cyanogenetic and Isothiocyanate glycosides:** Almond, Linseed, Mustard

3. Study of Morphology and Chemical test for following drugs: Bhilama, Palash.
4. Introduction to basic laboratory requirements, maintenance of plant tissue culture and production of callus culture.
5. Estimation of sennosides from senna.
6. Estimation of aloin fromaloe.
7. Isolation of Andrographolide from Kalmegh.

References Books:

1. Cultivation and Utilization of Medicinal Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989.
2. Supplement to Cultivation and Utilization of Medicinal Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi.
3. A Text book of Pharmacognosy: Shah C. S., Quadry J. S., B. S. Shah Prakashan, Ahmadabad. 15th Edition, 2009.
4. Pharmacognosy: Kokate C. K., Purohit A. P., Gokhale S. B., Nirali Prakashan Pune, 42nd edition, 2008.
5. Textbook of Pharmacognosy: Wallis T. E., CBS Publishers and Distributors, New Delhi, 5th Edition, reprinted, 2009.
6. Trease and Evans Pharmacognosy. 16th Edition, William Charles Evans, W. Saunders, Edinburg, London, New York, Philadelphia, St. Louis Sydney Toronto 2009.
7. Natural Products, Vol I & II, by Agrawal O. P., Goel Publishing House, Meerut, 28th Edition, 2004.
8. Comprehensive Biotechnology, 'The Principles, application and regulation of biotechnology in Industry, agriculture and Medicine Vol. 1-4 Alan T, Howard Dalton and Murray Mao-Young.
9. An introduction to Plant Tissue Culture Kalyan Kumar De, New Central Book Agency (P) Ltd., Calcutta
10. Plant Tissue Culture, Sharma Rajni, Campus Books International, 1st Edition, 2007.
11. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing house, New Delhi, 2005.
12. Medicinal plants glycosides- Sims. Toronto.
13. Natural Products as Medicinal Agents, Ed. Beal J. L. and Reinhard E., Hippocratos, Verlog, Stuttgart; 1982
14. Natural products, Ikan R., Academic Press, Califonia, 1st Edition, 2005.
15. Pharmacognosy and Pharmacobiotechnology , Ashutosh Kar, 2nd Edition, New Age International Pvt. Ltd.; New Delhi, 2007.
16. Pharmacognosy and Pharmacobiotechnology. Robbers J. E, Marilyn K. Speedie, Varro E. Tyler, Baltimore: Williams & Wilkins,1996; a Wavery Company, USA.
17. Pharmacognosy: Phytochemistry Medicinal Plants , Jean Bruneton, 2nd Edition, Intercept Publications, Ltd., TEC & DOC Paris, 1999.

18. The Organic Constituents of Higher Plants. Their Chemistry and Interrelationships. Trevor Robinson, Burges Publishing Company, Minneapolis, USA, 1963.
19. Practical Pharmacognosy, Technique and Experiment C. K. Kokate and S. B. Gokhale, Nirali Prakashan, Pune, 8th edition, 2005.
20. The Wealth of India (Raw Material & Industrial Product), Published by Council of Scientific Industrial Research, New Delhi, 1st and 2nd Edition, 2005, 2nd (1950-2014)
21. Indian Medicinal Plants by Kirtikar and Basu, 1st Edition, International Book Distributors, Dehradun, 1999.
22. Compendium of Indian Medicinal Plant Vol. 1 to 6, by Rastogi Ram P., Mehrotra B. N., CDRI & NISCOM, 1st Edition, New Delhi, 1998.
23. Review on Indian Medicinal Plants, Vol I to XI (2004 to 2014) Editor: Gupta AK & Tundon Neeraj. By: Indian Council of Medicinal Research (ICMR), New Delhi.
24. Powdered Vegetable Drugs Jeckson B. P. & Snewden D. W.
25. Chanhan .M .G & Pillai A. P.G, Microscopic profile of powdered drugs used in Indian system of medicine, Volume I, Bark drugs 2005, Institute of Ayurvedic Medicinal Plant Science, Gujarat Ayurved University, Jamnagar.
26. Chanhan .M .G & Pillai A. P.G, "Microscopic profile of powdered drugs used in Indian systems of Medicine, Leaf Drugs, Vol 2, 2007, Institute of P.G Teaching & Reaearch in Ayurveda, Gujarat Ayurved University, Jamnagar.
27. Chanhan .M .G & Pillai A. P.G, " Microscopic profile of Drugs used in Indian system of Medicine, Seed drugs, Volume- 3, part- 1,2011; Publisher: Prof Malati G Chauhan, P.G T- S.F C cell, I.P. G T. & R.A, Gujarat Ayurved University, Jamnagar.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name: Forensic Pharmacy
Subject Code: 2260001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Theory

Sr No	Course Contents	Total Hrs
1	Pharmacy an Introduction: Origin, development, scope, objectives and nature of pharmaceutical legislation in India. Code of Pharmaceutical Ethics.	2
2	Pharmaceutical education: A brief review	1
3	Pharmacy Act, 1948 and AICTE Act 1987, A Brief Study	10
4	The Drugs and Cosmetics Act, 1940 & Rules 1945 & Ammendments	15
5	An elaborate study of the following: (as amended to date) • Poisons Act 1919 • The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 • Medicinal and Toilet Preparations (Excise Duties) Act, 1955 • Prevention of Cruelty to Animals Act, 1960 • Patents Act 1970 • Medical Termination of Pregnancy Act, 1970 & Rules 1975 • Narcotic Drugs and Psychotropic Substances Act, 1985 • AICTE Act, 1987: A brief study. • Drugs (Price Control) order 1995	15
6	• Law regulating the introduction of new drugs.	2

References Books:

1. B.M. Mittal **–** Textbook of Forensic Pharmacy Vallabh Prakashan
2. Jain, N.K.A Textbook of Forensic Pharmacy. Vallabh Prakashan, New Delhi.
3. G K Jani, Textbook of pharmaceutical Jurisprudence, Atul Prakashan.
4. The patents act 1970 with patents rules 1972.
5. All Theory, Acts and Rules Published by Government of India.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name: Pharmaceutical Microbiology & Biotechnology – II
Subject Code: 2260002

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Introduction to microbial genetics** Mutation and its importance (Frame shift mutation and point mutation) Different mutagenic agents(Chemical, Physical, biological) Test to identify Mutants	05
2	**Genetic recombination:** • Transformation conjugation, transduction • Protoplast fusion, gene cloning and their applications, monoclonal antibodies and its application	06
3	Study of various drug produces by biotechnology e.g. Humulin, Human growth hormone, streptokinase, activase, monoclonal antibodies etc	02
4	**Analytical Microbiology:** • Sterility testing of Pharmaceuticals • Microbiological Assay of Antibiotics, Vitamins and Amino acids	07
5	**Immunology and Immunological Preparation:** • Immunity, primary and secondary defense mechanism, interferon • Principles of immunology, antigen antibody reactions and application, • Preparations, Standardization and storage of vaccines & toxoids diphtheria, tetanus toxoid,cholera, pertussis, plaque, BCG, rabies, polio, measles, typhoid, brief introduction to new generation vaccines-hepatitis, AIDS, Malaria, brief study of sera. • Various diagnostic tests based on immunological principle (widal, ELISA, various blotting techniques, tuberculin test, schick test)	12
6	**Blood Products and Plasma Substitutes:** Collection, processing and storage of whole human blood, concentrated human RBCs, dried human plasma, human fibrinogen, human thrombin, human normal immunoglobulin, human fibrin, foam plasma substitutes, -ideal requirements, PVP, dextran etc. for control of blood pressure as per I.P.;	04
7	**Fermentation :**	09

	a. Historical development of antibiotics, b. methods used for their standardization, Screening of soil for organisms producing antibiotics, c. Fermenter, its design, control of different parameters, fermentation process. d. Media, Sterilization (fermenter, media, air, etc.) I e. Detailed production of I) selected antibiotics: penicillins, streptomycins, tetracyclines II) vitamin B 12, Riboflavin III) others: citric acid, alcohol. f. Isolation and recovery of fermentation products	

PRACTICAL – 22600P2

1.	Microbiological assay of antibiotics vitamins and Amino acids
2.	Sterility testing of various pharmaceutical preparations
3.	Preparation and Standardization of vaccines
4.	Preparation of mutant • Gradient plate method • Velvet replicate method
5.	Design of fermentor
6.	Study of shake flask technique
7.	Production of alcohol using Bakers yeast
8.	Extraction of citric acid from fermented mass
9.	Preparation of anticoagulant solutions, coagulant foam/sheet

References Books:

1. Textbook of microbiology by Tortora.
2. Pharmaceutical microbiology, sixth edn, edited by W. B. Hugo and A. D. Rusell Blackwell science
3. Crommelin, Daan J.A., Pharmaceutical Biotechnology : An Introduction for Pharmacists, and Pharmaceutical Scientists, 2nded. London : Routledge, 2002
4. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
5. El-Mansi, Mansi, Fermentation Microbiology and Biotechnology, New York : Taylor & Francis, 2003
6. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi
7. Principles of fermentation tehchnology. Second edn. P. F. Stanbury, A. Whiteshaker and S. J. Hall Aditya Books Pvt Ltd. New Delhi.
8. Microbiology, Pelczar/Chan Kreig Tata McGraw Hill edn
9. Industrial microbiology L.E. Casida, Jr. New age international publishers
10. Fundamental principles of bacteriology. A. J. Sale, Tata McGraw Hill publishing company Ltd.
11. Remington Pharmaceutical Science, latest edn
12. I.P., B. P., USP
13. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name: Pharmaceutical Analysis IV
Subject Code: 2260003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	X-ray spectroscopy Introduction; Generation of X – rays; X-ray diffraction, Bragg's law; Applications of X- ray diffraction.	04
2	Overview of Scattering Spectroscopy like Raman spectroscopy, Nephlometry and Turbidimetry.	03
3	Gas Chromatography Introduction; Theory and Principle of Gas-Chromatography; Mobile phase, Stationary phases for GSC and GLC; Instrumentation (including temperature programming and derivatization) and applications of GC; Overview of GC-MS.	06
4	High Performance Liquid Chromatography Introduction; Theory, Classification and Principle of HPLC; Mobile phase, Stationary phases for normal and reversed phase HPLC; Instrumentation (including significance of guard column) and applications of HPLC; Comparison of HPLC with GC; Overview of LC-MS, LC-MS/MS. Basic principle, theory and applications of partition, adsorption, ion-exchange, size exclusion, Super critical fluid and Affinity chromatography.	13
5	HPTLC Principle; Comparison with HPLC; Instrumentation, applications, advantages and limitations of HPTLC	02
6	Radio chemical Methods Introduction; Nuclear reactions and radiation; Interaction of nuclear radiation with matter; Radioactive decay; Units of radioactive decay; Measurement of radioactivity; Activity analysis; Isotopes dilution analyses; Liquid scintillation systems; Applications of radio nuclides	05
7	Overview of radio-immuno assay (RIA) and ELISA (Immunochemical techniques).	02
8	GLP: Introduction; History, basic issues and quadrants of GLP; Responsibilities matrix; Calibration and Testing.	03
	IPR: Introduction; Steps of filing patents and Introduction of GATT and TRIPS	02
	ISO: Elements; Requirements and Interpretation of ISO 9001:2000; Quality Management System	03
	AMV: Analytical method validation; Validation parameters as per ICH guidelines.	02

Note:

Examples based on assays & structure elucidation shall be covered at concerned subtopics in each of the following chapters.

Practical – 22600P3

Sr. No.	Content
1	Quantitative analysis of market formulations by HPLC (Demo)
2	Quantitative analysis of market formulations by HPTLC (Demo)
3	Quantitative analysis of market formulations by GC (Demo)
4	Evaluation of Monographs as per I.P. : Complete testing including assay.
5	Colorimetric assay of non coloured drugs by derivatization method
6	Colorimetric assay of colored compound
7	Evaluation of linearity, range and accuracy of UV method
8	Evaluation of linearity, precision and robustness of UV method
9	Simultaneous estimation of drug by derivative or difference spectroscopy
10	To determine isoabsorptive point of two/three different drugs for selection of wavelength in HPLC for binary/ternary mixture
11	Determination of total sugar in fruits/jams
12	Determination of vitamin C in fruit juice
13	To determine total glucose in different brands of honey
14	Determination of total ash content in **food product**
15	Determination of **food additives** like preservatives, colors and flavours
16	Assay of **antibiotic** by nephelometry
17	To perform QC testing tablets
18	To perform QC testing tablets
19	To determine the % purity of Isoniazid and Rifampicin in combination tablets.
20	Separation and identification of slupha drugs by TC techniques

References Books:

1. Principles of Instrumental Analysis by Skoog, Holler and Nieman, 5th edition.
2. Instrumental Methods of Analysis, H.H. Willard, L.L. Meritt, J.A. Dean and F.A. Settle Wadsworath , New York.
3. Pharmaceutical Analysis: Modern methods Part A, Part B, James W. Munson.
4. Quality Assurance Guide by Organization of Pharmaceutical Products of India.
5. "Good Laboratory Practice Regulation" Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., S. Weinberg, Marcel Dekker Inc., N.Y.
6. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.
7. IPR Handbook for Pharma Students and researchers – Parikshit Bansal, Pharma Book Syndicate, Hyderabad
8. Pharmacopoeia of India, Govt. of India, Ministry of Health.
9. British Pharmacopoeia, ministry of health and social welfare, UK.
10. The United States Pharmacopeia–National Formulary (USP–NF)

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name: Pharmaceutical Chemistry – VIII (Medicinal Chemistry – II)
Subject Code: 2260004

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Receptors and Drug action:** • Types of receptors. • Theories of Drug-Receptor Interactions. • Various forces involved in drug-receptor interaction. • Factor affecting the drug-receptor interaction.	04
2	**Drug metabolism** a) Introduction, Xenobiotics, Site of drug metabolism, Phase-I and Phase-II Metabolism in detail, overview about CYP450 and its importance, Factor affecting drug metabolism, importance of drug metabolism in drug design	11
3	Introduction, history, classification, nomenclature, mechanism of action, adverse effects, therapeutic uses, structure activity relationship (SAR), synthetic procedures of selected drugs and recent developments of following categories to be covered	
	Drugs Acting on CNS:	
	CNS stimulants: Analeptics, Antidepressants, Hallucinogens • SAR:- Tricyclic antidepressants • Synthesis:- Amphetamine, Fluoxetine, Imipramine	05
	CNS Depressants: General and local anesthetics, Sedative and Hypnotics, Anxiolytics, Antiepileptics, Antipsychotics • SAR:- Benzoic acid and Aniline derivatives with Local anesthetic activity, Barbiturates, Benzodiazepines, Phenothiazines, Butyrophenones • Synthesis:- Halothane, Lignocaine, Thiopental sodium, Phenobarbitone, Chlordiazepoxide, Phenytoin, Carbamazepine, Chlopromazine	13
	Antiparkinson's agents • **Synthesis: L-Dopa**	02
	Non Steroidal Anti-Inflammatory Agents, Anti Gout and DMARDS: • Synthesis:- Paracetamol, Aspirin, Diclofenac, Ibuprofen, Indomethacin, Allopurinol, Mefenamic acid, Nimesulide,	07

	Naproxen	
	Alzheimer's disease	02
	Cognition enhancers	01

Practical – 22600P4

Sr. No.	Content	No. of practical hours
A	**Separation and qualitative analysis of Organic binary mixtures containing water insoluble components having salt, acidic, phenolic, amphoteric, basic and neutral nature (Solid + Solid, Solid + liquid, Liquid + liquid and Eutectic mixtures) with derivative preparations.** **1. Salts (sodium benzoate, Sodium salicylate etc.)** **2. Acids (Benzoic acid, salicylic acid, cinnamic acid, acetyl salicylic acid etc.)** **3. Phenols (α-Naphtol, β-Naphtol, o/m/p-nitrophenol, Phenol, o/m/p-cresol etc.)** **4. Strong acidic amphoterics (P-amino benzoic acid , o-amino benzoic acid, sulphanilic acid etc.) and weak acidic amphoteric (Sulphanilamide etc.)** **5. Bases (α-Naphthylamine,o/m/ p-anisidine, diphenyl amine, o/m/p-nitroaniline, Aniline, N-methyl aniline, N,N-dimethyl aniline etc.)** 6. **Neutrals (Benzophenone, Benzaldehyde, Acetophenone, Nitrobenzene, m-dinitrobenzene, acetanilide, benzamide, naphthalene etc.)**	33
1	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
2	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
3	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
4	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
5	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
6	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
7	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
8	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
9	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
10	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
11	Separation and qualitative analysis of Organic binary mixtures with derivative preparation	
B	**Synthesis of some organic compounds:**	12

12	Aspirin	
13	Paracetamol	
14	Methyl salicylate	
15	Phenytoin	

References Books:

1. J. N. Delagado and W. A. R. Remers, edn, Wilson and Giswolds Textbook of Organic Medicinal and Pharmaceutical Chemistry, J. Lippincott Co. Philadelphia
2. W. C. Foye, Principles of Medicinal Chemistry, Lea and Febiger, Philadelphia
3. H. E. Wolff, edn, Burgers Medicinal chemistry, John Wiley and sons, New York Oxford University Press, Oxfords
4. Daniel Lednicer, Strategies for organic drug synthesis and design, John Wiley and Sons USA
5. B. N. Ladu, H. G. Mandel and E. L. Way. Fundamentals of Drug Metabolism and Disposition. William and Willkins co. Baltimore
6. Vogel's Text books practical organic chemistry, ELBS/Longman, London
7. Mann and Saunders, Practical organic chemistry, Orient Longman, UK
8. Shriner, Hermann, Morill, Curtin and Fusion. The Systematic Identification of Organic Compounds, John Wiley and Sons
9. Hans Thacher Clarke, A Handbook of Organic Analysis Qualitative and Quantitative, Fourth edition, Orient Longmans Ltd.
10. Arthur Vogel, Elementary Practical Organic Chemistry, Part-I and II, Second edition, CBS Publisher.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name: Pharmacology and Pharmacotherapeutics–II
Subject Code: 2260005

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	Neuronal transmitters in CNS	04
	Pharmacology of following class of drugs:	
	General Anesthetics- classification, mechanism of action, stages of anaesthesia, inhalational and intravenous anaesthetics, pharmacokinetics of inhalational anaesthetics, complications, preanaesthetic medications	02
	Ethyl Alcohol- pharmacological actions, mechanism of actions, pharmacokinetics, drug interactions, contraindications, toxicity, treatment, clinical uses, Disulfiram, Methyl alcohol poisoning and treatment.	02
	CNS Stimulants and Psychotomimetic Agents, hallucinogens- classification, individual drugs	02
	Analgesic, Antipyretic, Anti-Inflammatory agents- classification, NSAIDS and Prostaglandin synthesis, pharmacological actions, pharmacokinetics, adverse effects, uses, drug interactions, COX-II inhibitors	02
	Opioid analgesics- classification, pharmacological actions, adverse effects, poisoning and its treatment, uses, opioid receptors and receptor mechanisms, opioid anatagonists, endogenous opioid peptides	03
2	**Definition, epidemiology, etiology, pathophysiology, signs and symptoms, diagnosis, complications, treatment and management of following diseases/conditions:**	
	Insomnia	02
	Anxiety	02
	Psychosis	03
	Depression	03
	Mania	02
	Epilepsy	03
	Parkinsonism	02
	Alzheimers disease	03
	Gout	02
	Rheumatoid Arthritis	02
3	**Drug dependence and drug abuse-** drug use, drug abuse, drug induced reward, psychological and physical dependence, tolerance, mechanisms, treatment of various drug addiction- alcohol, tobacco	02
4	**Immunomodulators-** immunosuppressant drugs- classification, details of each class, immunostimulants (vaccines, antisera, immunoglobulins)	04

Practical – 22600P5

Sr. No.	Content
1	Demonstration **Experiments on Central Nervous System:** Recording of Spontaneous Motor Activity
2	Demonstration **Experiments on Central Nervous System:** Recording of Stereotypy
3	Demonstration **Experiments on Central Nervous System:** Recording of Analgesia
4	Demonstration **Experiments on Central Nervous System:** Recording of Anti-inflammatory
5	Demonstration **Experiments on Central Nervous System:** Recording of Anticonvulsant activity
6	Demonstration **Experiments on Central Nervous System:** Recording of Muscle relaxant activity
7	To find out Nature of Unknown Drugs (Acetylcholine, Histamine, $Bacl_2$, Physostigmine, Atropine, Mepyramine and Papaverine) using Rat/Guinea Pig/Chicken Ileum Preparation.
8	To find out Nature of Unknown Drugs (Acetylcholine, Histamine, $Bacl_2$, Physostigmine, Atropine, Mepyramine and Papaverine) using Rat/Guinea Pig/Chicken Ileum Preparation.
9	To find out Nature of Unknown Drugs (Acetylcholine, Histamine, $Bacl_2$, Physostigmine, Atropine, Mepyramine and Papaverine) using Rat/Guinea Pig/Chicken Ileum Preparation.
10	To find out Nature of Unknown Drugs (Acetylcholine, Histamine, $Bacl_2$, Physostigmine, Atropine, Mepyramine and Papaverine) using Rat/Guinea Pig/Chicken Ileum Preparation.
11	Study on the Effects of CNS Stimulant (Coffee/Tea) on Human Volunteers.
12	Case studies (questions based on history, etiology, symptoms, investigations, medication, adverse effects, drug interactions, pharmacists' advice)
13	a. To evaluate case study of Rheumatoid arthritis (minimum 2 cases) b. To evaluate case study of gout (minimum 2 cases)
14	a. To evaluate case study of Parkinson's disease (minimum 2 cases) b. To evaluate case study of Alzheimer's disease (minimum 2 cases)
15	a. To evaluate case study of Psychosis or Depression (minimum 2 cases) b. To evaluate case study of Anxiety or Insomnia (minimum 2 cases)
	a. To evaluate case study of Epilepsy (minimum 2 cases) b. To evaluate case study of Drug abuse and dependence (minimum 2 cases)

References Books:

1. Rang H.P., Dale M.M., et al-Pharmacology (1995) 3rd Edn. Churchill livingstoneUSA.
2. Satoskar R.S.,et al-Pharmacology and Pharmacotherapeutics (1999) 6th Edn. Popular Prakashan, Mumbai.
3. Harvel, R.A., Champe P.C. et al —Pharmacology (1997) 2nd Edn. Lippincott-Raven Company, Philadelphia, New York.
4. Goodman and Gilman's —the Pharmacological basis of Therapeutics (1996) 9Edn. Pergamon Press, Singapore.
5. Seth,S.D. Text Book of pharmacology,B.l.Churchill, 1997.
6. Goyal, R.K, Mehta A.A.et al- ELEMENTS OF PHARMACOLOGY: B.S. Shah Prakashan, Ahmedabad
7. Goyal R.K.-Practicals in Pharmacology (1994-95) 1st Edn. M/s B. S. Shah Prakashan, Ahmedabad.
8. Sheth U.K. et al-Selected topics in Experimental Pharmacology(1972)15t Edn.The

Kothari Book Depot, Mumbai.
9. Kulakarni S.K.- handbook of Experimental Pharmacology (1993)2fld Edn. allabh Prakashan, New Delhi.
10. Ghosh M.N - Essentials of Experimental Pharmacology,(1984) Scientific book agency, Calcutta.
11. Clinical pharmacy and therapeutics . Roger Walker and Cate Whittlesea
12. Textbook of therapeutics. Drug and disease management. Eric T Herfindal Dick R Gourley

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name:Pharmacognosy-IV
Subject Code: 2260006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Alkaloids:** Definition, classification, physico-chemical properties, general methods for isolation, biological sources, agronomy (cultivation, collection), processing, commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic macroscopic, microscopic features and specific chemical tests of following alkaloid containing drugs a) **Pyridine – Piperidine:** Tobacco, Lobelia, Pomegranate, Piper, Areca nut b) **Tropane:** Datura, Belladonna, Hyocyamus, Scopolia, Withania, Dubosia, Cocca c) **Quinoline & Isoquinoline:** Cinchona, Ipecac, Opium, Camptotheca d) **Indole:** Ergot, Rauwolfia, Catharanthus, Nuxvomica, Physostigma e) **Imidazole:** Pilocarpus f) **Steroidal:** Veratrum, Kurchi, Kantakari g) **Alkaloidal Amine:** Ephedra, Colchicum h) **Purines:** Coffee, Tea, Cola i) **Quinazoline:** Vasaka j) **Diterpene Alkaloids:** Aconite, Taxus k) **Others:** Tylophora	31
2	**Enzymes:** Biological sources, preparation, identification test and uses of Diastase, Papain, Pepsin, Trypsin, Pancreatin, Bromalein, Ficin, Penicillinase, Hyalluronidase, Streptokinase, Urokinase.	6
3	**Pharmaceutical Aids:** Talc, Diatomite, Fibres and Natural colours.	4
4	**Marine Pharmacognosy:** Novel medicinal agents from marine sources	4

Practical – 22600P6

1. Study of Morphology, Microscopy and TLC of crude drugs: (T.S., Powder and TLC of underlined drugs):
   a. Datura, Tobacco, Pomegranate, *Piper longum, Piper nigrum*
   b. Withania (Root), Belladonna, Hyocyamus, Dubosia, Lobelia, Areca

c. Cinchona, Ipecac, Campotheca

d. Rauwolfia, Ergot

e. Nuxvomica, Catharanthus, Physostigma

f. Kurchi, Kantakari (Leaf & Stem)

g. Ephedra, Colchicum, (Seed & Corm)

h. Vasaka, Coffee, Tea, Cola

i. Tylophora, Aconite, Taxus

2. Study of Morphology and chemical tests of Talc, Diatomite, Fibres and Natural colour containing drugs. Microscopy of raw and absorbent Cotton, Wool, Jute, Silk and Rayon.
3. Isolation of Quinine from Cinchona.
4. Isolation of Caffeine from Tea
5. Isolation of Piperine from Black Piper.
6. Estimation of Total Alkaloids from Datura by Titrimetric method.
7. Estimation of Quinine by UV Spectroscopy.

References Books:

1. Cultivation and Utilization of Medicinal Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989.
2. Supplement to Cultivation and Utilization of Medicinal Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi.
3. A Text book of Pharmacognosy: Shah C. S., Quadry J. S., B. S. Shah Prakashan, Ahmadabad. 15th Edition, 2009.
4. Pharmacognosy: Kokate C. K., Purohit A. P., Gokhale S. B., Nirali Prakashan Pune, 42nd edition, 2008.
5. Textbook of Pharmacognosy: Wallis T. E., CBS Publishers and Distributors, New Delhi, 5th Edition, reprinted, 2009.
6. Trease and Evans Pharmacognosy. 16h Edition, William Charles Evans, W. Saunders, Edinburg London New York Philadelphia St. Louis Sydney Toronto 2009.
7. Natural Products, Vol I & II, by Agrawal O. P., Goel Publishing House, Meerut, 28th Edition, 2004.
8. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing house, New Delhi, 2005.
9. Medicinal Natural Products a Biosynthetic Approach, Dewick Paul M. John Wiley and Sons, West Sussex, 2009.
10. Natural Products as Medicinal Agents, Ed. Beal J. L. and Reinhard.E , Hippocratos Verlog Stuttgart; 1982
11. Natural products by Ikan R., Academic Press, Califonia, 1st Edition, 2005.
12. Pharmacognosy and Pharmacobiotechnology by Ashutosh Kar, 2nd Edition, New Age International Pvt. Ltd.; New Delhi, 2007.
13. Pharmacognosy and Pharmacobiotechnology. James E. Robbers, Marilyn K. Speedie, Varro E. Tyler, Baltimore: Williams & Wilkins, 1996; a Wavery Company, USA.

14. Pharmacognosy: Phytochemistry Medicinal Plants by Bruneton Jean, 2nd Edition, Intercept Publications, Ltd., TEC & DOC Paris, 1999.
15. The Organic Constituents of Higher Plants. Their chemistry and interrelationships. Robinson Trevor, Burges Publishing Company, Minneapolis, USA, 1963.
16. Practical Pharmacognosy, Technique and Experiment by Kokate C. K. and Gokhale S. B., Nirali Prakashan, Pune, 8th edition, 2005.
17. The Wealth of India (Raw Material & Industrial Product), Published by Council of Scientific Industrial Research, New Delhi, 1st Edition, (1950-2014).
18. Indian Medicinal Plants by Kirtikar and Basu, 1st Edition, International Book Distributors, Dehradun, 1999.
19. Compendium of Indian Medicinal Plant Vol. 1 to 6, by Rastogi Ram P., Mehrotra B. N., CDRI & NISCOM, 1st Edition, New Delhi, 1998.
20. Review on Indian Medicinal Plants, Vol I to XI (2004 to 2014) Editor: Gupta A K & Tundon Neeraj. By: Indian Council of Medicinal Research (ICMR), New Delhi.
21. Powdered Vegetable Drugs by Jeckson B. P. & Snewden D. W..
22. Chanhan M. G & Pillai A. P.G, Microscopic profile of powdered drugs used in Indian system of medicine, Volume I, Bark drugs 2005, Institute of Ayurvedic medicinal plant science, Gujarat Ayurved University, Jamnagar.
23. Chauhan M. G & Pillai A.P.G, "Microscopic profile of powdered drugs used in Indian systems of Medicine, Leaf Drugs, Vol 2, 2007, Institute of P.G Teaching & Reaearch in Ayurveda, Gujarat Ayurved University, Jamnagar.
24. Chauhan M. G & Pillai A.P.G, " Microscopic profile of Drugs used in Indian system of Medicine, Seed drugs, Volume- 3, part- 1, 2011; Publisher: Prof Malati G Chauhan, P.G T- S.F C cell, I.P. G T. & R.A, Gujarat Ayurved University, Jamnagar.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Dosage form Design I
Subject Code: 2270001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1	**Preformulation studies:** a) Study of physical properties of drug like physical form, particle size, shape, density, wetting, dielectric constant, dissolution and organoleptic property and their effect on formulation, stability and bioavailability. b) Study of chemical properties of drugs like hydrolysis, oxidation, reduction, polymorphisms, racemization, polymerization etc., and their influence on formulation and stability of products. c) Study of prodrugs in solving problems related to stability, bioavailability and elegance of formulations. Theoretical aspects for determining solubility and permeability of the drug, its assessment and application	**8**
2	**Pharmaceutical necessities:** Study of following adjuvant in pharmaceutical products: Natural Gums, bio-degradable polymers, semi-synthetic cellulosic derivatives, and polymers for achieving modified drug release.	**6**
3	**Stability of pharmaceuticals:** a) Kinetic principles and stability testing: Reaction rate and order, acid base catalysis, decomposition reactions and stabilization of pharmaceuticals. b) Stability of formulation, factors affecting formulation stability, MKT, climatic zones, matrixing and bracketing instability study, accelerated stability testing, real time stability. Current WHO, USFDA and stability testing as per ICH guidelines for pharmaceutical drug substances and drug products. c) Product stability: Requirements, shelf-life, overages, containers, closures. d) Overage calculations	**8**
4	**Biopharmaceutics:** a) Introduction to biopharmaceutics and its role in formulation development. b) Passage of drugs across biological barriers (passive diffusion, active transport, facilitated diffusion and pinocytosis. c) Factors influencing absorption, - physiochemical, physiological and pharmaceutical. d) Drug distribution in the body, plasma protein binding and drug excretion	**12**
5	**Bioavailability and Bioequivalence:** a) Measures of bioavailability, Cmax, tmax and area under the curve (AUC). b) Design of single dose bio-equivalence study and relevant statistics. c) Review of regulatory requirements for conduction of bio-equivalent studies.	**6**

6	**Introduction to BCS and dissolution study:** Definition: BCS, BDDCS(Biopharmaceutical Drug Disposition Classification System), Dissolution mechanisms, Factors affecting dissolution, Intrinsic dissolution rate measurement, Dissolution apparatus for various dosage forms, Dissolution profile comparison using model independent method (similarity factor, dissimilarity factor).	**5**

Practical – 22700P1

1	Determination of the angle of repose, Carr's index, Hausner's ratio of given powder/ granules.
2	Determination of solubility of given drug at different pH
3	To study the compression characteristic of different diluents.
4	To optimize the concentration of suspending agents.
5	To optimize the concentration of emulsifying agents.
6	To study the effect of various binders on performance of tablet.
7	To study the effect of various disintegrants on performance of tablet.
8	To evaluate the physical stability of emulsion and compare with marketed product.
9	To evaluate the physical stability of suspension and compare with marketed product
10	To study the Influence of temperature on the stability of aspirin/ ascorbic acid solution.
11	Compendial dissolution testing and data evaluation for given tablets and capsules.
12	In-vitro dissolution profile comparison of given tablet with reference product using similarity and dissimilarity factor.
13	Enhancement of solubility of poorly water soluble drug by solid dispersion.
14	Enhancement of solubility of poorly water soluble drug by β-Cyclodextrin complexation.
15	Preformulation studies including drug-excipient compatibility studies.
16	Calculation of bioavailability parameters from the given pattern of drug absorption from oral & IV formulations.

References Books:

1. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.
2. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J Kanig.
3. Pharmaceutical Preformulation by Carstensen JT, Technomic Publishing Company, Inc., New Holland Avenue, Lancaster, Pennysylvania, USA.
4. Remington's Pharmaceutical Sciences, Mack Publishing Company, Easton, Pennsylvania.
5. Pharmacokinetics by Milo Gibaldi and Donald Perrier.
6. Hanbook of Pharmaceutical excipients, Royal society of Great Britain, U.K.
7. Stability Studies, Marcel Dekker.
8. Pharmaceutical dissolution testing by Umesh V. Banker, Marcel Dekker Inc

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Pharmaceutical Technology I
Subject Code: 2270002

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1.	**Sterile dosage forms**: Definitions, Advantages, Disadvantages, Ideal requirements and Formulation of sterile dosage forms, Water for injection-Preparation and quality control, Design and requirements for production area-Aseptic techniques, sources of contamination and methods of prevention, design of aseptic area, laminar flow benches, services and maintenance, containers and closures, methods of filling including form fill and seal technology. Evaluation of sterile dosage forms, Parenteral suspensions, Prefilled syringes, Parenteral nutrients, Freeze dried products, Nanosuspensions etc, I.P. Products. Ophthalmic preparations: Requirements, formulations, methods of preparations, containers and evaluation. I.P. Products.	12
2.	**Liquid dosage forms**: Introduction, advantages and disadvantages, types of additives used-vehicles, stabilizers, preservatives, suspending agents, emulsifying agents, solubilizers, colors, flavors etc; manufacturing, packaging and evaluation of clear liquids, suspensions and emulsions (including microemulsion and multiple emulsion) and brief outline of other liquid products such as extracts, tincture, infusion etc., I.P. Products.	7
3.	**Semisolid dosage forms:** Definition, Advantages and disadvantages, types, mechanisms of drug penetration through skin, factors influencing penetration, semisolid bases, their selection and ideal requirements of bases. General formulation of semisolids, clear gels, suppositories; Manufacturing procedure, evaluation and packaging. I.P. products.	7
4.	**Pharmaceutical aerosols:** Definition, propellants, general formulation of aerosols, containers, manufacturing (cold filling and pressure filling technique) and packaging methods, pharmaceutical applications, evaluation of aerosol.	6
5.	**Cosmeticology and cosmetic preparations** Fundamentals of cosmetic science, structure and functions of skin and hair, formulation, preparation and packaging of cosmetics for skin -Sunscreen, moisturizers, cold cream, and vanishing cream, hair - Shampoo and conditioners, dentifrice-powders, gels, paste and manicure preparations like-nail polish, lipsticks, eye lashes, brief introduction to cosmeceuticals, baby care products, shaving cream, hygienic products	6
6.	**Good Manufacturing Practice for Pharmaceuticals and validation** Brief Introduction to GMP (schedule M) and quality assurance, practice of GMP-Procedure (SOPs), Building, Equipment, Personnel, Components, Documentation, Containers, Labeling, Laboratory Control, Distribution Records, Recovery & Reprocessing. Introduction to validation, validation of selective unit operations (e.g. granulation, compression, mixing) used in tablet manufacturing and steam sterilizer.	7

Practical – 22700P2

1.	Formulation and evaluation of syrup
2.	Formulation and evaluation of oral Liquids (emulsions, liniment, calamine lotion IP/BPC etc)
3.	Formulation and evaluation of milk of magnesia/aluminium hydroxide gel antacid suspension, dry suspension
4.	Formulation and evaluation of diclofenac sodium gel
5.	Preparation and evaluation of face powder
6.	Preparation and evaluation of lipstick
7.	Preparation and evaluation of cold cream
8.	Preparation and evaluation of vanishing cream
9.	Preparation and evaluation of tooth paste/ tooth powder
10.	Formulation and evaluation of dextrose injection
11.	Formulation and evaluation of NaCl injection
12.	Formulation and evaluation of Ascorbic Acid injection
13.	Formulation and evaluation of Diclofenac sodium injection
14.	Formulation and evaluation of any oil based injection.
15.	Formulation and evaluation of eye drops
16.	Formulation and evaluation of multidose injection.
17.	Formulation and evaluation of IV/peritoneal infusion
18.	Formulation and evaluation of microemulsion
19.	Formulation and evaluation of calcium gluconate injection

References Books:

1. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and JKanig.
2. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York
3. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
4. Pharmaceutics: The Science of Dosage Form Design by Michael E. Aulton
5. Pharmaceutical Dosage Forms: Disperse systems: Vol.1, Vol. 2 and Vol.3, Ed. by Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., New York.
6. Pharmaceutical Dosage Forms: Parenteral Medication: Vol.1, Vol. 2 and Vol.3, Ed. by Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., New York
7. GMP for Pharmaceuticals by S. H. Willig and J. R. Storker.
8. Cosmetics by Poucher
9. Latest editions of IP, BP, USP.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Pharmaceutical Chemistry – IX (Medicinal Chemistry - III)
Subject Code: 2270003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
	Introduction, history, classification, nomenclature, mechanism of action, adverse effects, therapeutic uses, structure activity relationship (SAR) and synthetic procedures of selected drugs and recent developments of following categories to be covered.	
1	**Chemotherapeutic Agents:**	
	Antibacterial agents: • SAR: Sulphonamides, fluoroquinolones • Synthesis of sulphacetamide, sulphamethoxazole, Trimethoprim, Ciprofloxacin, Ofloxacin, Norfloxacin	4
	β-Lactam Antibiotics: • SAR: Penicillins, Cephalosporins,	4
	Tetracyclines, Aminoglycosides, Macrolides and Miscellaneous Antibiotics: • SAR: Aminoglycosides, Tetracyclines, Macrolides. • Synthesis of Chloramphenicol	6
	Antimycobacterial Agents: Synthesis: Ethambutol, Isoniazid, Pyrazinamide	3
	Antifungal Agents: Synthesis: Clotrimazole, Ketoconazole	2
	Antiprotozoal Agents: **Antimalarial and Antiamoebic Agents** • SAR: Quinolines • Synthesis: Chloroquine, Primaquine, Pyrimethamine. Metronidazole	4
	Anthelmintics: Synthesis: Albendazole, Mebendazole.	2
	Antiviral and Anti-HIV Agents: Synthesis: Amantadine	3
2	**Antineoplastic agents:** Synthesis: Chlorambucil, Cyclophosphamide, Thiotepa, Methotrexate, Fluorouracil, Tamoxifen.	5
	Drug Design and Development:	
	QSAR Lipophilic, electronic and stearic parameters Hansch Linear Free Energy Relationship (LFER) model of QSAR Free Wilson Mathematical Model of QSAR	5
	De novo Drug Design Molecular modeling (MM) Computer Aided Drug Design (CADD)	3

	Methods of Lead Discovery Identification and Optimization of Lead	2
	Brief introduction to Combinatorial Chemistry and Parallel Synthesis	2

Practical – 22700P3

Sr. No.	Contents	No. of practical hours
1	**Synthesis, Reaction monitoring and purification of following organic compounds:** Anthranilic acid from pthalic anhydride Sulphanilamide from acetanilide 3-phenyl propionic acid from diethylmalonate Hippuric acid from glycine Dihydroxytryptycene from anthracene and p-benzoquinone Fluorescein from resorcinol and pthalic anhydride. Purification of synthesized fluorescein by column chromatography Microwave assisted synthesis of any two compound	33
2	**Characterization of synthesized compound with the help of UV and IR Spectroscopy**	6
3	**Demonstration of QSAR Models (Any two exercise)** Literature survey of any QSAR Model and calculation of various physicochemical parameters Perform multiple regression analysis in MS Excel Generation of Best equation.	6

References Books:

1. J. N. Delagado and W. A. R. Remers, 11th edn, Wilson and Giswolds Textbook oforganic medicinal and pharmaceutical chemistry, J. Lippincott Co. Philadelphia
2. W. C. Foye, Principles of medicinal chemistry, Lea and Febiger, Philadelphia.
3. H. E. Wolff, edn, Burgers Medicinal chemistry, John Wiley and sons, New York Oxford University Press, Oxfords
4. Daniel Lednicer, Strategies for organic drug synthesis and design, John Wiley and Sons USA
5. G. L. Patrick. An Introduction to Medicinal Chemistry, 4th Edition, Oxford University Press.
6. Vogel's Text books practical organic chemistry, ELBS/Longman, London.
7. Arthur Vogel, Elementary Practical Organic Chemistry, Part-I and II, Second edition, CBS Publisher.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Pharmacology and Pharmacotherapeutics – III
Subject Code: 2270004

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1.	**Chemotherapy**	**(21)**
	General principles of chemotherapy- definition, classification, problems arising with the use of antimicrobial agents, choice of antimicrobial agents, combined use of antimicrobials, disadvantages of antimicrobial combinations, prophylactic use of antimicrobials, failure of antimicrobial therapy	3
	Classification, antibacterial spectrum, mechanism of action, mechanism of resistance, pharmacokinetics, adverse effects, uses, drug interactions of the following:	
	• Sulfonamides, cotrimoxazole, Quinolones,	2
	• Beta lactam antibiotics (penicillin, cephalosporins, monobactam, carbapenem, beta lactamase inhibitors),	3
	• Macrolides, Lincosamide, Glycopeptide,	2
	• Tetracycline and Chloramphenicol	2
	• Aminoglycoside antibiotics	1
	• Antifungal drugs	2
	• Antiviral drugs	2
	• Anthelmintics including antifilarial drugs	1
	• Anticancer drugs	3
2	**Definition, epidemiology, etiology, pathophysiology, signs and symptoms, diagnosis, complications, treatment and management of following diseases/conditions:**	**(24)**
	• Tuberculosis	2
	• Leprosy	1
	• Malaria, Dengue, Chikunguniya	4
	• Amoebiasis	1
	• Urinary Tract Infections	2
	• Enteric Infections	1
	• Meningitis	1
	• Respiratory Tract Infections : Influenza A,B, H1N1, H5N1, SARS	2
	• Leptospirosis	1
	• Syphillis and Gonorrhea	1
	• Leishmaniasis and Congofever	1
	• Herpes and HIV Infections	2
		2
		1

	• Leukemia • Lymphomas • Breast Cancer, Cervical Cancer and Prostate Cancer	2

Practical – 22700P4

Sr. No.	Course Contents
	Case studies (questions based on history, etiology, symptoms, investigations, medication, adverse effects, drug interactions, pharmacists' advice)
1.	To evaluate case study of bacterial infection (minimum 3 cases)
2	To evaluate case study of cancer (minimum 2 cases) and protozoal infections (2 cases)
3	To evaluate case study of viral infection (minimum 3 cases)
4	To audit given prescription for format of prescription, essentiality and rationality and suggest carry home message (three prescriptions- ANS / GIT/ Respiratory)
5	To audit given prescription for format of prescription, essentiality and rationality and suggest carry home message (three p rescriptions- Anemia/ CNS/ Infectious diseases)
6	To suggest appropriate parenteral nutrition for hospitalized patients after proper nutritional assessments in different conditions, and enlist importance of medications necessary in a pharmacy for Intensive Care Unit management.
7	To evaluate drug-drug interactions for the type of drug interaction, the mechanism responsible for drug interactions, possible outcomes or clinical manifestations of interaction and suggestion corrective measure to overcome or prevent the drug interaction (at least 25 drug-drug
8	To evaluate cases for Interpretation of laboratory data: Renal/ Liver/ CVS/ Diabetes. (Min. three full cases with clinical and other relevant findings)
9	To evaluate cases for Interpretation of laboratory data: Hematological/ Respiratory/ Cancer/ Infectious diseases (Min. three full cases with clinical and other relevant findings)
10	To evaluate two cases involving skills of pharmacist for patient counselling.
11	To evaluate for dose adjustment in geriatrics (three cases)
12	To evaluate for dose adjustment in paediatrics (three cases)
13	To evaluate for dose adjustment in pregnant women (three cases)
14	To evaluate cases for Therapeutic Drug Monitoring (TDM) (two cases)
15	Collecting information for a given drug (Preferably recently approved drugs) regarding adverse drug reactions, drug interactions and contraindications using authenticated sources (Recent text books, Latest Journals and online drug data bases such as medscape).

References Books:

1. J Rang, H.P. and Dale, M.M. Pharmacology, 5th edition, 2010. Publisher : Churchil Livingstone.
2. Tripathi K.D., Essentials of medical pharmacology 6th ed, 2010, Jaypee brothers medical publishers pvt, ltd.
3. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics, 12th edition, 2011. Mc Graw Hill, Pergamon Press.
4. Katzung, B.G. Basic and Clinical Pharmacology, 8th Edition, McGraw Hill, New
5. York, 11th edn, 2009
6. Satoskar, R.S. and Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics, 20th edition (single volume), 2010, Popular, Dubai
7. Kulkarni S.K. Handbook of experimental pharmacology, 3rd edition, 2009, Vallabh

Prakashan, New Delhi.
8. Clinical pharmacy and therapeutics . Roger Walker and Cate Whittlesea
9. Textbook of therapeutics. Drug and disease management. Eric T Herfindal Dick R Gourley

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Pharmacognosy-V
Subject Code: 2270005

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Theory

Sr No	Course Contents	Total Hrs
1.	**Biosynthetic studies and basic metabolic pathways:** Brief introduction to biosynthetic pathways of secondary metabolite. Biogenesis of pharmaceutically important compounds **Acetate mevalonate:** Menthol, Vitamin-A, Diosgenin, β-amyrin, Glycyrrhetinic acid, Carotenoids **Shikimic acid:** Atropine, Quinine, Reserpine, Morphine, Podophyllotoxin, Ephedrine, Colchicine, Ergot Alkaloids **Acetate malonate:** Linoleic acid, Omega-3 fatty acid	**12**
2.	**Natural allergens, Photosensitizing agents, Fungal toxins, Toxic plants** and toxicological risk of plant drugs.	**4**
3.	**Pesticides and herbicides**	**2**
4.	**Herbal cosmetics**	**2**
5.	**Nutraceuticals**	**2**
6.	**Plant sweeteners**	**1**
7.	**Concept of Ayurveda, Ayurvedic formulations and their quality control:** Introduction and principles of Ayurvedic, Unani, Siddha and Homeopathic systems of medicines. The holistic concept of Ayurvedic system of medicine. A study on different types of Ayurvedic formulations like Churna, Kwath, Gutika, Taila, Ghrita, Avaleha, Asavas, Arista, Bhasma and Pisti. Evaluation of Ayurvedic formulations.	**10**
8.	**Detail study of Ayurvedic Drugs:** Studies of traditional drugs, Common vernacular names, Botanical sources, Morphology, Chemical nature of chief constituents, Pharmacological categories, common uses and marketed formulations of following indigenous drugs **Stem:** Galo **Leaf:** Nagod **Bark:** Shirish **Root:** Chitrak, Rasna **Fruit:** Malkangni, Kalijiri **Seed:** Mucuna **Flower:** Dhatakipushpa **Entire herb:** Shankhpushpi, Punarnava **Unorganised:** Shilajit	**12**

Practical – 22700P5

1. Study of Morphology, Microscopy & TLC study of following crude drugs (T.S., Powder, Microscopy & TLC of underlined drugs) :
   - Galo
   - Nagod
   - Shirish
   - Chitrak (red and White)
   - Rasna (Pluchea & Alpinia)
   - Punarnava
   - Malkangani, Kalijiri, Dhatakipushpa, Shilajit, Mucuna, Shankpushpi

2. Study of plant used as insecticide, pesticide and herbicides
3. Preparation and evalulation of Herbal Cosmetics (Hair oil, Shampoo, Cream)
4. Preparation and evalulation of Churna (Triphala & Trikatu)
5. Preparation, Physical and chemical evaluation of Ayurvedic Preparations
   Asavas, Aristha, Taila, Pills/Tablets.
6. Preparation of Avaleha and Kwath.
7. Study of Toxic Plants
8. Study of Plant Sweeteners

References Books:

1. Cultivation and Utilization of Medicinal Plants, Atal C. K. and Kapur B. M., RRL Jammu, 1st Edition, 1989.
2. Supplement to Cultivation and Utilization of Medicinal Plants, Handa, S.S. and Kaul, M.K., 1996. RRL, CSIR Publication, Jammu Tawi.
3. Pharmacognosy: C. K. Kokate, A. P. Purohit, S. B. Gokhale, Nirali Prakashan Pune, 42nd edition, 2008.
4. Trease and Evans Pharmacognosy. 16th Edition, William Charles Evans, W. Saunders, Edinburg, London, New York, Philadelphia, St. Louis, Sydney, Toronto, 2013.
5. Natural Products, Vol I & II, 28th edi Agrawal O. P., Goel Publishing House, Meerut, 28th Edition, 2004.
6. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing House, New Delhi, 2005.
7. Medicinal Natural Products, A Biosynthetic Approach. Dewick Paul M, John Wiley and Sons, West Sussex, 2009.
8. The Organic Constituents of Higher Plants. Their chemistry and interrelationships. Trevor Robinson, Burges Publishing Company, Minneapolis, USA, 1963.
9. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals. Mukherjee P K, Business Horizons Pharmaceutical Publishers; 2002
10. The Ayurvedic Pharmacopoeia of India, Part I, (Vol. I–V) , part II (I & II) Govt. of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, New Delhi 2008.

11. The Ayurvedic Formulary of India, Vol. I, II and III, Published by Government of India, New Delhi, 1st Edition, 2000.
12. The Wealth of India (Raw Material & Industrial Product), Published by Council of Scientific Research, New Delhi, 1st Edition, 2005.
13. Indian Medicinal Plants, Kirtikar and Basu, 1st Edition, International Book Distributors, Dehradun, 1999.
14. Ayurveda Unravelled, Sharadini Dahanukar and Urmila Thatte, 1st Edition, 1996, National Book Trust, New Delhi.
15. Compendium of Indian Medicinal Plant Vol. 1 to 6, Rastogi R. P., Mehrotra B. N., CDRI & NISCOM, 1st Edition, New Delhi, 1998
16. Indian Herbal Pharmacopoeia, 1st revised Edition, Published by RRL, Jammu and IDMA, Mumbai, 2002.
17. Quality standards of Indian medicinal plants, Volume I to XI (2003 to 2013) Editor: Neeraj Tundon & Parul Sharma; By : Medicinal plant Unit, ICMR, New Delhi.
18. Malati G Chanhan & A. P.G Pillai, Microscopic profile of powdered drugs used in Indian system of medicine, Volume I, Bark drugs 2005, Institute of Ayurvedic medicinal plant science, Gujarat ayurved unit Jamnagar; CPTA.
19. Malati G Chauhan & A.P.G Pillai, "Microscopic profile of powdered drugs used in Indian systems of Medicine, Leaf Drugs, Vol 2, 2007, Institute of P.G Teaching & Reaearch in Ayurveda, Gujarat Ayurved University, Jamnagar.
20. Malati G Chauhan & A.P.G Pillai, " Microscopic profile of Drugs used in Indian system of Medicine, Seed drugs, Volume- 3, part- 1, 2011; Publisher: Prof Malati G Chauhan, P.G T-S.F C cell, I.P. G T. & R.A, Gujarat Ayurved University, Jamnagar.
21. Review on Indian Medicinal Plants, Vol I to XI (2004 to 2012) Editor: A K Gupta & Neeraj Tundon. By: Indian council of medicinal Research (ICMR), New Delhi.
22. R. D Chaudhry, Herbal Drug Industry, Eastern Publications, New Delhi.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Cyber Security
Subject Code: 2270006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	**Introduction to Cybercrime** Definition and Origins of the Word, Cybercrime and Information Security, Who are Cybercriminals? Classifications of Cybercrimes: E-Mail Spoofing, Spamming, Cyber defamation, Internet Time Theft, Salami Attack/Salami Technique, Data Diddling, Forgery, Web Jacking, Newsgroup Spam/Crimes Emanating from Usenet Newsgroup, Industrial Spying/Industrial Espionage, Hacking, Online Frauds, Pornographic Offenses , Software Piracy, Computer Sabotage, E-Mail Bombing/Mail Bombs, Usenet Newsgroup as the Source of Cybercrimes , Computer Network Intrusions, Password Sniffing, Credit Card Frauds, Identity Theft	7
2	**Cyberoffenses and Law** Introduction, Categories of Cybercrime, How Criminals Plan the Attacks: Reconnaissance, Passive Attack, Active Attacks, Scanning/Scrutinizing gathered Information, Attack (Gaining and Maintaining the System Access), Social Engineering-Classification of Social Engineering, Cyber stalking: Types of Stalkers, Cases Reported on Cyber stalking, How Stalking Works? Cyber cafe and Cybercrimes, Botnets: The Fuel for Cybercrime, Attack Vector, Cloud Computing: Why Cloud Computing? Types of Services, Cybercrime and Cloud Computing. Attacks on mobile devices. Recognizing and Defining Computer Crime, Contemporary Crimes, Computers as Targets, Contaminants and Destruction of Data, Security Policies, WWW policies, Email Security policies, Information Security Standards-ISO, Copyright Act, Patent Law, IPR. Cyber Laws in India; IT Act 2000 Provisions, Intellectual Property Law: Copy Right Law, Software License, Semiconductor Law and Patent Law	11
3	**Network Defense tools** Firewalls and Packet Filters: Firewall Basics, How a Firewall Protects a Network, basic of Virtual Private Networks, Linux Firewall, Windows Firewall, Snort: intrusion detection system	5
4	**Cybercrime: Mobile and Wireless Devices** Introduction, Proliferation of Mobile and Wireless Devices, Trends in Mobility, Credit Card Frauds in Mobile and Wireless Computing Era: Types and Techniques of Credit Card Frauds, Security Challenges Posed by Mobile Devices Attacks on Mobile/Cell Phones: Mobile Phone Theft, Mobile Viruses, Mishing, Vishing, Smishing, Hacking Bluetooth, Mobile Devices: Security Implications for	10

	Organizations: Managing Diversity and Proliferation of Hand-Held Devices, Unconventional/Stealth Storage Devices Threats through Lost and Stolen Devices, Protecting Data on Lost Devices, Educating the Laptop Users Organizational Measures for Handling Mobile Devices-Related Security Issues: Encrypting Organizational Databases, Including Mobile Devices in Security Strategy, Organizational Security Policies and Measures in Mobile Computing Era: Importance of Security Policies relating to Mobile Computing Devices, Operating Guidelines for Implementing Mobile Device Security Policies, Organizational Policies for the Use of Mobile Hand-Held Devices, Laptops: Physical Security Countermeasures	
5	**Introduction to Cyber Crime Investigation** assword Cracking, Keyloggers and Spyware, Virus and Warms, Trojan and backdoors, Steganography, DoS and DDoS attack, SQL injection, Buffer Overflow, Attack on wireless Networks.	5
6	**Organizational and Cybersecurity**: Introduction to implications of insider, outsider attacks, Cost of cybercrimes and IPR issues, overview of webthreats to organizations, security and privacy implications from Cloud Computing, Over view of Social media : use, security risks and peril for organization	7

References Books:

1. Cyber Security Understanding Cyber Crimes, Computer Forensics and Legal Perspectives by Nina Godbole and Sunit Belpure, Publication Wiley.
2. Anti-Hacker Tool Kit (Indian Edition) by Mike Shema, Publication Mc Graw Hill.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Environmental Toxicology and Green Audit
Subject Code: 2270007

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Contents	Total Hrs
1.	**Concepts and Principles of Ecotoxicology**: Principles of Ecology and Toxicology; Dose effect and Dose response relationship, acute toxicity, chronic toxicity, carcinogenicity and mutagenicity; Pathways of toxicants into ecosystem, bioconcentration, biotransfer factors, biomarkers and effects of toxicants; Factors affecting toxicity; Tests for assessing toxicity (carcinogenicity and mutagenesis); Bio-assay techniques; Concepts of LD_{50} and LC_{50}	8
2.	**Classification of toxicants**: Natural and synthetic toxins; Toxic natural products: Mycotoxins, plant toxin, insect toxin, spider toxin and reptile toxin; Toxic inorganic compounds: carbon, nitrogen, silicon, phosphorus and sulfur compounds; Toxicology of Hydrocarbons (Alkanes, unsaturated non-aromatic hydrocarbon and aromatic hydrocarbons); Toxicology of organooxygen compounds, organonitrogen compounds, organosulfur compounds; Toxicology of metals	12
3.	**Toxicological Chemistry:** The role of environment in carcinogenesis; Metabolic reactions of xenobiotic compounds, Phase I reactions, Phase II reactions of toxicants, Biochemical mechanism of toxicity, Biochemistry of mutagenesis, Biochemistry of carcinogenesis, Ionizing radiation; Risk assessment, Human health risk assessment, and Ecological risk assessment; Regulatory toxicology: Legal approaches to the regulation of toxic substances	14
4.	**Green (Environmental) Audit:** Sustainable development; Framework of environmental auditing, Nature conservation, Energy, land use planning, conservation audit, Pollution control, Wastes and recycling, community awareness; Management of the environment auditing process and future prospect of environment auditing; Environmental regulatory criteria, standards for environmentally friendly products.	11

Reference Books:

1. Stanley E. Manahan, Toxicological Chemistry and Biochemistry 3rd Edition, Lewis Publishers, CRC Press, 2003.
2. Lorris G. Cockerham and S. Shane. Basic Environmental Toxicology, CRC Press, 1993.
3. Wayne G. Landi, Ming-HoYu, Introduction to Environmental Toxicology:Introduction to Environmental Toxicology: Impacts of Chemicals Upon Ecological Systems, Third Edition, CRC Press, 2003.
4. David A. Wright and Pamela Welbourn, Environmental Toxicology. Cambridge University Press, First Edition, 2002.
   A. K. Shrivastava, Environment Auditing. APH Publishing Corporation.
5. Donald G. Crosby. (1998) Environmental Toxicology and Chemistry. Oxford University Press

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Nutraceuticals
Subject Code: 2270008

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Historical perspective, classification, scope & future prospects. Applied aspects of the Nutraceutical Science. Sources of Nutraceuticals. Relation of Nutraceutical Science with other Sciences, current market trend in nutraceuticals industry, sourcing information of various nutraceuticals through web data mining	8
2	Food as remedies: Nutraceutical remedies for common disorders like arthritis, bronchitis, circulatory problems, hypoglycemia, nephrological disorders, liver disorders, osteoporosis, psoriasis and ulcers etc.	9
3	Nutraceutical rich supplements like green tea, lecithin, mushroom extract, chlorophyll, spirulina, glucosamine, octacosanol, lycopene, carnitine, melatonin, grape products, flaxseed, Soy proteins and soy isoflavones in human health	8
4	Health Food: Dietary fibers, prebiotics and probiotics vegetables, cereals, milk and dairy products as functional foods. Health effects of common beans, capsicum annum, mustards, ginseng, garlic, citrus fruits, fish oils, and sea foods	8
5	Bioavailability enhancers and Herbal beverages and drinks: health drink	3
6	Packaging strategies for nutraceutical products and labeling and claims for nutraceuticals products	3
7	Toxicity studies and regulatory guidelines for nutraceutical products, current Good Manufacturing Practices (cGMPs), DSHEA act and Global regulatory agencies and bodies for nutraceuticals in different countries.	6

References Books:

1. Pathak YV. Handbook of Nutraceuticals Volume I: Ingredients, Formulations, and Applications, CRC Press, 2009. Ed: 1th
2. Aluko RE. Functional Foods and Nutraceuticals, Springer Verlag GMBH, 2012
3. Hildebert Wagner and Sabine Bladt, Plant Drug Analysis: A Thin Layer Chromatography Atlas;, New Delhi: Springer (India) Pvt. Ltd., 2nd ed. 1996
4. D'Amelio, Frank S. Sr., Botanical: A Phytocosmetic Desk Reference; New York: CRC Press, I Llc, Boca Raton, Florida, U.S.A. 1999
5. Stephen J. Cutler and Horace G. Cutler, Biologically Active Natural Products: Pharmaceuticals; CRC Press, Boca Rotan London, New York. Washington DC 2000
6. Marc Paye, André O. Barel, Howard I. Maibach, Handbook of Cosmetic Sciences, Informa Press, Tylor and Francis, LLC, 2006
7. Vermeer BJ, Definition In: Peter Elsener, Howard I. Maibach, editors Cosmeceuticals: Drugs vs. Cosmetics, New York, Marcel Dekker, 2000

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Pharmaceutical Marketing Management
Subject Code: 2270009

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	**General principles of Marketing and applications to pharmaceutical marketing**	**30**
A	Marketing research:-Healthcare environment, Medical professional organizations, Pharmaceutical professional and industry organizations, Pharmaceutical market size and growth factors, Pharmaceutical marketing environment versus consumer marketing, Tools of research, Opportunities for existing and new innovative products	3
B	Strategic marketing Option :- Active pharmaceutical ingredients (bulk drugs), Over the counter drugs (OTC), Prescription drugs, Biologics & Biopharmaceuticals, Herbal & traditional systems of medicine based products, Medical devices, Surgical products	3
C	Roll of pharmaceutical marketing within organization and medical profession, Marketing organization structure in pharma company	3
D	Product development & Management- Development, Positioning & promotional strategy, Development of effective communication aids, Modern promotion tools, Market segmentation- by indications, by patient profile, by medical practitioners type, by dosage form	4
E	Product Lifecycle management - Marketing mix -4 P's (product, pricing, place & promotion), Post Market stability surveillance	3
F	Sales force management –Recruitment & training, Sales forecasting & targeting , Reporting, Performance appraisal, Incentive types, Customer relation management	4
G	Distribution Management & Logistics –Supply chain, Cold chain, Applications of IT & Management information systems for efficient marketing, controlling expiry & returned goods	3
H	Domestic Market- Indian scenario-Government & Institution supply, hospital & trade supply, Ethical marketing & Franchise (sales promoters) marketing	4
I	International Marketing- Regulated, semi regulated & rest of the world markets, Marketing and manufacturing authorization, Pricing & Inco terms like CIF, FOB, commercial documents, Marketing & distribution strategy, Export incentives, Role of Pharmexcil and other Government institutions	3
2	**Regulatory Aspects**	**15**
A	Essential drugs, DPCO provisions & implications of pricing in India	2
B	Implications of patents and trademarks on marketing	2
C	Registration of drugs in India, US, Europe and African countries – Dossier preparation	6
D	Pharmacovigilance and Pharmacovigilance program of India (PVPI)	2

E	Wholesale & Retail licence requirements	1
F	Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations 2002	1
G	Uniform code of Pharmaceutical Marketing Practices (UCPMP)	1

References Books:

1. Marketing management by Philip Kotler
2. Sales Management by Still, Cundiff and Govoni
3. Managing a Sales Force , Mike T Wilson
4. Drugs and Cosmetic Act and Rules
5. www.cdsco.nic.in (official website of CDSCO)
6. www.nppaindia.nic.in (official website of NPPA)
7. www.fda.gov (official website of USFDA)
8. www.ema.europa (official website of EMA)
9. www.edqm.eu (official website of EDQM)
10. www.mciindia.org (official website of Medical Council of India)
11. www.pharmaceuticals.gov.in (official website of department of pharmaceuticals)

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Pharmacovigilance
Subject Code: 2270010

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Pharmacovigilance- Introduction, Scope, Definition, Purpose, Methods, History	03
2	Fundamental Clinical Aspects of ADRs- Definition, Types, Factors, Mechanisms, Seriousness and Severity, causality assessment, Markers, Management Pharmacogenetic causes, ADR in Public Health	11
3	Important ADRs and 'Risk Driving' ADRs of Important Medicines Serious and important ADRs in various organ class, ADR of various anti infective drugs	04
4	Individual Case Safety Reports (ICSRs)- Definition, Types, Contents, Structure, Validity and assessment of ICSRs reports, Role ICSRs in Pharmacovigilance	06
5	Pharmacovigilance in Clinical Trials- Characterization, Pre and post authorisation studies, observational studies	03
6	Counterfeiting, Quality Defects and Medication Errors- Definition of substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC) medicines, Pattern and scale of counterfeiting, Medication error-Definition, types, detections	07
7	Spontaneous ICSR Reporting Systems (SRS) Definition, Potential and limitations of SRS, Forms and formats of ICSR transmission as per various regulatory bodies, descriptive statistics, access and confidentiality	06
8	Signal Detection and Management Definition, Sources, Validation, Assessment, Scope	02
9	Industry and Regulatory Authorities, Mandatory Procedures from Legislation Pharmacovigilance system and SOPs, Benefit risk assessment, crisis management plan, WHO international drug monitoring programme, medDRA, Pharmacovigilance regulation in INDIA, USA, EUROPE, CANADA	03

References Books:

1. Talbot J, Aronson JK (eds.) Stephen's detection and evaluation of adverse drug Reactions
2. Andrews E, Moore N (eds.) Mann's Pharmacovigilance
3. Van Boxtel CJ, Santoso B, Edwards IR (eds.) Drug benefits and risks
4. Rawlins MD Therapeutics, evidence and decision-making

5. Aronson JK (ed.) Meyler's side effects of drugs
6. Sweetman SC (ed.) Martindale - the complete drug reference
7. World Health Organization WHO model formulary
8. S. K. Gupta Text book of Pharmacovigilance

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Herbal Cosmetics
Subject Code: 2270011

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Introduction: The scope, historical background and present status of herbal cosmetics, cosmetic market and herbal cosmetics, classification of herbal cosmetics	5
2	Raw materials used for formulation of skin care and hair care cosmetics: source and description of raw materials of natural origin like fixed oils, waxes, gums, hydrophilic colloids, colours, perfumes, protective agents, bleaching agents, preservatives, antioxidants and other ancillary agents used in the cosmetic formulations	10
3	Skin Structure and physiology	3
4	Herbal skin care cosmetics: • Cleansing agents - apricot. • Emollients - aloe, almond. • Astringent – amla • Freshening agent - chandan, khus. • Skin Pigmentation - saffron, ambi haldi.	8
5	Herbs used as antioxidants, free-radical scavenger, antiseptic, antibacterial, anti-wrinkle, anti-fungal	4
6	Hair structure and physiology • Herbal hair care cosmetics • Hair grooming : apricot, aloe • Hair growth promotors: brahmi, manjistha, jatamansi. • Hair Tonics: Bavachi, Hibiscus, Amla • Anti-dandruff: tulsi, neem, wheat gram oil, lemon, orange, aritha • Hair colorants: henna, amla, bhringaraja (*E. alba*), chamomile • Hair cleansing: ritha, shikakai, amla	10
7	Regulatory guidelines: Compliance of Drug & Cosmetic Act 1940 with reference to provisions for packaging and labelling (Rule 150 A, schedule S), permitted colors, flavors etc. BIS guidelines for cosmetic products and raw materials	5

References Books:

1. Marvin Balsam, Edward Sagarin; Cosmetic Science and Technology Vol I, II, III Ed. 2nd, John Wiley & Co. England
2. Chopra RN, Indian Herbs

3. The Wealth of India: Raw Materials (11 Vol.+ 2 Suppl.). Head, NISCIR, Dr. K. S. Krishnan Marg, Pusa Campus New Delhi-110 012, India. 1950.
4. Bare P., Cosmetics Analysis selective methods with techniques.
5. Behl PN, Srivastava G. Herbs Useful in Dermatological Therapy. Ed. 2nd New Delhi, India: CBS Publishers. 2002
6. Hand Book of herbal products Vol I & II by NIIR Board of Technologist. National Institute of Industrial Research,
7. Trease and Evans Pharmacognosy: William Charles Evans Revised with the assistance of Daphne Evans Ed. 16th Elsevier 2009.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Green Chemistry
Subject Code: 2270012

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Contents	Total Hrs
1.	**Introduction to Green Chemistry:** • Definition. • Need for Green Chemistry & eco efficiency. • Goals of Green Chemistry. • Limitations/Obstacles in the pursuit of the goals of Green Chemistry. • Twelve principles of Green Chemistry with their explanations and examples. • Inception of Green Chemistry. • Designing a green synthesis – Prevention of waste / byproducts – Atom economy. • Awards for Green Chemistry & international organizations promoting green chemistry	10
2.	**Designing Green Synthesis** • Designing and choice of starting materials/solvents/reagents • Bio catalysts • Polymer Supported Catalysts • Green solvents, solvent less processes, immobilized solvents and ionic liquids; energy requirements for reactions - use of microwaves, ultrasonic energy • Avoidance of unnecessary derivatization • Careful use of blocking/protecting groups & use of catalytic reagents • Microwave-assisted organic synthesis (MAOS)	15
3.	**Green Reactions:** • Green Synthesis of the following compounds: adipic acid, catechol, BHT, 4-aminodiphenylamine, benzyl bromide, acetaldehyde, citral, ibuprofen, paracetamol, • Microwave assisted reactions in water: o Hofmann Elimination, o Hydrolysis (of benzyl chloride, benzamide, n-phenyl benzamide) o Oxidation (of toluene, alcohols). o Fries rearrangement, o Claisen Rearrangement, o Diels Alder Reaction, o Decarboxylation. o Microwave assisted solid state reactions: Deacetylation, Saponification of esters o Reductions:, synthesis of nitriles from aldehydes; anhydrides from dicarboxylic	15

	acid • Ultrasound assisted reactions: Esterification, saponification, substitution reactions, Alkylations, oxidation, reduction, coupling reaction, Cannizaro reaction, Strecker synthesis, Reformatsky reaction.	
4.	**Future Trends in Green Chemistry** • Oxidation reagents and catalysts; Biomimetic, multifunctional reagents. • Combinatorial Green Chemistry. • Proliferation of solventless reactions. • Noncovalent Derivatization & Green Chemistry Applications. • Green chemistry in sustainable development	5

Reference Books:

1. M.A. Ryan & M. Tinnesand, Introduction to Green Chemistry, American Chemical Society, Washington (2002).
2. V.K. Ahluwalia & M.R. Kidwai: New Trends in Green Chemistry, Anamalaya Publishers (2005).
3. P.T. Anastes & J.K. Warmer: Oxford Green Chemistry- Theory and Practical, University Press (1998).
4. A.S. Matlack: Introduction to Green Chemistry, Marcel Deckkar, (2001).
5. M.C. Cann & M.E. Connely: Real-World cases in Green Chemistry, American Chemical Society, Washington (2000).

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Agronomy and Forestry of Medicinal Plants
Subject Code: 2270013

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Ecosystem system structure. Ecology, diversity, and conservation of plants and ecosystems in India. Phytogeographical regions and vegetation of India	5
2	The Indian Forest Act, 1927; The National Forest Policy 1894, 1952 and 1988; Forests extent, basis for classification and distribution in India; geographical distribution and salient features of major forest types	5
3	Role of forests in national economy	3
4	The cultivation of medicinal plants in agroforestry systems	4
5	Biodiversity; Principles of conservation of biological diversity *in-situ* and *ex-situ*. Causes of loss of biodiversity. Biodiversity in relation to global environmental changes; biodiversity hot spots in India and world impact of cultivation and gathering of medicinal plants on biodiversity. The Indian Biodiversity Act 2002; biodiversity and economics with special reference to India	10
6	The Forest Conservation Act, 1980. The Wildlife Protection Act, 1972; Methods of conservation, role of national parks, wildlife sanctuaries, biosphere reserves; national and global conservation measures, institutions and conventions	5
7	Guidelines on the conservation of medicinal plants;WHO, IUCN, WWF & TRAFFIC	3
8	Definition, object and scope of silviculture. Silviculture of important species - acacia, eucalyptus, dalbergia, tectona, shorea, pterocarpus, anogeissus, santalum, quercus etc	5
9	Importance of medicinal and aromatic plants in human health, national economy and related industries, classification of medicinal and aromatic plants according to botanical characteristics and uses	5

References Books:

1. Chadha KL & Gupta R. 1995. Advances in Horticulture. Vol. II. Medicinal and Aromatic Plants. Malhotra Publ.
2. Das NR. 2007. Introduction to Crops of India. Scientific Publ.
3. Handa SS. 1984. Cultivation and Utilization of Medicinal Plants. RRL, CSIR, Jammu.
4. Hussain A. 1984. Essential Oil Plants and their Cultivation. CIMAP, Lucknow.
5. Hussain A. 1993. Medicinal Plants and their Cultivation. CIMAP, Lucknow.
6. ICAR 2006. Hand Book of Agriculture. ICAR, New Delhi.
7. Kumar N, Khader MD. Abdul, Rangaswami JBM & Irulappan 1997, Introduction to Spices, Plantation Crops, Medicinal and Aromatic Plants. Oxford & IBH.
8. Prajapati ND, Purohit SS, Sharma AK & Kumar T. 2003. A Hand Book of Medicinal Plants: A Complete Source Book. Agrobios.

9. Sharma R. 2004. Agro-Techniques of Medicinal Plants. Daya Publ. House.
10. Atal CK. And Kapur BM, Cultivation and Utilization of Medicinal Plants, RRL Jammu, 1st Edition, 1989.
11. Atal CK And Kapur BM, Cultivation and Utilization of Aromatic Plants, RRL Jammu, 1st Edition, 1989.
12. Handa SS. and Kaul MK; Supplement to Cultivation and Utilization of Medicinal Plants, 1996. RRl, CSIR Publication, Jammu Tawi.
13. Handa SS and Kaul MK,; Supplement to Cultivation and Utilization of Aromatic Plants, 1996. RRl, CSIR Publication, Jammu Tawi.

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm
SEMESTER: VII

Subject Name: Instrumental and Process Validation
Subject Code: 2270014

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr. No.	Contents	Hours
1	**Pharmaceutical Process Validation** Introduction to pharmaceutical validation: definition, manufacturing process model, scope of validation, advantage of validation, organization for validation, validation master plan, process validation as Quality assurance tool. Types of Process validation: prospective, concurrent, retrospective and revalidation. Validation of tablet manufacturing process and manufacturing process for sterile products Equipment qualification: Design qualification, Installation qualification, Operational qualification, Performance qualification. Qualification of equipments (e.g. Dry powder mixers, and Autoclave) Cleaning validation: cleaning of equipment, cleaning of facilities.	**18**
2	Instrumentation of HPLC, HPTLC and GC, Validation of HPLC and GC instruments.	**7**
3	**HPLC Method Development** Basics of separation including Column resolution, Plate number, Plate height, Selectivity factor, Capacity factor and their optimization. Selection of detector and column Mobile phase optimization including selection of correct pH value	**10**
4	**Bio analytical HPLC method development and validation** Biological sample preparation: Protein precipitation, liquid liquid extractions, solid phase extractions and membrane separations **LC/MS** – Hints and recommendations on optimization and troubleshooting	**5**
5	**Laboratory Automation** Principle of automation, automated instruments, types of automated analytical systems, process control, flow injection analysis.	**5**

REFERENCES:

1. Pharmaceutical Process Validation, A. H. Wachter and R. A. Nash, Drugs and Pharmaceutical Sciences Series, Vol. 129, Marcel Dekker Inc., 2011, New York.
2. Validation of Aseptic Pharmaceutical Processes, F.J. Carleton and J.P. Agalloco, Marcel Dekker Inc., 1986, New York.
3. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries by S. I. Haider and E. S. Asif, CRC Press, Taylor and Francis Group, 2010, Florida.
4. Practical HPLC Method Development, Second edition, L. R. Snyder, J. J. Kirkland and J. L. Glajch, A Wiley Interscience Publication, 1997, USA.
5. HPLC Made to Measure, S. Kromidas, Wiley-VCH Verlag GmbH & Co. KGaA, 2006, Weinheim.

6. Instrumental Analysis, D. A. Skoog, F. J. Holler, S. R. Crouch, Cenage Learning India Private Limited, 2012, New Delhi.
7. Instrumental Methods of Analysis, Seventh edition, H. H. Willard, L. L. Merritt, J. A. Dean, F. A. Settle, CBS Publishers & Distributors Pvt. Ltd., 2009, New Delhi.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Quality by Design (QbD) and Process Analytical Technology (PAT)
Subject Code: 2270015

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

.	Topic	Hours
1	**Introduction to QbD**: History, Current approch and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization.	2
2	**Pharmaceutical Development:** Introduction, Pharmaceutical Development, Submission of Pharmaceutical Development And Related Information In Common Technical Documents (CTD) Format, Design of experiments –Methods and applications Optimization techniques: Concept of optimization, optimization parameters, classical optimization. Statistical designs, Question Based Review (QbR).	10
3	**Quality Risk Management:**Introduction- What is quality? Relevence of quality with resepect to pharmaceuticals, Scope, Principles of Quality Risk Management ICH Q9, HACCP, FMEA, General Quality Risk Management Process.	3
4	**Pharmaceutical Quality Management**: Pharmaceutical Quality System, Management Responsibility, Continual Improvement of Process Performance And Product Quality, Continual Improvement of the Pharmaceutical Quality System.	5
5	**Detailed case study of QbD** for Immediate release dosage forms, Modified release dosage forms. Emphsis should be given to prototype QbD for various dosage forms considering manufacturing process variables, raw materials and desired attributes.	15
6	**Process Analytical Technology:** Introduction, Scope, Background, PAT Framework, PAT Tools, Risk-Based Approach, Integrated Systems Approach, Real Time Release, Strategy For Implementation, Regulatory Approach, Examples of PAT Implementation.	10

References:

1. ICH Guidelines
2. FDA Guidelines

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Innovations in Conventional Drug Delivery System
Subject Code: 2270016

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Innovation in Tablets (Fast dispersible tablet, matrix tablet, orodispersible tablet, sublingual tablet, soluble tablet, osmotic tablet etc)	10
2	Innovations in capsules (capsule shell and fill materials)	5
3	Innovations in pelletization and pellets	3
4	Innovations in semisolids	3
5	Innovations in parenterals including pre-filled syringes	6
6	Innovations in ophthalmic drug delivery	5
7	Innovations in aerosols drug delivery	4
8	Innovations in solutions	3
9	Innovations in disperse systems (suspensions and emulsions)	6

References Books:

1. Novel drug delivery systems. Y. W. Chein
2. Novel drug delivery system. N.K. Jain and others.
3. Novel drug delivery system. R. K. Khar and others.
4. Current updates available from web resources.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VII

Subject Name: Disaster Management
Subject Code: 2270017

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	**Understanding Disasters** Understanding the Concepts and definitions of Disaster, Hazard, Vulnerability, Risk, Capacity – Disaster and Development, and disaster management	05
2	**Types, Trends, Causes, Consequences and Control of Disasters** Geological Disasters (earthquakes, landslides, tsunami, mining); Hydro-Meteorological Disasters (floods, cyclones, lightning, thunder-storms, hail storms, avalanches, droughts, cold and heat waves); Biological Disasters (epidemics, pest attacks, forest fire); Technological Disasters (chemical, industrial, radiological, nuclear) and Man-made Disasters (building collapse, rural and urban fire, road and rail accidents, nuclear, radiological, chemicals and biological disasters); Global Disaster Trends – Emerging Risks of Disasters – Climate Change and Urban Disasters	13
3	**Disaster Management Cycle and Framework** Disaster Management Cycle – Paradigm Shift in Disaster Management Pre-Disaster – Risk Assessment and Analysis, Risk Mapping, zonation and Microzonation, Prevention and Mitigation of Disasters, Early Warning System; Preparedness, Capacity Development; Awareness During Disaster– Evacuation– Disaster Communication– Search and Rescue– Emergency Operation Centre– Incident Command System– Relief and Rehabilitation– Post-disaster– Damage and Needs Assessment, Restoration of Critical Infrastructure.	12
4	**Disaster Management in India** Disaster Profile of India – Mega Disasters of India and Lessons Learnt Disaster Management Act 2005 – Institutional and Financial Mechanism, National Policy on Disaster Management, National Guidelines and Plans on Disaster Management; Role of Government (local, state and national), Non-Government and Inter-Governmental Agencies	12
5	**Applications of Science and Technology for Disaster Management & Mitigation** Geo-informatics in Disaster Management (RS, GIS, GPS and RS) Disaster Communication System (Early Warning and Its Dissemination) S&T Institutions for Disaster Management in India	03

Reference Books:

1 Coppola D P, 2007. Introduction to International Disaster Management, Elsevier Science (B/H), London.

2. Manual on natural disaster management in India, M C Gupta, NIDM, New Delhi

3. An overview on natural & man-made disasters and their reduction, R K Bhandani, CSIR, New Delhi

4. World Disasters Report, 2009. International Federation of Red Cross and Red Crescent, Switzerland

5. Encyclopedia of disaster management, Vol I, II and IIIL Disaster management policy and administration, S L Goyal, Deep & Deep, New Delhi, 2006

6. Encyclopedia of Disasters – Environmental Catastrophes and Human Tragedies, Vol. 1 & 2,Angus M. Gunn, Greenwood Press, 2008

7 Disasters in India Studies of grim reality, Anu Kapur & others, 2005, 283 pages, Rawat Publishers, Jaipur

8. Management of Natural Disasters in developing countries, H.N. Srivastava & G.D. Gupta, Daya Publishers, Delhi, 2006, 201 pages

9. Natural Disasters, David Alexander, Kluwer Academic London, 1999.

10 Disaster Management Act 2005, Publisher by Govt. of India.

11 Publications of National Disaster Management Authority (NDMA) on Various Templates and Guidelines for Disaster Management NIDM Publications

12 High Power Committee Report, 2001, J.C. Pant

13 Disaster Mitigation in Asia & Pacific, Asian Development Bank

14 National Disaster Management Policy, 2009, Government of India

15 Disaster Preparedness Kit, American Red Cross

16 Bryant Edwards (2005): Natural Hazards, Cambridge University Press, U.K.

17 Carter, W. Nick, 1991: Disaster Management, Asian Development Bank, Manila.

18 Sahni, Pardeep et.al. (eds.) 2002, Disaster Mitigation Experiences and Reflections, Prentice Hall of India, New Delhi.

19 Roy, P.S. (2000): Space Technology for Disaster management: A Remote Sensing & GIS Perspective, Indian

Institute of Remote Sensing (NRSA) Dehradun.

20 Sharma, R.K. & Sharma, G. (2005) (ed) Natural Disaster, APH Publishing Corporation, New Delhi.

21 Kasperson, J.X., R.E. Kasperson, and B.L. Turner III (Eds.), 1995, Regions at Risk: Comparisons of

Threatened Environments, United Nations University Press, Tokyo

22 Singh Satendra (2003): Disaster Management in the Hills, Concept Publishing Company, New Delhi.

23 Taori, K (2005) Disaster Management through Panchayati Raj, Concept Publishing Company, New Delhi.

List of Open Source Software/learning website:

www.gis.development.net
www.iirs.n
rsa.org
http://quak

e.usgs.gov
www.nidmi
ndia.nic.in

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Dosage form Design II
Subject Code: 2280001

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

No	Course Content	Hrs
1	**Controlled and sustained release dosage forms** Design of oral sustained release systems: Biological factors, Physicochemical factors Diffusional systems: -Reservoir system, Lag time, Burst effect, Matrix system, Effect of porosity and tortuosity Dissolution controlled system, Cube route dissolution equation, Diffusion layer controlled dissolution. Bioerodible and Combination of diffusion and dissolution systems. Design, development and evaluation of oral and parenteral controlled release formulations.	8
2	**Novel drug delivery system** (a) Modified drug delivery systems: Fundamentals, rational of modified release drug delivery, factors influencing the design and performance, pharmacokinetic and pharmacodynamic basis for modified drug delivery systems, estimation of loading and maintenance dose. (b) Design and development of oral modified release dosage forms: Matrix tablets, microspheres, hydrogels, osmotic pressure controlled systems, gastro retentive systems, colon targeting. (c) Fabrication of parenteral drug delivery systems: Parenteral emulsions & parenteral suspensions, microspheres, liposomes, niosomes, nanoparticles. (d) Formulation and evaluation of Transdermal drug delivery systems. (e) A brief study of site specific and targeted drug delivery systems, transmucosal and ocular drug delivery systems.	22
3	**Pharmacokinetics** (a) Definition and scope, significance of plasma drug concentration measurement. (b) Compartment model: Phamacokinetics of drug absorption Zero order and first order absorption rate constant using Wagner-Nelson and Loo-Riegelman method. (c) Volume of distribution and distribution coefficient. (d) Compartment kinetics-one compartment and two compartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intra vascular and oral route. (e) Curve fitting (Method of Residuals), regression procedures. (f) Clearance concept, mechanism of renal clearance, clearance ratio, determination of renal clearance. (g) Hepatic elimination of drugs, first pass effect, extraction ratio, hepatic clearance, biliary excretion, extrahepatic circulation. (h) Non-linear pharmacokinetics with special reference to one compartment model after I.V. drug administration, Michaeles Menten Equation, detection of nonlinearity (Saturation mechanism). (i) Numericals related to pharmacokinetic parameters using one compartmental model.	10
4	**Clinical Pharmacokinetics** a) Definition and scope b) Dosage adjustment in patients with and without renal and hepatic failure. c) Pharmacokinetic drug interactions and their significance in combination therapy	5

Practical – 22800P1

1.	Preparation and evaluation of matrix tablet of BCS class I drug with erosion and diffusion based mechanisms.
2.	Preparation and evaluation of tablet coating
3.	Preparation and evaluation of osmotic drug delivery system
4.	Preparation and evaluation of floating drug delivery system
5.	Preparation and evaluation of buccal tablet
6.	Preparation and evaluation of buccal film
7.	Preparation and evaluation of transdermal patch
8.	Preparation and evaluation of colon drug delivery system
9.	Preparation and evaluation of Sodium alginate beads
10.	Preparation and evaluation of in situ gel
11.	Preparation and evaluation of microparticles by solvent change method
12.	Calculation of absorption rate by residual method
13.	Calculation of absorption rate by Wagner Nelson method
14.	Calculation of elimination rate by urinary excretion method

References Books:

1 Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu.

2 Pharmacokinetics by Milo Gibaldi and Donald Perrier

3 Remington's Pharmaceutical Sciences, Mack Publishing Company,Easton, Pennsylvania.

4 Clinical Pharmacokinetics: Concepts and Applications by Rowland and Tozar, Lippincott Williams & Wilkins.

5 Controlled Drug delivery, Fundamentals and Applications by J.R. Robinson & Uinvent Lee, Marcel Dekkar Inc.

6 Noval Drug Delivery Systems by Y. W. Chian Ed. James Swarbrick, Marcel Dekker.

7 Hanbook of Pharmaceutical excipients, Royal society of Great Britain, U.K. Stability Studies, Marcel Dekker.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Pharmaceutical Technology II
Subject Code: 2280002

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

No	Course Content	Hrs
1	**Tablet** (a) Definition, Advantages and disadvantages, Introduction to types of tablets**,** formulation of different types of tablets; excipients, granulation techniques, Directly compressible excipients, machinery for large scale granulation and compression, physics of tablet making, compression and compaction, In process controls, processing problems and remedies, (b) Evaluation (Pharmacopoeial and nonpharmacopoeial test) and equipments. Brief outline on manufacturing method and evaluation of mouth dissolving tablets, buccal tablets, floating tablets, tablets of colon drug delivery, matrix tablets. (c) **Coating of Tablets:** Objectives, types of coating, film forming materials, formulations of coating solution, equipments for coating, coating process, evaluation of coated tablets, coating defects, specialized coating processes. (d) **Pharmaceutical Tablet Compression Tooling:** Terminology, tablet design, specification and information required, use and care of the tooling, problem solving.	15
2	**Capsules** **Hard Capsules:** Definitions, advantages, disadvantages, Ideal requirements, Production of Hard capsules (Gelatin and nongelatin e.g. vegetable), Capsule storage, size of capsules, formulation and methods of capsule filling, problems and remedies, quality control, climatic control in capsule department, I.P capsules. **Soft Gelatin Capsules:** Formulation of shell and capsule coat, quality control with special emphasis on current dissolution testing. **Microcapsules/Microspheres:** Importance of microcapsule and microsphere in pharmacy, methods of preparation: Phase separation, coacervation, multiorifice centrifugal methods, spray congealing, polymerization, complex emulsion, Air suspension technique, coating pan and other techniques, evaluation of microcapsules, Applications of biodegradable and nonbiodegradable polymers in Microcapsules/Microspheres.	10
3	**Extrusion and Pelletization :** Factors affecting pellet properties, Cold extrusion, Melt extrusion, Applications of extrusion in pharmacy (including preparation of solid solution), selective equipments used for extrusion and pelletization, Use of polyethylene oxide and Eudragit in melt extrusion, Use of MCC in pelletization	7
4	**Supercritical fluids :** Introduction to supercritical fluids, Pharmaceutical applications of supercritical fluids in extraction, size reduction, preparation of inclusion complexes, preparation of solid dispersions, etc., Equipments for SCF processing.	8

	Pharmaceutical Packaging: Definition, Packaging components, types, specifications and methods of evaluation, stability aspects of packing. Primary and secondary packaging, packaging materials, containers and closures; and tamper-evident packaging, packaging equipments. Regulatory requirements in pharmaceutical packaging.	5

Practical – 22800P2

	Practical 3 hrs/week
1.	Filling of powder/ granules/ pellets in hard gelatin capsule and its evaluation.
2.	Preparation of gelatin microcapsules by simple coacervation method.
3.	Preparation of pellets by extrusion and spheronization
4.	Formulation and evaluation of controlled release pellets
5.	Preparation and evaluation of tablets employing direct compression
6.	Preparation and evaluation of tablets employing wet granulation.
7.	Preparation and evaluation of tablets employing dry granulation (slugging).
8.	Preparation and evaluation of Soluble Aspirin Tablet.
9.	Preparation and evaluation of Paracetamol tablet or any NSAID tablet.
10.	Preparation and evaluation of any calcium supplement tablet (eg ca lactate, $CaCO_3$, DCP etc)
11.	Preparation and evaluation of any antibiotic tablet.
12.	Preparation and evaluation of iron supplement tablet (eg $FeSO_4$)
13.	Preparation and evaluation of Chewable Antacid tablet.
14.	Preparation and evaluation of Fast Dispersible tablet using Effervescent agent.
15.	Preparation and evaluation of Fast Dispersible tablet using superdisintegrant.

References Books:

1. The Theory and Practice of Industrial Pharmacy by L Lachman, H Lieberman and J Kanig
2. Pharmaceutical Dosage Forms and Drug Delivery Systems by Ansel & others.
3. Pharmaceutics: The Science of Dosage Form Design by Michael E. Aulton
4. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York.
5. Pharmaceutical Dosage Forms: Tablets: Vol.1, Vol. 2 and Vol.3, Ed. by Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., New York
6. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes, Marcel Dekker, Inc., New York.
7. Latest editions of IP, BP, USP.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Pharmaceutical Chemistry – X (Medicinal Chemistry - III)
Subject Code: 2280003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Sr. No.	Course content	Teaching Hours To be allotted
1	Introduction, history, classification, nomenclature, mechanism of action, adverse effects, therapeutic uses, structure activity relationship (SAR) and synthetic procedures of selected drugs and recent developments of following categories to be covered.	
	Drugs acting on Cardiovascular System:	
	Cardiotonic Agents SAR: Cardiac glycosides Synthesis: Dobutamine	4
	Antihypertensive Agents SAR: ACE Inhibitors, Dihydropyridnes Synthesis: Nifedipine, Amlodipine, Atenolol, Metoprolol, Captopril, Hydralazine.	8
	Antiarrhythmic Agents Synthesis: Lignocaine, Flecainide.	3
	Antianginal Agents Synthesis: Glyceryltrinitrate, Isosorbidedinitrate	2
	Antihyperlipidemic agents: SAR: HMG CoA Reductase inhibitors Synthesis :Clofibrate	4
	Coagulants and Anticoagulants Synthesis of warfarin	2
	Antiplatelet Agents	2
	Thrombolytic Agents	1
	Plasma expanders	1
2	**Diuretics:** SAR: Thiazide diuretics, 5-Sulfamoyl benzoic acid derivatives. Synthesis: Hydrochlorthiazide, Acetazolamide, Furosemide, Ethacrinic acid	4

3	**Endocrine system**	
	Antidiabetic agents: Synthesis: Glipizide, Metformin, Pioglitazone, Tolbutamide,Glimipride.	5
	Thyroid Hormones and Antithyroid Drugs Synthesis: Methimazole, Carbimazole.	2
	Steroids and Therapeutically related compounds Nomenclature and stereochemistry of steroids Adrenocorticoids – Mineralocorticoids, Glucocorticoids Estrogens, Progestins and Androgens SAR: Estrogens and Adrenocorticoids, Progestins, Androgens	4
4	**Anti-obesity drugs**	1
5	**Immunomodulators**	2

Practical – 22800P3

Sr. No.	Content	No. of practical hours
1	Synthesis, Reaction monitoring and purification of following organic compounds: a) p-Nitro aniline from Acetanilide b) Benzillic acid from benzoin c) Benzamide from Benzaldehyde d) m-Nitrophenol from Nitrobenzene e) p-Aminophenol from Nitrobenzene f) Chalcone from Benzaldehyde and Acetophenone g) Barbituric acid from Urea and Dimethyl malonate	33
2	Characterization of synthesized compounds with the help of UV and IR spectroscopy.	12

References Books:

1. J. N. Delagado and W. A. R. Remers, 11thedn, Wilson and Giswolds Textbook oforganic medicinal and pharmaceutical chemistry, J. Lippincott Co. Philadelphia.
2. W. C. Foye, Principles of medicinal Chemistry, Lea and Febiger, Philadelphia
3. H. E. Wolff, edn, Burgers Medicinal chemistry, John Wiley and sons, New YorkOxford University Press, Oxfords.
4. Daniel Lednicer, Strategies for organic drug synthesis and design, John Wiley andSons USA
5. L. Finar. Organic chemistry Vol. I and Vol. II. ELBS/Longman, London
6. Vogel's Text books practical organic chemistry, ELBS/Longman, London

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Pharmacology and Pharmacotherapeutics – IV
Subject Code: 2280004

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Sr. No	Course Content	Total Hrs.
1.	**Definition, epidemiology, etiology, pathophysiology, signs and symptoms, diagnosis, complications, treatment and management of following diseases/conditions:**	**(20)**
	• Hypertension	3
	• Coronary heart diesease	3
	• Congestive heart failure	2
	• Cardiac arrhythmias	2
	• Thrombosis	2
	• Dyslipidemia	2
	• Acute and Chronic renal failure.	4
	• Anemia	2
2.	**Pharmacology of following class of drugs:-**	**(8)**
	• Diuretics and Antidiuretics	2
	• Hematinics and Erythropoietin	
	• Drugs Affecting Coagulation and Bleeding:	2
	Coagulants	3
	Anticoagulants including direct thrombin inhibitors	
	Fibrinolytics	
	Antifibrinolytics	
	Antiplatelet drugs	
	• Plasma Expanders	1

3	**Definition, epidemiology, etiology, pathophysiology, signs and symptoms, diagnosis, complications, treatment and management of following diseases/conditions:** • Diabetes mellitus and Hypoglycaemia • Thyroid and Parathyroid disorders • Erectile dysfunction • Menstrual cycle disorders • Bone disorders • Obesity	**(12)** 3 2 1 3 2 1
4	**Pharmacology of following class of drugs:** • Estrogens, Antiestrogens, and SERM, Aromatase inhibitors, Progestins, and antiprogestins • Hormonal contraceptives • Androgens and antiandrogens • Oxytocics and Tocolytics	**(5)** 2 1 1 1

Practical – 22800P4

1.	Introduction to general principles of bioassay, pharmacopoeial bioassays and biostandardization of various drugs
2.	Alternatives to animal experiments (High throughput screening, refinement, reduction, replacement, rehabilitation, in vitro pyrogen test, embryonic stem cell test, local lymph node assay for skin sensitization, skin patch test in human, neutral red uptake assay, carcinogenicity and toxicity tests using cell lines, developmental neurotoxicity tests)
3.	Bioassay of Acetylcholine using Chick/Rat ileum by Graphical method
4.	Bioassay of Acetylcholine using Chick/Rat ileum by matching, method
5.	Bioassay of Acetylcholine using Chick/Rat ileum by three point method
6.	Bioassay of Histamine using Chick/ Guinea pig by matching method
7.	Bioassay of Histamine using Chick/ Guinea pig by three point method
8.	Bioassay of Atropine using Chick/Rat ileum by Graphical method
9.	Simulation Experiments on Cardiovascular System: Effects of Various Drugs on Isolated Frog Heart.
	Case studies (questions based on history, etiology, symptoms, investigations, medications, adverse effects, drug interactions, pharmacists' advice)
10.	To evaluate case study of Hypertension (minimum 3 cases)
11.	To evaluate case study of Congestive Heart failure (minimum 2 cases) To evaluate case study of Angina pectoris (minimum 2 cases)

12	To evaluate case study of thyroid disorders (minimum 3 cases)
13	To evaluate case study of renal failure (minimum 3 cases)
14	To evaluate case study of anaemia (minimum 3 cases)
15	To evaluate case study of Diabetes mellitus (minimum 3 cases)

References Books:

1. Rang, H.P. and Dale, M.M. Pharmacology, 5th edition, 2010. Publisher : Churchil Livingstone.
1. Tripathi K.D., Essentials of medical pharmacology 6th ed, 2010, Jaypee brothers medical publishers pvt, ltd.
2. Goodman Gilman A., Rall T.W., Nies A.I.S. and Taylor, P. Goodman and Gilman's The Pharmacological Basis of therapeutics, 12th edition, 2011. Mc Graw Hill, Pergamon Press.
3. Katzung, B.G. Basic and Clinical Pharmacology, 8th Edition, McGraw Hill, New York, 11th edn, 2009
4. Satoskar, R.S. and Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics, 20th edition (single volume), 2010, Popular, Dubai
5. Kulkarni S.K. Handbook of experimental pharmacology, 3rd edition, 2009, Vallabh Prakashan, New Delhi.
6. Clinical pharmacy and therapeutics . Roger Walker and Cate Whittlesea
7. Textbook of therapeutics. Drug and disease management. Eric T Herfindal Dick R Gourley
8. Fundamentals of experimental Pharmacology. M.N.Ghosh. Hilton and Co.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Pharmacognosy-VI
Subject Code: 2280005

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

Sr. No	Course Content	Total Hrs.
1.	**Preparation of Herbal Extracts and their standardization:** Introduction to different methods of preparation of plant extracts. Preparation of standardized plant extracts and principles of Garcenia, Garlic, Turmeric, Aswagandha and Amla.	7
2.	**Evaluation of Phytopharmaceuticals:** Phytopharmaceutical evaluation and modern analytical techniques for analysis of herbal drugs.	6
3	**Isolation, identification and analysis of phytoconstituents:** a. **Terpenoids:** β - carotenoids, Menthol, Citral, Artemisin, Vitamin A b. **Glycosides:** Sennosides, Diosgenin, Glycyrrhetinic acid and Rutin c. **Alkaloids:** Atropine, Quinine, Reserpine, Morphine, Ephedrine, Caffeine d. **Resin:** Podophllotoxin, Curcumin e. **Antibiotic:** Penicillin, Streptomycin	18
4	**Herbal Drug Industry:** Scope, Study of infrastructure, Staff requirement, Project profiles, Plant and equipment, Processing, Research and development and pilot scale up techniques. Quality assurance and concept of Schedule T, GMP and ISO-9000 in herbal drug industry.	7
5	**Phytopharmacovigilance**	2
6	**Herbal drugs for modern diseases:** Recent developments of natural products used as Anticancer agents, Antidiabetics, Hepatoprotectives, Antiasthematic, Hypolipidemic, lythotryptic, Immunomodulators, Tranquilisers, Memory enhancer, Hypnotics	5

Practical – 22800P5

1. Isolation of Diosgenin from Fenugreek by preparative TLC and identification by TLC
2. Isolation of Diosgenin from Fenugreek by column chromatography.
3. Estimation of Diosgenin by quantitive TLC.

4. Estimation of Diosgenin by colorimetric method.
5. Isolation of Ephedrine and identification by TLC.
6. Estimation of Glycyrrhizinic acid by colorimetric method.
7. Isolation of Triammonium Glycyrrhizinate from Glycyrrhiza.
8. Estimation of carbohydrates in crude drugs/ extracts
9. TLC study of flavonoids of lemon peel, estimation of total flavonoids and isolation hesperidin.
10. Estimation of Total Phenolics and tannins from Harde.
11. Estimation of Total Phenolics and tannins in Trifala.
12. Preparation and evulation of Amla extract.
13. Preparation and evulation of Curcuma extract

References Books:

1. Pharmacognosy: C. K. Kokate, A. P. Purohit, S. B. Gokhale, Nirali Prakashan Pune, 42nd edition, 2008.
2. Trease and Evans Pharmacognosy. 16th Edition, William Charles Evans, W. Saunders, Edinburg, London, New York, Philadelphia, St. Louis, Sydney, Toronto, 2013.
3. Textbook of Industrial Pharmacognosy, A. N.Kalia, CBS Publishers & Distributors Pvt. Ltd., 1st Rev. Edition, 2011.
4. Herbal Drug Industry, R. D Chaudhry, Eastern Publications, New Delhi.
5. Natural Products as Medicinal Agents, Ed. J. L. Beal and E. Reinhard, Hippocratos Verlog Stuttgart; 1982
6. Chemistry of Natural products. S. V. Bhat, B. A. Nagasampagi, S. Meenakshi, Narosa Publishing House, New Delhi, 2005.
7. Medicinal plants glycosides,Sims,Toronto.
8. Natural Products, Vol I & II, O.P. Agrawal, Goel Publishing House, Meerut, 28th Edition, 2004.
9. Modern Methods of Plant Analysis, K. Peach and M. V. Tracey, Vol.1-4, Narosa Publisher House, New Delhi
10. Practical Pharmacognosy, Technique and Experiment, C. K. Kokate and S. B. Gokhale, Nirali Prakashan, Pune, 8th edition, 2005.
11. The Organic Constituents of Higher Plants. Their chemistry and interrelationships, Trevor Robinson, Burges Publishing Company, Minneapolis, USA, 1963.
12. Pharmacognosy: Phytochemistry Medicinal Plants, Jean Bruneton, 2nd Edition, Intercept Publications, Ltd., Editions TEC & DOC Paris, 1999.
13. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals, P. K. Mukherjee, Business Horizons Pharmaceutical Publishers; 2002

14. The Practical Evaluation of Phytopharmaceutics,K. R. Brain and R. D. Turner, Wrigth-Scientechnics, Bristol.

15. Plant Drug Analysis: A Thin Layer Chromatography Atlas, H. Wagner, S Bladt, Springer, New York, 2nd Edition, 2007.

16. Thin Layer Chromatography – A Laboratory Hand Book, E. Stahl, Springer (I) Pvt. Ltd., 2nd Edition, 2007.

17. WHO Publication.

18. The Wealth of India (Raw Material & Industrial Product), Council of Scientific Research, New Delhi, 1st Edition, 2005.

19. Indian Medicinal Plants, Kirtikar and Basu, 1st Edition, volume I to IV International Book Distributors, Dehradun, 1999.

20. The Ayurvedic Pharmacopoeia of India, Part I, (Vol. I–V) , part II (I & II) Govt. of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, New Delhi 2008.

21. The Ayurvedic Formulary of India, Vol. I, II and III, Published by Government of India, New Delhi, 1st Edition, 2000.

22. Indian Herbal Pharmacopoeia, 1st revised Edition, Published by RRL, Jammu and IDMA, Mumbai, 2002.

23. Quality Standards of Indian Medicinal Plants, Volume I to XI (2003 to 2013) Editor: Neeraj Tandon & Parul Sharma; By: Medicinal Plant Unit, ICMR, New Delhi.

24. Clark, E.C.G., Isolation and Identification of Drugs, The Pharmaceutics Press, London, 2nd Edition, 1986.

25. Laboratory Handbook for the fractionation of Natutal extracts, Peter Houghton and Amala Raman, Chapman & Hall, Madras, 1st Edition, 1998.

26. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association, 4th Edition, 1996.

27. Phytochemical reference standards of selected Indian Medicinal Plants, Vol I & II (2010 to 2012) Editor: Neeraj Tandon & Parul Sharma By: Indian Council of Medical Research, New Delhi.

28. Compendium of Indian Medicinal Plant Vol. 1 to 6, by Rastogi Ram P., Mehrotra B. N., CDRI & NISCOM, 1st Edition, New Delhi, 1998.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Computer Applications in drug discovery
Subject Code: 2280006

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr. No	Course Content	Total
1.	Introduction A. Introduction to drug discovery concept / process and importance of drug design approaches in drug discovery. Various approaches to drug discovery B. Ligand Databases for Computer-Aided Drug Design 1. Preparation of Ligand Libraries for Computer-Aided Drug Design. 2. Representation of Small Molecules as "SMILES". 3. Small Molecule Representations for Modern Search Engines: InChIKey. C. Target Data Bases for Computer-Aided Drug Discovery/Design	**2** **4** **2**
2.	Structure-Based Computer-Aided Drug Design (SBDD) A. Preparation of a Target Structure 1. Comparative Modeling. Template identification and alignment.; Model building.; Model refinement and evaluation.; Model data bases. 2. Binding Site Detection and Characterization. Geometric method.; Energy-based approaches ; Pocket matching; Molecular dynamics-based detection. B. Representing Small Molecules and Target Protein for Docking Simulations C. Sampling Algorithms for Protein-Ligand Docking Systematic Methods : Molecular Dynamics Simulations; Monte Carlo Search with Metropolis Criterion ; Genetic Algorithms; Incorporating Target Flexibility in Docking. D. Scoring Functions for Evaluation Protein-Ligand Complexes Force-Field or Molecular Mechanics-Based Scoring Functions; Empirical Scoring Functions; Knowledge-Based Scoring Function; Consensus-Scoring Functions. E. Structure-Based Virtual High-Throughput Screening F. Atomic-Detail/High-Resolution Docking G. Binding Site Characterization H. Pharmacophore Model Virtual Screening Using a Pharmacophore Model; Multitarget Inhibitors Using Common Pharmacophore Models; Dynamic Pharmacophore Models That Account for Protein Flexibility.	**2** **2** **2** **4** **3** **2** **1** **1** **3**

3	Ligand-Based Computer-Aided Drug Design A. Molecular Descriptors/Features Functional Groups. Prediction of Psychochemical Properties : Electronegativity and partial charge; Polarizability; Octanol/water partition coefficient. Converting Properties into Descriptors; Binary molecular fingerprints; 2D description of molecular constitution; 3D Description of molecular configuration and conformation. B. Quantitative Structure-Activity Relationship Models Multidimensional QSAR: 4D and 5D Descriptors; Receptor-Dependent 3D/4D-QSAR; Linear Regression and Related Methods; Quantitative Structure-Activity Relationship Application in Ligand-Based Computer-Aided Drug Design. C. Selection of Optimal Descriptors/Features D. Pharmacophore Mapping Superimposing Active Compounds to Create a Pharmacophore Pharmacophore Feature Extraction; Pharmacophore Algorithms and Software Packages	**4** **2** **2** **3**
4	Prediction and Optimization of Drug Metabolism and Pharmacokinetics Properties Including Absorption, Distribution, Metabolism, Excretion, and the Potential for Toxicity Properties Compound Library Filters; Lead Improvement: Metabolism and Distribution; Prediction of Human Ether-a-go-go related Gene Binding; Drug Metabolism and Pharmacokinetics/Absorption, Distribution, Metabolism, and Excretion and the Potential for Toxicity Prediction Software Packages and Algorithms.	**6**

References Books:

1. H. Smith & H. J. William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
2. Burger Medicinal Chemistry – The Basis of Medicinal Chemistry by Manfred S. Wolff, Part – I, John Wiley & Sons.
3. W. O. Foye – Principals of Medicinal Chemistry, Lipincott Williams and Wilkins.
4. C. Hansch and Leo – Comprehensive Medicinal Chemistry Vol. 4, Pergamon Press.
5. E. H. Kerns and L. Di – Drug like properties, concepts, structure design and methods, Academic Press.
6. Molecular Modeling in Drug Design by Cohen N. C.
7. D. C. Young – Computational Drug Design, John Wiley & Sons, Inc.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Pharmacy Practice
Subject Code: 2280007

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Introduction to daily activities of a clinical/ community/ hospital pharmacist	**1**
2	Prescription processing: Accurate interpretation of prescription orders, Appropriateness of medication choice, dosage form, dosage, route of administration, regimen and duration of therapy, Review drug-drug/ food interaction and drug allergies Compliance issues (adherence) and financial consideration	**5**
3	Medication review: 3 Significance, components, collection and interpretation of patient-specific information, assessment of therapeutic goals, and identification of drug related problems, clinical progress review	**3**
4	Drug utilisation evaluation (DUE) : Definition, objectives, DUE cycle, types of DUE, Role of pharmacist in DUE	**2**
5	Communication skills: Dialogue and interview techniques, verbal and nonverbal listening, probing and gathering information	**2**
6	Participation in ward round Goals and objectives, ward rounds-the Indian scenario, pre-ward round preparation, intervention and communication during ward round, ward round follow-up	**2**
7	Patient counselling: Patient counselling on self diagnostic/monitoring tools: Home blood glucose monitor, blood pressure monitoring and home pregnancy test kits Patient counselling on OTC medications: Patient counselling on prescription medications: Direction for proper use of medicine Duration of therapy and onset of action Management of common adverse effects, interaction and missed doses Storage and handling requirements Patient counselling to promote adherence to regimens and therapy: Strategies to optimize adherence, identification of under-utilization and over-utilization of medications	**4**

8	Drug information: Selection of suitable drug information resources: Primary, secondary and tertiary resources, Journals, Cochrane collaborative library, Medline, Answering drug information questions	**3**
9	Medication and patient safety practices: Essential Drugs concept and Rational Drug Therapy Development of Therapeutic guidelines; Meaning, need for guideline, development, evidences for effectiveness and limitations of guideline Therapeutic guidelines for management of various diseases (Asthma, Hypertension, Tuberculosis) Dispensing errors Prescription Audit Pharmacovigilance- adverse drug reaction monitoring and reporting	**10**
10	Promotion of healthy life style and preventive health (immunization and tobacco, alcohol cessation etc.)	**2**
11	Paediatric pharmacy practice: Dose calculation, pharmacokinetic aspects of drug therapy, therapeutic drug monitoring in paediatrics	**2**
12	Geriatrics pharmacy practice: Precaution in medication, pharmacokinetic and dynamic changes with ageing, common problems in the elderly and role of clinical pharmacist	**2**
13	Pharmacy practice in pregnant and lactating women: Estimation of risks during pregnancy and lactation, dietary supplements requirement, pharmacokinetic and dynamic aspects, discontinuation of medications associated with withdrawal	**3**
14	Inventory control: Purchasing, Pricing, Outdated medications, Return to wholesaler and Return to stock/Returns from patients	**2**
15	Quality assurance of pharmacy services	**2**

Recommended 7 days (2hr/day) visit to multi specialities hospital to understand concept of pharmacy practice

Pharmacy practice teaching shall be accomplished by relevant case studies
Reference Books:

1. A textbook of Clinical pharmacy practice- Parthasarthi G., 2nd edition-2012.
2. Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh, 3rd edition-2006.
3. Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.
4. Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley, 7th edition.
5. Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, 17th edition, Eugene & Others.
6. Melmon and Morrells Clinical Pharmacology, 4th Edition – S George Carrythers.
7. Clinical Pharmacology- P.N. Bennett, M. J. Brown, 9th edition-2003.
8. A text book of clinical pharmacology and therapeutics- James M. Ritter, Lionel D. Lewis- 5th edition-2008.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Bioavailability and Therapeatic Drug Monitoring
Subject Code: 2280008

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Relative and absolute bioavailability, bioequivalence, first pass clearance, Objectives of BA studies	**2**
2	Rate and extent of absorption, Factors affecting bioavailability(physicochemical and formulation related)	**2**
3	Methods and parameters of assessing bioavailability, Determination of AUC, Pharmacodynamic and pharmacokinetic models, Invitro dissolution and Bioavailability, Theories of dissolution, Invivo - invitro correlation studies, Techniques for enhancing Bioavailability	**6**
4	Study designs and analysis of BA-BE studies (protocol preparation of BA-BE studies as per CDSCO , Schedule Y guidelines, GCP guidelines)	**4**
5	TDM- introduction and definition, Recommendations and uses of TDM, Target drug ranges for TDM	**2**
6	Collection and storage of samples of body fluids, Sample preparation (Extraction, de-proteinization), Problems of interference of biological matrix	**4**
7	Criteria for selection of method for TDM : Physicochemical parameters of drug and sample related parameters	**3**
8	Techniques used in TDM: **Physical methods** HPLC, HPTLC, GC: Sensitivity and selectivity of detection with respect to applications for TDM and related pharmacoeconomics. **Immunoassays** RIA, ELISA, FPIA, EMITH, NIIA: Sensitivity and selectivity of detection with respect to applications for TDM and related pharmacoeconomics	**9**
9	TDM of specific drugs- digoxin, gentamicin, lidocaine, lithium, theophylline, phenytoin, phenobarbitone, carbamazepine, valproic acid, addictive drugs, immunosuppressants Study of clinical pharmacokinetics, general guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reactions and drug interactions, techniques used for estimation, importance, interpretation of results of above mentioned drugs	**12**

10	Role of clinical pharmacist in TDM	**1**

Reference Books:

1. Michael Makoid, Philip Vuchetich, Umesh Banakar. Basic Pharmacokinetics. First edition. Pkinbook.
2. L. Shargel, and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT, 1993.
3. Shargel Leon and Alan Mutnick. Comprehensive Pharmacy Review. Wolters Kluwer/Lippincott Williams and Wilkins, 2007.
4. Atkinsons Arthur. Principles of Clinical Pharmacology. 3rd edition. Academic Press. 2012.
5. Parthsarathi G, Karin Nyfort-Hansen, Milap Nahata. A textbook of Clinical Pharmacy practice. 2nd edition. University Press.
6. Bauer L A. Applied Clinical Pharmacokinetics. Mc Graw Hill Professional.
7. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publications. 1993.
8. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, NY
9. M. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, 3rd edition. Lea & Febiger, Philadelphia.
10. P.G.Welling, F.L.S. Tse and S.V. Dighe (eds*) Pharmaceutical Bioequivalence*, Marcel Dekker Inc. New York, USA 1991.
11. Mike Hallworth, Nigel Kapps.Therapeutic Drug Monitoring and clinical biochemistry. ACB Venture. 1993.
12. Daniel Robinson, William J. Taylor. Simkin Handbook of Therapeutic Monitoring. 2nd edition. Harvey Whitney Books. 1993.
13. Evans WE, Schentag JJ and Jusko WJ. Applied pharmacokinetics, principles of therapeutic drug monitoring. 3rd edition. Applied therapeutics Inc.
14. B.Widdop. Therapeutic drug monitoring. Churchill Livingstone. 1985.
15. Irving Sunshine. Recent developments in TDM and clinical toxicology. Marcel Dekker. 1992.
16. Leonardo D. Azevedo Calderon. Chromatography- The most versatile method of chemical analysis. CC BY 3.0 license. © The Author(s)
17. Ganesh R. Naik. Applied biological Engineering . Principles and practice. InTech. 2012.
18. Michael Hallworth. Ian Watson. TDM Clinical guide. Abbott.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Food Analysis
Subject Code: 2280009

Teaching Scheme				Evaluation Scheme			
Theory	**Tutorial**	**Practical**	**Total**	**Theory**		**Practical**	
				External	**Internal**	**External**	**Internal**
3	0	0	3	80	20	0	0

Sr No	**Course Content**	**Teaching hrs**
1.	Introduction to Instrumentation Techniques;	
a.	Centrifuge techniques: Zonal, density, gradient and ultra-centrifugation techniques and their applications.	2
b.	Electrophoresis: zonal, paper, gel electrophoresis and isoelectric focusing and their application	**2**
c.	Spectroscopy: Basic concepts, Beer-Lambert law & brief description of colourimetry, UV–VIS, IR, NMR, fluorescence, mass spectroscopy, flame photometry and x-ray diffraction.	**4**
2.	Analysis of chemical constituents, their characterization and significance- moisture, ash, minerals, lipids, fat, proteins, fibre, starch, reducing sugars	**5**
3.	Analysis of vitamins, pigments, flavours, extraneous matter, pesticides and mycotoxins. Microscopic analysis of foods other methods- potentiometry, enzymatic, immunoassays, thermal analysis. Analysis of genetically modified foods	**8**
4.	Chromatographic methods for analysis of food and additives like TLC, HPTLC, GLC, HPLC, SFC and Flash chromatography.	**5**
5.	Legislation for food, the Food safety act, Food standards and nutrition, general chemical and instrumental methods for food analysis.	**4**
6.	Contaminants in food: contaminants in food material and food additives. Standards for food additives.	**4**
7.	Analysis of sugar, preservatives, starch products, beverages, chocolate, herbs, spices, cereals, oils and fats, dairy products.	**4**
8.	Detection of common adulterants, microbial contamination, toxic trace metals, pesticides and insect infestation in food products.	**4**
9	Stability studies of food products.	**3**

References Books:

1. Samuel A. Matz, The Chemistry and Technology of Cereals as Food and Feed, Medtech, Van Nostrand Reinhold/AVI, 115, Fifth Avenue, New York 10003, Ed: 2nd 2013
2. Bernard W. Minifie; Chocolate, Cocoa and Confectionery: Science and Technology, Van Nostrand Reinhold /AVI, 115, Fifth Avenue, New York 10003 Ed.3rd 1989.
3. Peter KV. Handbook of Herbs and Spices: Woodhead Publishing Ltd, 80 High Street, Cambridge, UK 2012
4. Deshpande SS, Handbook of Food Toxicology, Indus Therapeutic Inc. Heyderabad, India; Marcel Dekker, Inc., 270, Medisone Avenue, New York, NY 10016, 2002
5. Steven R. Tannenbaum, Nutritional and Safety Aspects of Food Processing, Marcel Dekker, Inc., New York, NY; 1979.
6. Green JH, and Kramer A,; Food Processing Waste Management. AVI Publishing Co., Westport, CT; 214 (1984).

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Hospital Management and Medical Tourism
Subject Code: 2280010

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Content	Teaching hrs
1.	History of hospital as an organization and its structure	
2.	Departments of a Hospital Outpatient department and front office • Nursing services • Radiology and Imaging services • Pathology and Clinical Laboratory services • Operation theatre services • ICU/ CCU/ NICU/ PICU • Cardiac Catheterization services • Emergency Medical Services • Blood Bank services • Surgical and Medical wards • Obstetric and Gynecologic wards and Labor room suite • Central Sterile Supply Department • Medicolegal Services • Laundry and Linen services • Housekeeping services • Biomedical waste disposal • Kitchen and Catering services • Medical Records Department • Accounts and Billing department	
3.	Health Administration in India	
4.	Illness and Infection Control Defining Illness: Direct and indirect causes -Classification and description of disease- Medical asepsis, Nosocomial infection and communicable diseases-Reservoir, carrier and mode of transmission-Infection control measures-Sterilisation and aseptic techniques Infection control committee: purpose, composition and terms of reference	
5.	Services, Health and Hospitals Services, Classification of Service Organisations, Characteristics, Challenges-History of Medicine, Healthcare Revolution, Health, Dimensions of Health, Indicators of Health- Types of Healthcare Organisations, Composition of Health Sector, Types of Care, Pyramidal Structure of Health Services, Hospitals, Types of Hospitals and Role of Hospital in Healthcare, Complexity of Hospital Organisation	
6.	Hospital Management: Levels and Roles Governing Board, Executive Board and Advisory Board- CEO, Medical Administration, Nursing Administration and Hospital Administration-Middle Level Managers in Hospital and their Responsibilities-Structuring Hospital Organisation	
7.	Current Issues in Healthcare Accreditation-Tele health-Health Tourism-Health Insurance and Managed Care-Disaster	
8.	Herbal Drug/Intellectual Property Rights (IPR).	

9.	Management-Hospital Wastes Management	

References Books:

1. S. Srinivasan (ed.), Management Process in Health Care (Voluntary Health Association of India, New Delhi)
2. C.M. Francis and et al., Hospital Administration (Jaypee Brothers Medical Publishers Pvt. Ltd., New Delhi)
3. Sana's Guidelines for Hospital Infection Control – By Mohd. S. Khan –Jaypee Brothers, New Delhi.
4. Hospital Waste Management & it's Monitoring – By Madhuri Sharma Jaypee Brothers, New Delhi.
5. Medical Stores Management – By Shakti Gupta & Sunil Kant – Jaypee Brothers, New Delhi.
6. Medical Records, Organisation & Management – By G.P. Mogli Jaypee Brothers, New Delhi.
7. Guidelines on Effective Hospital Administration- Dr. P.V.Bokil
8. Emergency Medical Services & Disaster Management – By D.K. Dave& Shakti Gupta – Jaypee Brothers, New Delhi.
9. Syed Amin Tabish, Hospital and Health services administration ~ principles and practice, *oxford* university press, New Delhi, 2001.
10. James A.F.Stoner, R.Edward Freeman and Denier R. Gilbert Jr., Management, Prentice Hall India, New Delhi, 1997.
11. Kountz Harold, Heinz Weihrich, Management - A global perspective, 19th edition, Mc Graw Hill International, New Delhi, 2005.
12. Srinivasan A.V. Japanese management - The Indian context, Tata Me Oraw Hill, New Delhi, 2000.
13. Koontz Harold, Heinz Weihrich, Essentials of management, Mc Oraw Hill Intenational, New Delhi, 2004.
14. L.M.Prasad, Principles and practice of Management, 6th edition, Sultan Chand Pilblisher, New Delhi, 2001.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Drug Approval Process
Subject Code: 2280011

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Content	Teaching hrs
1.	**Basics in drug approval process:** Various phases of drug development and approval including clinical and nonclinical development.	3
2.	**Overview on:** Orange book, Freedom of information, Inactive Ingredient Guide and Drug Master File.	7
3.	**Types of Approval:** INDA, NDA and ANDA. Content, format and application. Concept of para I to IV and generic exclusivity. Special emphasis on approval under 505 (b) (2).	10
4.	**Drug Approval in India:** Requirements and guidelines from CDSCO.	4
5.	**Drug Approval in Developed Countries and Rest of World (Row) markets:** Common Technical Document (CTD) and brief introduction to various regulatory agencies like USFDA, MCA, TGA, MHRA, ANVISA, WHO and ICH.	14
6.	**Scale Up and Post Approval Changes (SUPAC) guidance:** SUPAC-IR, MR and SS.	4
7.	**Approval of Biopharmaceuticals:** Difference from drug approval and concept of bio-similarity.	3

References Books:

1. The guidance documents shall be procured from the website of the respective government

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Intellectual Property Rights and Patents
Subject Code: 2280012

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Content	Teaching hrs
1.	Concept and definition of IPR	03
2.	Definition of patent, Types of Patents , The essential elements for innovation to be patentable	12
3.	Indian patent act 1970 and its all subsequent amendments, Non patentable invention as per Indian patent act	10
4.	Recent litigation and judgements related to pharmaceutical patents	08
5.	Concept and genesis of GATT and WTO	05
6.	Establishment of WIPO and its function	04
7.	TRIPS agreement and its impact on international trade	03

References Books:

1. W.R. Cornish, Intellectual Property, Sweet & Maxwell, London (2000)
2. Terrell On Patent, 2000
3. P. Narayana, Patent Law, Wadhwa Publication.
4. Merges, Patent Law and Policy: Cases and Materials, 1996
5. Brian C. Reid, A Practical Guide to Patent Law, 2nd Edition, 1993
6. Brinkhof (Edited), Patent Cases, Wolters Kluwer
7. Prof. Willem Hoyng & Frank Eijsvogels, Global Patent Litigation, Strategy and Practice, Wolters Kluwer
8. Feroz Ali Khader, The Law of Patents – with a special Focus on Pharmaceuticals in India, LexisNexis Butterworths Wadhwa, Nagpur.
9. N.S. Gopalakrishnan & T.G. Agitha, Principles of Intellectual Property (2009), Eastern Book Company, Lucknow

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Medical Writing and coding
Subject Code: 2280013

Teaching Scheme				Evaluation Scheme			
Theory	**Tutorial**	**Practical**	**Total**	**Theory**		**Practical**	
				External	**Internal**	**External**	**Internal**
3	0	0	3	80	20	0	0

Sr No	**Course Content**	**Teaching hrs**
1.	Introduction to Medical Coding	
2.	Introduction to Diagnosis Coding	
3.	Introduction to ICD-10-CM coding.(the International Classification of Diseases, Tenth Revision, Clinical Modification) ICD-10-CM Coding and Structure	
4.	Reimbursement	
5.	Introduction to Current Procedural Terminology (CPT) CPT Coding and Structure	
6.	Evaluation and Management (E/M) Coding	
7.	Surgery and Integumentary System Coding	
8	Anesthesia CPT Codes	
9	Cardiovascular, Respiratory, Musculoskeletal Systems	
10	Radiology and Pathology Coding	
11	Introduction to Documentation (Medical History) - Health Information Management and Documentation	
12	Medical Examination, Decision Making, Selecting the Correct Code	
13	Issues with Fraud and Abuse	

References Books:

1. International statistical classification of diseases and related health problems. - 10th revision, edition 2010. World Health Organization, ISBN 978 92 4 154834 2.
2. Carol J. Buck, Workbook for Step-By-Step Medical Coding, 2015 Edition, Elsevier - Health Sciences Division. ISBN 9780323279802.
3. BarCharts Inc, Medical Coding: ICD-10-CM, ISBN 9781423218722.
4. American Medical Association, CPT 2014 Standard Edition (Current Procedural Terminology (Standard))1st Edition

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Commerce of herbs and Phytoconstitutents
Subject Code: 2280014

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Content	Teaching hrs
1.	Contribution of natural products in modern drug discovery: overview of drug molecules discovered from natural products; detailed study of following in drug discovery: vinca alkaloids, morphine, atropine, δ-tubocurarine, ephedrine, artemisinin, camplothecin, taxol, curcumin, diosgenin, papain etc.	**5**
2.	World-wide trade in medicinal plants: withania, senna, liquorice, echinacea, ginseng, aloe, ipecac, boswellia, guggulu etc	**5**
3.	Industrially important aromatic plants and their derived products.	**5**
4.	Herbal Drug Trade: WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Geneva; WHO guidelines on good manufacturing practices for the manufacture of herbal medicines; International trade, drug registration for export import.	**5**
5.	Production, supply and distribution.	**5**
6.	Wild harvesting, cultivated material.	**5**
7.	Constraints to the development of trade.	**5**
8.	Herbal Drug/Intellectual Property Rights (IPR).	**5**
9.	Medicinal plant based industries in indigenous system of medicine (ISM), standardization.	**5**

References Books:

1. Atal CK and Kapoor LD; CSIR, 1982, Cultivation and utilization of Medicinal plants.
2. Handa SS, 1996, CSIR, Supplement to cultivation and utilization of Medicinal plants.
3. Atal CK and Kapoor LD, CSIR, 1982, Cultivation and utilization of Aromatic plants.

4. Handa SS and Kaul CL; CSIR, 1998, Supplement to cultivation and utilization of Aromatic plants.
5. Chaudhary RD, Herbal Drug Industry, Eastern Publications, New Delhi.

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Genetic engineering and gene therapy
Subject Code: 2280015

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Content	Teaching hrs
1.	Introduction to genetic engineering, basis of genetic engineering (gene organization, gene expression, genes and genomes)	2
2.	Isolation of DNA and RNA, handling and quantification of nucleic acids, Radiolabelling of nucleic acids, nucleic acid hybridisation, gel electrophoresis, DNA sequencing	5
3.	Types and uses of - Restriction enzymes, DNA modifying enzymes, DNA ligases	2
4.	Host cells and vectors (Host cell types, Plasmid vectors, bacteriophage vectors, vectors for use in eukaryotic cells, DNA delivery methods (transformation, transfection, packaging phase DNA invitro))	6
5.	Cloning strategies (cloning from mRNA, cloning from genomic DNA, advanced cloning strategies)	3
6.	Polymerase chain reaction ((methodology- features of PCR, primer designing and DNA polymerases for PCR) ,PCR techniques, processing of PCR products and applications of PCR)	5
7.	Genetic selection (use of chromogenic substrates), screening method (immunological screening for expressed genes), analysis of cloned genes (blotting techniques and DNA sequencing)	3
8.	Applications of ribozymes, antisense-oligonucleotide based therapy	3
9.	Genetic engineering and biotechnology products (proteins, enzymes, therapeutic products, DNA vaccines (against cancer and viruses))	3
10.	Applications of gene manipulation: diagnosis and characterization of medical conditions, treatment using rDNA technology , DNA profiling, Transgenic plants, Transgenic animal models (including knock out models)	4
11	Gene therapy for hematopoietic disorders, cardiovascular diseases, respiratory conditions, cancer, neurological diseases, inborn errors of metabolism, HIV infection, skin and systemic disorders, childhood onset blindness, immunodeficiencies, pain management	9

References Books:

1. Gene and cell therapy. Nancy Smyth Templeton. Marcel Dekker Inc. 2004.
2. Gene therapy- tools and potential applications. Francisco Martin Molina. Intech publications. 2013.
3. Nicholl Desmond ST, "An Introduction to Genetic Engineering" Cambridge University Press, 2002.
4. Concepts of genetics- William S Klug. Macmillan 1994.
5. Emery's Elements of Medical Genetics- Peter D Turnpenny, Sian Ellard. Churchill Livingstone. 2007
6. Pharmaceutical biotechnology by O Kayser and R. H. Muller. Wiley – VCH Verlag GmbH & Co. KGaA.
7. Old RW and Primrose SB .Sixth edition, "Principles of gene manipulation ", BlackWell Scientific Publications, 2001.
8. Gene cloning and DNA analysis. T.A. Brown. 6th edition. Wiley Blackwell Publications.
9. Biotechnology – U. Satyanarayan

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm
SEMESTER: VIII

Subject Name: Current advances in Novel Drug Delivery Systems
Subject Code: 2280016

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
	Basics, polymers/excipients used, Formulation, Innovations, Evaluation of	
1.	Vesicular drug delivery system like liposomes, niosomes etc.	7
2.	Multi unit drug delivery systems like microspheres, microcapsules, pellets, beads, minitablets etc.	7
3.	Transdermal drug delivery systems, sonophoresis, iontophoresis	9
4.	Mucoadhesive films, patches, diskette, strips	5
5.	Nanoparticulate drug delivery system	7
6.	Self emulsifying drug delivery system	7
7.	In situ gels	3

References Books:

1. Lachman L., Liberman H. A., Kanig J. L., The theory and practise of industrial
2. pharmacy. 2nd Edition 1991, Varghese publishing house,
3. Remington:the science and practice of pharmacy.
4. James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Marcel Dekker.
5. G.S.Banker, Modern Pharmaceutics.
6. Robinson & Lee, Controlled Drug Delivery: Fundamentals and applications.
7. Y. W. Chein, Novel drug delivery systems.
8. N.K. Jain and others, Novel drug delivery system.
9. R. K. Khar and others, Novel drug delivery system.
10. Current updates/ articles available from web resources.

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm
SEMESTER: VIII

Subject Name: Elementary Mathematics
Subject Code: 2280017

Teaching Scheme				Evaluation Scheme			
Theory	**Tutorial**	**Practical**	**Total**	**Theory**		**Practical**	
				External	**Internal**	**External**	**Internal**
3	0	0	3	80	20	0	0

No.	Course Content	Hrs (45)
1.	Algebra: Equation reducible to quadratic, simultaneous (linear & quadratic), Determinants, properties of solution of simultaneous equations by Cramer's rule, matrices, definition of special kind of matrices, arithmetic operations on matrices, pharmaceutical applications of determinants & matrices, Evaluation of En1, En2 & En3 mensuration & its pharmaceutical applications.	8
2.	Measures of dispersion: Range, average deviation, standard deviation, probability & probability distribution.	6
3.	Permutation, combination, AP and GP	8
4.	Trigonometry: Measurement of angle, T-ratios, addition, subtraction & transformation formulae, Application of logarithm in pharmaceutical computation.	7
5.	Analytical plans geometry: Distance between two points in plane, areas of triangle, equation of straight line, slope of line, intercept of line, linear inequality for two variables.	8
6.	Calculus: Differential: Definition, standard derivative & use of standard derivative Integral: Difference batween differential & integral, standard integral, use of standard integral Differential equation: Order, degree, variable separable method, homogenous, linear differential equation, pharmaceutical applications on differential equation.	8

References Books:

1. Remedial Mathematics by Gupta & Prabhakar; Pragati Prakashan
2. Remedial Mathematics for Pharmacy by R.C.Kachot; Mahajan Prakashan
3. College Mathematics by Kai L. NILSON, Barnes & Noble inc.

Gujarat Technological University

Subject Codes/ Teaching/Evaluation Scheme for M. Pharm.

Semester I-(Revised from July-2012)

Branch Code	Branch Name/Specialization	Subject	Subject Code	Subject Name	Teaching Scheme		Evaluation Scheme			
					Credits		Theory		Practical	
					Theory	Practical	External	Internal	External	Internal
00	GENERAL	**Modern Analytical Techniques**	910001	Modern Analytical Techniques	6	6	80	20	80	20
01	Pharm. Chemistry	**Subject of specialization Paper I**	910101	Advance Organic Chemistry -	6	6	80	20	80	20
02	Pharmaceutical Tech. and Pharmaceutics		910102	Pharmaceutical Formulation Development & Biophamaceutics	6	6	80	20	80	20
03	Pharmacology		910103	Cellular and Molecular pharmacology	6	6	80	20	80	20
04	Qual. Assurance		910104	Biological Evaluations and Clinical Research	6	6	80	20	80	20
05	Pharmacognosy		910105	Chemistry of Medicinical Natural Products	6	6	80	20	80	20
06	Clinical Pharmacy		910106	Clinical Pharmacy Practice	6	6	80	20	80	20
07	Pharmaceutical Analysis		910107	Pharmaceutical Analysis-I	6	6	80	20	80	20
08	Pharmaceutics		910102	Pharmaceutical Formulation Development & Biophamaceutics	6	6	80	20	80	20
09	Pharmaceutical Quality Assurance		910104	Biological Evaluations and Clinical Research	6	6	80	20	80	20
10	Pharmaceutical Technology		910102	Pharmaceutical Formulation Development & Biophamaceutics	6	6	80	20	80	20
11	Pharmacology &Toxicology		910103	Cellular and Molecular pharmacology	6	6	80	20	80	20
12	Industrial Pharmacy		910108	Industrial Pharmacy-I	6	6	80	20	80	20
13	Quality Assurance Technique		910104	Biological Evaluations and Clinical Research	6	6	80	20	80	20
14	Medical Chemistry		910101	Advance Organic Chemistry - I	6	6	80	20	80	20
15	Quality Assurance and Pharm Regulatory Affairs		910104	Biological Evaluations and Clinical Research	6	6	80	20	80	20

16	Pharmaceutical Management and Regulatory Affairs		1911601	cGMP and Documentation	6	6	80	20	80	20
01	Pharm. Chemistry		910201	Chemistry of natural Products	6	0	80	20	-	-
02	Pharmaceutical Tech. and Pharmaceutics		910202	Industrial Pharmacy Practice	6	0	80	20	-	-
03	Pharmacology		910203	Advances in Pharmacology	6	0	80	20	-	-
04	Qual. Assurance		910204	Good manufacturing and Good Laboratory Practice	6	0	80	20	-	-
05	Pharmacognosy		910205	biotechnology and Cultivation of Medical Plants	6	0	80	20	-	-
06	Clinical Pharmacy		910206	Clinical and Hospital Pharmacy	6	0	80	20	-	-
07	Pharmaceutical Analysis-I		910207	Advanced Spectroscopic Techniques	6	0	80	20	-	-
08	Pharmaceutics	**Subject of Specialization Paper II**	910202	Industrial Pharmacy Practice	6	0	80	20	-	-
09	Pharmaceutical Quality Assurance		910204	Good manufacturing and Good Laboratory Practice	6	0	80	20	-	-
10	Pharmaceutical Technology		910202	Industrial Pharmacy Practice	6	0	80	20	-	-
11	Pharmacology &Toxicology		910203	Advances in Pharmacology	6	0	80	20	-	-
12	Industrial Pharmacy		910208	Industrial Pharmacy-II	6	0	80	20	-	-
13	Quality Assurance Technique		910204	Good manufacturing and Good Laboratory Practice	6	0	80	20	-	-
14	Medical Chemistry		910201	Chemistry of natural Products	6	0	80	20	-	-
15	Quality Assurance and Pharm Regulatory Affairs		1911502	Basic Concepts of Regulatory Affairs	6	0	80	20	-	-
16	Pharmaceutical Management and Regulatory Affairs		1911602	Pharm Management-1	6	0	80	20	-	-

Gujarat Technological University

M. Pharm.
Semester – I

Structure for First Semester of Master of Pharmacy Course

Sr. No.	Subject (Code No,)	Teaching scheme		
		Theory	Practical	Credits
1	Modern Analytical Techniuqe (910001)	6	6	12
2	Subject of Specialisation Paper – I (910101 to 910108)	6	6	12
3	Subject of Specialisation Paper – II (910201 to 910208)	6	--	6
	Total	**18**	**12**	**30**

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code 910001

MODERN ANALYTICAL TECHNIQUES

(Common to all disciplines)

Theory

(Four hours per week, 6 Credits)

Course Content: **Hours**

1. UV-VISIBLE SPECTROSCOPY: **05**

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward –Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra.

2. INFRARED SPECTROPHOTOMETRY: **05**

Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), near infra red Spectroscopy (NIR) -theory and applications.

3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: **07**

Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

4. MASS SPECTROMETRY: **07**

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), interpretation of spectra and applications in Pharmacy.

5. ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY:

Principle, instrumentation, interferences and applications in Pharmacy. **03**

6. X-RAY DIFFRACTION METHODS: **03**

Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

7. OPTICAL ROTARY DISPERSION: **03**

Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

8. THERMAL METHODS OF ANALYSIS: **04**

Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC). And Thermo Mechanical Analysis (TMA).

9. CHROMATOGRAPHIC TECHNIQUES: **15**

a) Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation.

b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC.

c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, and chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS: **03**

Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY: 03

Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT.

12. Reference standards source, preparation, characterization, usage, storage and records. **02**

MODERN ANALYTICAL TECHNIQUES

Practicals

(Four hours per week, 6 Credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
    a. Vitamins
    b. Oral antidiabetics
    c. NSAIDs
    d. Antimicrobials
    e. Antihistamines
    f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoieal compounds.
7. Experiments on Electrophoresis.
8. Experiments of Chromatography.
    (a) Thin Layer Chromatography.
    (b) Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
11. Any other relevant exercises based on theory.

Recommended books:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
5. Organic Spectroscopy – William Kemp, 3rd Edition.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th dition.
8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.
9. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
10. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
11. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
12. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer,Franklin Book

14. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
18. Clarke's Analysis of Drugs and Poisons, A.C.Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.

Gujarat Technological University
M. Pharm. Syllabus
Semester I

Paper code-910102

Subject: - Specialization Paper-I

Pharmaceutical Formulation, Development & Bio pharmaceutics

Theory
(Four hours per week, 6 Credits)

1. **Preformulation studies** **08**
   (a) Physical, Chemical and Pharmaceutical factors influencing formulation
   (b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties
   (c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form
   (d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.
   (e) Drug-excipient compatibility study
   (f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents).
   (g) Preformulation studies of Biotechnological derived products and reference guidelines.

2. **Solubilization and solubilized system** **08**
   (a) Theoretical aspects and applications.
   (b) Techniques for improvement in drug solubilization for development of various dosage forms.

3. **Dissolution study** **08**
   (a) Importance, objectives, equipments,
   (b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
   (c) Selection of dissolution media and conditions.
   (d) Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.

4. **Stability Study** **08**
   (a) Basic concept and objectives of stability study,
   (b) Order of reaction and their applications in predicting shelf life and half life of pharmaceutical formulations,
   (c) Importance of accelerated stability study,
   (d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.
   (e) Regulatory requirements related to stability testing with emphasis on matrixing / bracketting techniques, climates zone, impurities in stability study, photostability testing etc.,
   (f) Applications of microcalorimetry in stability study.

5. **Drug Absorption** **08**
   (a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.

(b) Method of studying bioavailability and bioequivalence.
(c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

6. Pharmacokinetic parameters **08**

(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.
(b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.

7. In-vitro In-vivo Correlation (IVIVC) **06**

(a) Methods of establishing IVIVC
(b) Factors affecting IVIVC

8. Cosmetic, Dental and Herbal products **06**

(a) Formulation and evaluation of various cosmetic and dental products
(b) Formulation and evaluation of products containing herbal ingredients.

Reference Books:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman "**The theory and Practice of Industrial Pharmacy" 3rd edition.
3. Pharmaceutics "The Science of Dosage form design" **by Aulton**
4. Pharmaceutical dispensing **by Husa**.
5. Modern pharmaceutics **by G. S. Banker.**
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing **by Banaker.**
8. United States Pharmacopeia.
9. Techniques of Solubilization of Drugs **by Yalkowsky.**
10. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
11. Stability of drug and dosage forms **by Yoskioka.**
12. Applied Biopharmaceutics and pharmacokinetics by **Leon Shargel**, 4th edition.
13. Pharmacokinetics **by Welling and Tse.**
14. Pharmacokinetics **by Gibaldi and Perrier**
15. Biopharmmaceutics and pharmacokinetics: An introduction **by Notari.**
16. Pharmacokinetics for pharmaceutical scientist **by John Wagner.**
17. Dissolution, Bioavailability and Bioequivalence **by Abdul.**
18. Clinical Pharmacokinetics, Concepts and applications **by Rowland and Tozer.**
19. Novel Cosmetic Drug Delivery Systems, **by Magdassi and Touitou.**
20. Cosmetics **by Sagerin.**
21. Perfumes, Cosmetics and Soaps **by Poucher.**

Pharmaceutical Formulation, Development & Bio pharmaceutics Practical

(Four hours per week, 6 Credits)

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. Direct Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.

10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating (Dip Coating)
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.

Gujarat Technological University
M. Pharm. Syllabus
Semester I

Paper code-910202

Subject: - Specialization Paper-II
Industrial Pharmacy

Theory

Four hours per week, 6 Credits

Course Content:

1. Pharmaceutical factory location: Selection, layout and planning.
2. Utility services, Service facilities, HVAC and personnel facilities.
3. Preparation of qualitative and quantitative departmental layout with equipments
4. Required for different dosage forms, solids, liquids, semisolids, sterile.
5. Detailed study of the equipments required in the manufacture of different dosage
6. Forms as per Schedule-M.
7. Preparation of documents like batch manufacturing record, batch packing record,
8. Validation protocols.
9. Preparation of standard operative procedure (SOPs) for equipments
10. And manufacturing or processing steps.
11. GMP and its implementation
12. Production planning and materials control.
13. Pilot plant, scale up technique.

Reference Books:

1. **Lachman** "The theory and Practice of Industrial Pharmacy
2. **Remingtons** "Pharmaceutical Sciences"
3. Bentley's **Pharmaceutics.**
4. Pilot plants model and scale-up methods**, by Johnstone and Thring.**
5. GMP practices for pharmaceutical –**James Swarbrick.**
6. How to practice GMP**s by P.P.Sharma.**
7. Chemical Engineering Plant Design **by Vibrant.**
8. Pharmaceutical Process Validation **by Loftus and Nash.**
9. Drug and Cosmetic Act 1940 and rules.

Gujarat Technological University
M. Pharm. Syllabus
Semester I

910103: Subject of Specialization Paper- I

Cellular and Molecular Pharmacology

Theory

(Four hours per week, 6 Credits)

Course Content:

Hours

1. Molecular structure of biological membrane and, transport mechanism across the cell membrane **03**
2. Molecular biology of receptor system: structure, receptor pharmacology, signal transduction mechanism and termination of receptor activity, regulation of receptor, their involvement in various biological processes including diseases resulting from receptor malfunction and their role in pharmaco-therapeutics. Radio ligand binding studies. Theories of drug receptor interaction. Dose response relationship, potency and efficacy and different types of antagonisms **15**
3. Classification of cholinergic and adrenergic receptors, their signal transduction mechanism, agonists and antagonists **04**
4. NMDA, GABA, Glycine, Serotonin, , Dopamine, Histamine and Endothelin (ET) receptors, their classification, signal transduction mechanism, agonists and antagonists **10**
5. Pharmacology of sodium, calcium and potassium channels and their modulators **05**
6. The role of nitric oxide in various physiological functions and its importance in pharmacotherapy of disorders like hypertension, angina and erectile dysfunction. **04**
7. Pharmacology of purines and peptides. **03**
8. Role of Cytokines, Prostaglandins, TNF-α, Bradykinins, Leucotrienes, PAF, Interferons and Adhesion molecules in various immunological and inflammatory disorders. **06**
9. Cellular and molecular pharmacology of apoptosis and necrosis, stress induced expression of genes and their role in neurochemistry of aging and anti-aging drugs. (With special emphasis on CNS) **07**

10. Gene therapy **03**

910103: Cellular and Molecular Pharmacology
Practical

Four hours per week, 6 Credits

1. Introduction to experimental animals, ethics in pharmacological experiments, CPCSEA Guidelines
2. Methods for euthanasia, anesthesia, dosing (i.v., oral, i.p., s.c., i.m.) and blood collection by various techniques
3. To study the effects of various agonists (pD_2) and antagonist (pA_2) using isolated preparations (rat ileum, guinea pig ileum, rat fundus strip, rat anococcygeus muscle, rat vas deference, rat uterus, guinea pig taenia coli, rat/guinea pig heart, guinea pig tracheal chain, rat aortic strip)

4. To study the effects of calcium channel blockers on responses of various agonists on rat/guinea pig ileum
5. To study the effect of various drugs on rat blood pressure by invasive/non invasive techniques

Reference Books:

1. Pharmacological Basis of Therapeutics-Goodman and Gilman
2. Pharmacology-Rang and Dale
3. Basic and Clinical Pharmacology – Bertam G. Katzung
4. Principles of Pharmacology – Paul L. Munson
5. Lewis's Pharmacology – James Crossland – Churchil Livingstone
6. Review of Medical Physiology – Ganong William F.
7. Fundamentals of Experimental Pharmacology- Ghosh M.N.
8. Basic and Clinical Immunology- Peakman, Mark
9. Handbook of Experimental Pharmacology- Goyal R.K.
10. Handbook of Experimental Pharmacology- Kulkarni S.K.
11. Pharmacology and Toxicology- Kale S.R.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
910203 : Subject of Specialization Paper- II
Advances in Pharmacology
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

Recent advances in pharmacology of the following:

1. **Drugs acting on the peripheral nervous system**: Sympathomimetics, Sympatholytics, Parasympathomimetics, Parasympatholytics, Ganglion blockers & Stimulants, Neuromuscular blockers. **15**
2. **Autacoids** : Eicosanoids, Polypeptides, Histamine, 5-HT **07**
3. **Antimicrobial and Antineoplastic agents** : Introduction to infectious disease, general Principles of Chemotherapy and management of infectious disease, Sulphonamides & Co-trimoxazole, Penicillins, Cephalosporins, Macrolide antibiotics, Aminoglycosides, Quinolones, Tetracycline & Chloramphanicol, Chemotherapy of Tuberculosis & Leprosy, Antifungal agents, Anti-viral agents, Anti-protozoal agents, Anthelmintics, Chemotherapy of Sexually Transmitted Disease (STD), Types of cancers ,their management with Anti- Cancer agents and radiation therapy. **30**
4. **Immunopharmacological agents:**
   Immunostimulants, Immunosuppressant **08**

Reference Books:

1. Pharmacological basis of Therapeutics-Goodman and Gilman
2. Pharmacology-Rang and Dale
3. Principles of Pharmacology – Paul L. Munson
4. Lewis's Pharmacology – James Crossland – Churchil Livingstone
5. Modern Pharmacology with clinical applications- Craig, Charles R.
6. Lippincott's illustrated reviews of Pharmacology- Mycek Mary J.
7. Goth's Medical Pharmacology- Wesley G. Clark
8. Principles of pharmacology.--H. L. Sharma
9. Essentials of medical pharmacology --K. D. Tripathi

Gujarat Technological University
M. Pharm. Syllabus
Semester I
910101 : Subject of Specialization Paper – I
Advanced Organic Chemistry – I

Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. Chemical Bonding and Structure: **06**
Chemical Bonding, Bond Energies, Orbital Theory, Orbital Hybridization, Resonance, Electronegativity, Polarity, Hyperconjugation.

2. Chemical Reactivity and Molecular Structure **06**
Kinetics, Stearic, Inductive and electrostatic effect on reactivity, Acids and Bases.

3. Various Reaction Mechanisms

a. **Substitution Reaction:** Nucleophilic substitution reaction in aliphatic systems, SN1, SN2 reactions, Hydride transfer reaction, Cram's rule, Participation of neighbouring group in nucleophilic substitution reaction and rearrangements.

   Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, Reactivity, orientation in electrophilic substitution. **12**

b. **Elimination Reaction:** Beta Elimination reactions, E1, E2 and E1cb mechanisms, Hoffman and saytzeff's rule for elimination. **06**

c. **Addition Reaction:** Electrophilic and Nucleophilic additions, Stereochemiistry involved, Markonikov's rule. **03**

d. **Rearrangement Reactions:** Transannular rearrangement, Pinacol rearrangements, Beckman rearrangement, Hofmann rearrangement. **05**

e. **Free Radical Reaction:** Formation, Detection, Reactions, Homolysis and free radical displacements, addition and rearrangements of free radicals. **04**

4. Reactions of carboxylic acids and esters
BAC2, AAc2, BAL2, BAL1, AAL1, Claisen condensation, decarboxylation, carbanions, enolisation, keto-enol equilibria **08**

5. Y-lides: Introduction, generation and reactions involving phosphorus, sulphur and nitrogen y-lides. **05**

6. Photochemistry: Theory, energy transfer, characteristics of photoreactions, typical photochemical reactions **05**

910101: Advanced Organic Chemistry – I

Practical

(Four hours per week, 6 Credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

Reference Books:

1. Advanced Organic Chemistry – Reaction, Mechanism and Structure – J. March, John Wiley & Sons, New York.
2. Advanced Organic Chemistry Part – A & B – F. A. Carey & R. J. Sundberg, Kluwer Academic / Plenum Publishers, New York.
3. Organic Chemistry, Clayden, Greeves, Waren and Wothers, Oxford University Press, New York.
4. Organic Chemistry, G. Marc Loudon, Oxford University Press., New York.
5. Organic Synthesis, Collective Volumes, Ed. W. E. Noland, John Wiley & Sons, New York.
6. Strategic Application of named reaction in organic synthesis by Laszlo Kurti & Barbara Czako, Elsevier Academic Press.
7. Vogel's textbook of practical organic chemistry, Pearson Education Ltd.
8. "Experimental Organic Chemistry" L. M. Harwood, L. J. Moody, J. M. Percy, Blackwell Science.
9. Techniques and Experiment of Organic Chemistry, Addison Ault, University Science Books.
10. Introduction to Organic Laboratory Techniques, A Microscale Approach, Donald L. Pavia, Gary M. Lampman, George S. Kriz, Harcourt College Pub.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
910201: Chemistry of Natural Products

Theory
Four hours per week, 6 Credits

Course Content: Hours

1. Carbohydrates: 10
Brief introduction, Configuration of monosaccharids, ring structure of monosaccharides, disaccharides – determination of structures of sucrose, maltose and lactose, Polysaccharides – cellulose and starch, Introduction to pectin and pectic substances

2. Amino acids and polypeptides: 12
Introduction, classification, synthesis of amino acids, protein classification, Synthesis of naturally occurring proteins, structure of polypeptides, amino and carboxyl end degradation, polypeptide synthesis, composition, structure and chemistry of oxytocin, insulin and angiotensin, peptides of medicinal importance.

3. Alkaloids: 08
Classification, general methods of degradation and structure determination, morphine, ergotamine, reserpine, colchicine, vinca and podophyllum alkaloids.

4. Steroids: 08
Stereochemistry, conformational studies of steroidal nucleus, chemistry of cholesterol, stereochemistry of side chain at C-17, cholic acid, vit. D_3, cortisone, aldosterone.

5. Anthocyanins: 05
Introduction, general nature, synthesis, structure of anthocyanidin, flavones, isoflavones and depsides.

6. Purines and nucleic acids 03

7. Heterocyclic Chemistry 14
Introduction, nomenclature, properties, synthesis and reactions involved in five and six member heterocycles. Heterocycles with one, two or more than two hetero atoms, biological importance of heterocles.

Reference Books:

1. Organic Chemistry, Vol. I & II by Finar, Pearson Education.
2. Organic Chemistry, R. T. Morrison, R. N. Boyd, Prentice-Hall of India Pvt. Ltd., New Delhi.
3. Organic Chemistry, G. Marc Loudon, Oxford University Press., New York.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code:910104
QUALITY ASSURANCE SPECIALISATION
Biological Evaluations and Clinical Research

Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. **Biological Standardization:** General Principles, Scope & limitations of Bioassays. Bio-assays of some Official Drugs. **04**
2. **Sterility Tests:** Methodology & Interpretation. **04**
3. **Pyrogen -** chemistry and properties of bacterial pyrogens and endotoxins. Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests. **05**

4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. **05**

5. **Microbiological Limit Tests,** Tests for effectiveness of antimicrobial preservatives. **06**
6. **Radio immunoassay:** General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc. **04**
7. Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 & ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity and mutagenicity. **07**
8. **Clinical Research—**
   a. Clinical Research Protocols, objective and protocol design.
   b. Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study.
   c. Good Clinical Practices. **10**
9. **Bioavailability:-** Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems. **07**
10. **Pharmacokinetics:-** Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems. **08**

BIOLOGICAL EVALUATION AND CLINICAL RESEARCH
Practical

(Four hours per week, 6 Credits)

1. Bio-analytical method development and its validation.
2. Analysis of biological fluids.

3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. Any other relevant exercises based on theory.

Reference Books:

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. Bengt Ljunggvist and Berit Davis “Microbiological Risk Assessment in Pharm. Clean rooms”. Harwood International Publishing.
5. Richard Prince, “Microbiology in Pharmaceutical Manufacturing”. Davis Harwood International Publishing.
6. Akers, “Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing,” 2nd Edition (Marcel Dekker).
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi..
8. Mark C. Rogge and David R Taft, “Prclinical Drug Development”, Drugs and Pharm. Sci. Series, Vol. 152, Marcel D
9. ekker Inc., N.Y.
11. Donald Monkhouse, Charles Carney and JimClark, “Drug Products For Clinical Trials”. 2nd Ed. v Drugs and Pharm. Sci. Series, Vol. 147, 2nd Ed., Marcel Dekker Inc., N.Y.
12. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
13. Welling and Tse.-Pharmacokinetic
14. Gibaldi and Perrier-Pharmacokinetics
15. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
16. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
17. Notari.-Biopharmaceutics and Pharmacokinetics-An introduction.
18. John Wagner- Pharmacokinetics for Pharmaceutical scientist.
19. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910204
QUALITY ASSURANCE SPECIALISATION
Good Manufacturing and Good Laboratory Practice
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. Concepts of Philosophy of QA, GMP, GLP **03**
2. Good Manufacturing Practices: I
   a. Organization & Personnel, responsibilities, training, hygiene. **03**
   b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination. **04**
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP). **04**
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms. **02**
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities. **08**
   f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc. **05**
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials. **02**
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities. **06**
   i. Finished product release, quality review, quality audits and batch release documents. **03**
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management. **02**
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing. **02**
   l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents. **02**
   m. Waste disposal, scrap disposal procedures and records. **02**
3. Good Laboratory Practices. **04**
4. WHO certification. **02**
5. Testing of Packaging materials. **02**
6. Quality Audit. **02**
7. Specifications for materials, intermediates and finished product. **02**

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.

2. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 135, 4th Ed., Marcel Dekker Inc., N.Y
3. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
4. P. P .Sharma “How to practice GMPs”, 3rd edition Vandana Publication.
5. P. P. Sharma “How to practice GLP” Vandana Publication.
6. S. Weinberg, “Good Laboratory Practice Regulation” Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
7. WHO’s “Drug” Bulletins.
8. Remingtons “Pharmaceutical Sciences”.
9. GMP practices for pharmaceutical-James Swarbrick.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910105
Chemistry of Medicinal Natural Products
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. **Study of different biogenetic pathways of therapeutically important Active constituents.** **15**
2. **Classification, Isolation, structure determination stereochemistry, biological activity of following categories of Naturally occurring components:** **30**
    a. Carbohydrates, Mono, di, oligo- and polysaccharides, Glycoproteins, lipoproteins and glycopeptidolipids.
    b. Lipids and autocoids
    c. Alkaloids: Camptothecin, Vincristine.
    d. Glycosides: Calanolides, Glycyrrhetinic acid,
    e. Resins: Podophyllotoxin.
    f. Terpenoids: Taxol
    g. Antibiotics: Gresiofulvin, Penicillin, Sterptomycin
3. **Advanced methods of extraction of plant metabolites.** **15**
4. **Immunoglobins from Natural source specifically from plants.** **08**

Chemistry of Medicinal Natural Products

Practical
(Four hours per week, 6 Credits)

Practical exercises based on the relevant topics mentioned in theory syllabus.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910205
Biotechnology and Cultivation of Medicinal Plants

Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1. Factors affecting quality of plant drugs, safe and economical methods for documentation and preservation of herbs and herbal products detection of common adulterants, microbial contamination, toxic trace metals, pesticides and insect infestation in whole and powdered drugs. **15**
2. Cultivation of *Taxus baccata, Ginseng, Artemisia annua*, *Boswelia serrata, Curcuma longa.* **08**
3. Importance of monographs of standards of medicinal plants and Their parts, comparative study of BHP, API, Chinese, Japanese Herbal Pharmacopoeia, European pharmacopeia, US formulary, WHO, EMEA and ESCOP guidelines for herbal medicinal products. **15**
4. Medicinal Plant Biotechnology. **08**
5. Plant tissue culture techniques: including types, media, methodology, micropropagation, hairy root culture, protoplast culture, biotransformation, immobilization, Role of elicitors, artificial seeds, transgenic plants and commercial applications. **12**
6. Phytomics and metabolomics **08**

Reference Books:

1. Recent progress in medicinal plants: Volumes-1 to 22.
2. Ramstad-Modern pharmaconosy
3. Herskowitz- Principles of Genetics
4. Stricknerger- Genetics
5. Hess-Plant Physiology
6. Kruse Patterson- Tissue culture methods and Applications
7. Handa SS and Kaul KS – Supplement to cultivation and utilization of medicinal plants
8. Wealth of India, raw materials
9. Atal & Kappor- Cultivation and utilization of medicinal plants.
10. Purthi JS- Major spices of India.
11. Alan T, Howard Dalton and Murray Mao-Young—Comprehensive Biotechnology, 'The Principles, application and regulation of biotechnology in Industry,agriculture and Medicine. Vol-1 to 4.
12. Pharmacognosy and Pharmacobiotechnology. Robbers JE, Speedie MK, Tyler VE. William and Wilkins, USA; 1996.
13. Medicinal Natural Products a biosynthetic Approach. Dewick PM. John Wiley and Sons, Torronto, 1998.
14. Chemistry of Natural products. Bhat SV, Nagasampagi BA, Meenakshi S. Narosa Publishing house, New Delhi, 2005.
15. Recent Progress in medicinal Plants. Volumes 1-25. Govil JN, Singh VK, Siddiqui NT. Studim press, LLC USA; 2007.
16. Pharmacodynamic basis of herbal medicines. Ebadi M, CRC press Washington; 2002.
17. Laboratory handbook for fractionation of Natural Products. Houghton PJ and Raman A. Chapman and Hall New York; 1998.

18. Pharmacognosy and Pharmacobiotechnology. Kar A. New Age International Pvt. Ltd.; New Delhi 2003.
19. Pharmacognosy and Phytochemistry of medicinal Plants. 2nd edition. Brunreton J. Intercept Ltd.; New York; 1999.
20. Quality Control, Herbal Drugs, An approach to evaluation of Botanicals. Dr. Pulok K. Mukherjee. Business Horizons Pharmaceutical Publishers; 2002.
21. Herbs of Choice, The Theraputic use of Phytomedicinals. Robbers JE, Tyler VE. Haworth Press Inc., USA; 2002.

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code 910106

CLINICAL PHARMACY SPECIALISATION

CLINICAL PHARMACY PRACTICE

Theory

(Four hours per week, 6 Credits)

Course Content:		**Hours**
1	**Definitions, development and scope of clinical pharmacy**	**02**
2	**Pharmaceutical care concept**	**02**
3	**Role of clinical Pharmacist in the health care system**	**02**
4	**Routine activities of clinical Pharmacist** a) Drug Therapy monitoring: Medication chart review, Clinical review, Pharmacist interventions. b) Ward round participation c) Recording of Medical History d) Adverse drug reaction monitoring e) Communication skills including patient counseling techniques f) Drug utilization evaluation and review	
5	**Quality assurance of clinical pharmacy services**	**02**
6	**Concept of essential drugs and rational drug usage**	**04**
7	**Self-medication and non-prescription drug usage**	**02**
8	**Prescription monitoring and medication errors**	**03**
9	**Patient Compliance**	**02**
10	**Interpretation of clinical laboratory tests** Hematological, liver function, renal function, thyroid function tests Tests associated with cardiac disorders Fluid and electrolyte balance Micorbiological culture sensitivity tests Pulmonary function tests	**08**
11	**Patient data analysis and Case presentation**	**02**
12	**Drug induced diseases**	**02**
13	**Drug interactions** Documentation and other methods for minimizing clinically relevant drug interactions	**05**
14	**Pharmacovigilance** Scope, definition and aims of pharmacovigilance Adverse drug reactions – Classification, mechanism, predisposing factors and causality assessment. Role of clinical pharmacist in Reporting, evaluation, monitoring, prevention and management of ADR	**07**
15	**Pharmacoeconomics** Definition, history, needs of pharmacoeconomic evaluations Outcome assessment and types of phamacoeconomic evaluations: cost-minimization, cost-benefit, cost-effectiveness, cost utility. Applications of pharmacoeconomics: case study	**07**
16	**Critical evaluation of biomedical literature**	**02**

CLINICAL PHARMACY PRACTICE
PRACTICAL
(Four hours per week, 6 Credits)

In order to gain practice in clinical setting, students have to undergo compulsory postings in clinical settings, utilizing prior understanding and knowledge attained in identifying and resolving the pharmaceutical care issues.

It is mandatory that each student has to complete and maintain a record of at least 15 case studies based on the following theory topics;
*Patient medication history interview
Case studies related to laboratory investigations (Haematological, Bio-chemical, Pathological and Diagnostic Tests)
Patient medication counseling
Pharmacoeconomics : case study
Pharmacovigilance : case study
Medication and administration record review
ADR/Medication error identification and documentation

Assignments

The students are required to submit a minimum of two written assignments selected from the topics given to them.

Reference Books:

1 Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002
2 Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
3 Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
4 Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
5 Practice Standards and Definitions – The Society of Hospital Pharmacists ofAustralia.
6 Basic Skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists Inc.
7 Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall Publication.
8 A textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G. Parthasarthi et al.
9 Australian drug information- Procedure manual. The Society of Hospital Pharmacists of Australia.
10 Textbook of Medical laboratory Technology. Praful B. Godkar, Darshan P.Godkar, Bhalani Publication House, Mumbai. 2nd edition.
11 Clinical Pharmacokinetics- Rowland Tozer, Williams and Wilkins Publication.
12 Pharmaceutical Statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker Inc.
13 Drug Interaction Facts, 2003. David S. Tatro.
14 Hand Book of Pharmacy Health Care. The Pharmaceutical Press
15 Manual of basis techniques for a health laboratory, 2nd edition, World Health Organization, Geneva.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910206

CLINICAL PHARMACY SPECIALISATION

CLINICAL AND HOSPITAL PHARMACY (THEORY ONLY)
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1 Pharamcoepidemiology **10**

Definition, Origin and evaluation of pharmacoepidemiology, aims and applications, need for pharmacoepidemiology.
Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement.
Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio.
Drug utilization review, surveys of drug use, case reports, case series, cross-sectional studies, cohort studies, case control studies, meta-analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

2 Clinical Pharmacokinetics and therapeutic drug monitoring **15**

Clinical Pharmacokinetics
Introduction to clinical pharmacokinetics
Normograms and tabulations in designing dosage regimen, conversion from intravenous to oral dosing, determination of dose and dosing interval, drug dosing in the elderly and pediatrics and obese patients.
Pharmacokinetic drug interactions, Inhibition and induction of drug metabolism, Inhibition of biliary excretion
Therapeutic drug monitoring
Introduction
Individualization of drug dosage regimen (variability – genetic, age and weight, disease, interacting drugs).
Indications for TDM, Protocol for TDM
Pharmacokinetic/Pharmacodynamic correlation in drug therapy
TDM of drugs use in the following disease conditions: cardiovascular disease, CNS conditions etc
Dosage adjustment in renal and hepatic disease
Renal impairment
Pharmacokinetic considerations
General approach for dosage adjustment in renal disease
Measurement of glomerular filtration rate and creatinine clearance
Effect of hepatic disease of pharmacokinetics

3 Clinical Toxicology **08**
General principles involved in the management of poisoning
Antidotes and their clinical applications
Supportive care in clinical toxicology

Gut decontamination
Elimination enhancement
Toxicokinetics

4 **Clinical symptoms and management of acute poisoning with the following agents:** **07**

Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids Opiate overdose, Antidepressants, Barbiturates and benzodiazepines, Alcohol: ethanol, methanol, Paracetamol and salicylates, Non steroidal anti-inflammatory drugs, Radiation poisoning

5 **Clinical symptoms and management of chronic poisoning with the following agents:** **05**

Heavy metals: Arsenic, lead, mercury, iron, copper
Food poisoning

HOSPITAL PHARMACY

6 **Hospital pharmacy – organization and management** **03**

Organisational structure – staff, infrastructure & work load statistics
Management of materials and finance
Roles & responsibilities of hospital pharmacist
The budget – Preparation and implementation

7 **Hospital drug policy** **02**

Pharmacy and therapeutic committee (PTC)
Hospital formulary
Hospital committees: Infection committee, Research and Ethical committee

8 **Hospital pharmacy services** **05**

Procurement & warehousing of drugs and pharmaceuticals
Inventory control: definition, methods of inventory control, ABC, VED, EOQ, lead time, safety stock.

9 **Drug distribution in the hospital** **05**

Individual prescription method
Floor stock method
Unit dose drug distribution method
Distribution of Narcotic and other controlled substances
Central sterile supply services – role of pharmacist
Radio pharmaceuticals – handling and packaging

ASSIGNMENTS

- The students are required to submit a minimum of two written assignments selected from the topics given to them.

Reference Books:

1 Malcolm Rowland & Thomasn Tozer. Clinical Pharmacakinetics & Concepts and Applications Lippincott Williams & Wilkins 1995
2 Ellenhorns Medical Toxicology – Diagnosis and treatment of poisoning. Mathew J. Ellenhorn.. Williams and Willkins publication, London. Second Edition
3 Hospital Pharmacy by William E. Hassan
4 Brian L. Strom, Stephen E. Kimmel. Textbook of Pharmacoepidemiology. Wiley
5 rug Interactions. Stockley I.H. (1996). The Pharmaceutical Press
6 oxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
7 oxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries,

Mannfred A. Hollinger
8 rug Interaction Facts, 2003. David S. Tatro.
9 oxicology - The basic science of poisons, international edition, Curtis D.Klaassen, 6th edition
10 oxicology – Principles and Applications, Raymond J.M.Niesink, John de.Vries, Mannfred A. Hollinger

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code - 910107

Subject:- Specialisation Paper - I

Pharmaceutical Analysis-I

Theory –

Four hours per week; 6 Credits

Course Content: **Hours**

1) Application of instrumental methods in the development of medicines, concept of analytical method development. **05**

2) Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC. **10**

3) Ion Selective electrodes: Classification, instrumentation and applications in drug analysis. **02**

4) Principles and procedures involved in quantitative determination of following groups (a) Hydroxyl, (b) Aldehyde, (c) Ketone, (d) Ester (e) Amine. **05**

5) A detailed study of principle and procedures involved in various physicochemical methods of analysis including instrumental methods of analysis of Pharmaceutical dosage forms containing the following classes of drugs: **20**

a. Sulphonamides.
b. Barbiturates - i.e., Barbituric acid derivatives and Xanthine derivatives.
c. Steroids such as Adrenocortical steroids, Progesterone, Androgens and Cholesterol.
d. Vitamins like Vitamin A, B_1, B_2, B_{12}, C & E.
e. Antibiotics like Chloramphenicol, Erythromycin, Penicillin & Streptomycin.
f. Alkaloids of Cinchona, Ergot, Opium & Rauwolfia.
g. Glycosides such as Digitoxin, Digoxin & Strophanthin.

6) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and iodine. **05**

7) Principles and procedures involved in the use of the following reagents in Pharmaceutical analysis : **08**

a. N_1-naphthyl ethylene diamine.
b. *p*-dimethylaminobenzaldehyde (PDAB).
c. 2,6-Dichloro quinone chlorimide.
d. 1,2-Naphtho quinone 4 - sulphonate.
e. 2,3,5-Triphenyl Tetrazolium Salt.
f. Ninhydrin.
g. Folin - Ciocalteau reagent.
h. *P*-dimethylaminocinnamaldehyde.
i. 3-methyl-2-benzothiazoline hydrazone (MBTH).
j. 2,4-dinitrophyenylhydrazine.

8) Analysis of excipients in solid state - Particle size analysis, X-ray diffraction. **05**

Pharmaceutical Analysis-I

PRACTICALS

4 Hours per week, 6 Credits

1. Calibration and validation of UV-Visible, IR, Flourimeter, HPLC & HPTLC.
2. Assays of official compounds by fluorimetry :
   a) Quinine b) Codeine c) Thiamine and d) Riboflavin.
3. Study of Quenching effect in fluorimetry : quenching of quinine by potassium Iodide.
4. Determination of 'Sodium' in Sodium chloride injection.
5. Colorimetric estimation of Sulphacetamide in 'eye drops' using NED.
6. Assay of Reserpine injection IP.
7. Quantitative Analysis of drugs in the following 'Multicomponent dosage form' - Ibuprofen & Paracetamol Tablet, Paracetamol and Nimesulide Tablet, Ciprofloxacin and Tinidazole Tablet.
8. Q
   uantitative Determination of functional groups like:
   a) Hydroxylgroupb)Carbonylgroupc)Am
      i.
9. Quantitative Colorimetric determination of suitable drugs using following reagents :
10. a) *P*-dimethylaminocinnamaldehyde b) MBTH c) F-C reagent
11. d) 2,6-dichloroquinonechlorimide e) Ninhydrin.
12. Assay of the following official formulations :
    a) a) Frusemide Tablet b) Metformin Tablet c) Chloroquine Tablet
    b) d) Chloramphenicol Capsule e) Digoxin Tablet.
13. HPLC & HPTLC analysis of drugs.

Reference Books:

1. Vogel's : Textbook of quantitative chemical analysis revised by G. H. Jeffery, J. Bassett, J. Mendham, R. C. Denney, 6th Edition, Pearson Education Publishers -New Delhi, 1989, India..
2. H. Beckett and Stenlake, Practical Pharmaceutical Chemistry, Vol. I and Vol. II, 4th Edition CBS Publishers, 1997, New Delhi.
3. K.A Connors : Text Book of Pharmaceutical Analysis, 3rd Edition, Wiley- Inter Science Publication, 1999, New York.
4. Indian Pharmacopoeia, Vol. I & II, 1996, The Controller of Publications, Government of India.
5. John H. Kennedy, Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, 1990, New York.
6. Higuchi, Bechmman and Hassan : Pharmaceutical Analysis, 2nd Edition, John Wiley and Sons, New York.
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi.
8. P. D. Sethi, Quantitative Analysis of Drugs in Pharmaceutical Formulation, 3rd Edition.
9. J. W. Munson, Pharmaceutical Analysis - Modern Methods, Part - A & B, 2001.

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper Code - 910207

Subject: - Specialization Paper - II

Advanced Spectroscopic Techniques

Theory - Four hours per week; 6 Credits

Course Content: **Hours**

1. Basic principles, instrumentation and application of Chemiluminescence **05**
2. Basic principles, classification, instrumentation and application of LASER. **05**
3. Electron spin resonance (ESR) principle, instrumentation, correlation with proton magnetic resonance, derivative curves, interpretation and application. **08**
4. **Raman Spectroscopy**: Introduction, Principle and application of Raman Spectroscopy. **06**
5. **Photoacoustic Spectroscopy:** Principles, instrumentation and application. **05**
6. **Radiochemical Analysis:** Instruments used-analytical and screening, isotopic dilution, neutron activation and positron emission tomography (PET) **08**
7. **Nuclear Magnetic Resonance Spectroscopy:** Effect of stereochemistry on the spectrum, shift reagent. Introduction to the following techniques would be covered DEPT, APT, COSY, NOESY and INADEQUATE. **13**
8. **^{13}C Nuclear Magnetic Resonance (^{13}C - NMR)**
   Natural abundance of 13C, resolution and multiplicity FT mode, RF mode, uses of proton coupled, decoupled and off resonance decoupling techniques, deuterium substitution, chemical equivalence in peak assignment, chemical shift, Effect of substitution on chemical shifts, position of alkanes, alkenes, alkynes and benzene spin coupling and C13-H1 coupling **10**

Reference Books:

1. R. M. Silverstein and F. X. Webster, Spectrometric identification of Organic compounds, John Wiley & Sons, New York. (Latest edition).
2. William Kemp, Organic Spectroscopy, ELBS Mac millan, Hampshire, (U. K).
3. D. L. Pavia, G. M. Lampman and G. S. Kriz, Introduction to spectroscopy- A guide for students of Organic chemistry, Harcourt college publishers. (Latest edition).
4. D. H. Williams and I. Fleming, Spectroscopic methods in Organic chemistry, Tata Mc Graw Hill publishing company Ltd, New Delhi, India. (Latest edition).

Gujarat Technological University
M. Pharm. Syllabus
Semester I

Paper code: 910108
Subject of Specialization paper –I
Industrial Pharmacy Paper-I
Theory
(Four hours per week, 6 Credits)

Course Content: **Hours**

1) Pharmaceutical factory location: Selection, layout and planning. Utility services like Humidity, Temperature, Ventilating and air conditioning (HVAC), water system (RO, WFI, hot and cold water), Steam, Electrical services, Compressed air, Vacuum systems, Dust collection, Effluent treatment plant, etc. Service facilities, and personnel facilities **10**
2) Preparation of qualitative and quantitative departmental layout with equipments required for different dosage forms, solids, liquids, semisolids, sterile.
   Plant and Machinery based on various dosage forms: Equipment design, material of plant constructions, selection criteria, factors affecting equipment design, properties and types of material used for plant construction. **10**
3) Detailed study of the equipments required in the manufacture of different dosage forms as per Schedule-M. **10**
4) Preparation of documents like batch manufacturing record (BMR), batch packing record (BPR), and validation protocols **08**
   Preparation of standard operative procedure (SOPs) for equipments and manufacturing or processing steps **08**
5) GMP and its implementation and introduction to PAT **14**
   a. Organization & Personnel, responsibilities, training, hygiene.
   b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination.
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
   f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.
   g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials.
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.
   i. Finished product release, quality review, quality audits and batch release documents.
   j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.
   k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
   l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

m. Waste disposal, scrap disposal procedures and records.

Reference Books:

1. **Lachman** "The theory and Practice of Industrial Pharmacy
2. **Remingtons** "Pharmaceutical Sciences"
3. Bentley's **Pharmaceutics.**
4. Pharmaceutical facilities: Design, layouts and validation by **Manohar A Potdar**
5. GMP practices for pharmaceutical –**James Swarbrick.**
6. How to practice GMP**s by P.P.Sharma.**
7. Chemical Engineering Plant Design **by Vibrant.**
8. Pharmaceutical Process Validation **by Loftus and Nash.**
9. **G.S. Banker & C.T. Rhodes**, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
10. SOP guidelines by D. H. Shah
11. Drug and Cosmetic Act 1940 and rules.

Industrial Pharmacy Paper-I
Practicals
(Four hours per week, 6 Credits)

Practical exercises formulated bases on the topics mentioned in the theory such as
Illustrative flow sheets of each dosage form with detailed idea of placement of equipment, men and material movement and service lines, Equipment selection factors, size and maintenance, preparation of BMR & BPR, Validation , Sampling plans (Product wise), preparation of SOP (Equipment, Process and service lines) and other records.

Gujarat Technological University

M. Pharm. Syllabus

Semester I

Paper code: 910208

Subject of Specialization paper –II

Industrial Pharmacy Paper-II

Theory

(Four hours per week, 6 Credits)

Course Content: **Hours**

1) **Pilot plant and manufacturing scale up technique:** **15**
   Significance, and general requirements, scale up study of some important dosage forms such as tablets, capsules, semi solids, liquids orals and injectables; discussion on important parameters such as formula, equipments, product uniformity, stability, and challenges.
2) **Production, Planning, Control and Documentation:** **15**
   Production scheduling and forecasting; vendor development capacity assessment (Plant, machines, raw materials, human resources); production management, production organization, objectives and policies
   Guide to pharmaceutical manufacturing practices and facilities; implications of reducing costs; documentation.
3) **Inventory Management, Material Management and Maintenance Management:** **20**
   Costs in inventory, inventory categories-special considerations, selective inventory control, recorder quality methods and EOQ, inventory models, safety stock-stock out, lead time-recorder time methods, modern inventory management systems, inventory evaluation. Material- quality and quantity, value analysis, purchasing-centralized and salvaging and disposal of scrap and surplus Selection of material handling systems, maintenance of material-handling equipment, unit-load, pelletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled maintenance, preventive maintenance, predictive maintenance.
4) **Industrial hazards, safety, pollution and effective treatment:** **10**
   Introduction, Factory act and rules, fundamentals of accident prevention, organizing for safety, electrical hazards, industrial chemical and their health hazards, Material handling, Fire prevention and control. Physicochemical measurements of effluents, BOD, COD, Determination of some contaminates Effluent treatment of some characteristic effluent.

Reference Books:

1. Michael Levin, “Pharmaceutical Process Scale up”, Second edition, Marcel Dekker Inc., Volume 157.
2. Joseph F. despautz,” Automation and Validation of Information in Pharmaceutical Processing”, Marcel Dekker Inc., Volume 90.
3. L.C. Jhamb, “Industrial Management”, Everest Publications.
4. C.V.S. Subramanyam, “Pharmaceutical Production and Management”,
5. Leon Lachman, “Theory and Principles of Industrial Pharmacy”, Third edition.
6. G.S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
7. **Remingtons** “Pharmaceutical Sciences”
8. Bentley’s **Pharmaceutics.**
9. Pilot plants model and scale-up methods**, by Johnstone and Thring.**
10. How to practice GMP**s by P.P.Sharma.**
11. Chemical Engineering Plant Design **by Vibrant.**
12. Pharmaceutical Facility management **by J.P.S. kohli**

Gujarat Technological University

Subject Codes/ Teaching/Evaluation Scheme for M. Pharm.

Semester II-(Revised from Jan-2013)

Branch Code	Branch Name/Specialization	Subject	Subject Code	Subject Name	Teaching Credits		Evaluation Scheme			
							Theory		Practical	
					Theory	Practical	External	Internal	External	Internal
00	GENERAL	**Research Methodology**	2920001	Research Methodology	7	-	80	20	-	-
01	Pharm. Chemistry	**Subject of specialization Paper III**	2920101	Advanced Organic Chemistry - II	7	8	80	20	80	20
02	Pharmaceutical Tech. and Pharmaceutics		2920102	Novel Drug Delivery System Part-I	7	8	80	20	80	20
03	Pharmacology		2920103	Pharmacometrics and Methods of biological evaluation of drugs	7	8	80	20	80	20
04	Qual. Assurance		2920104	Modern Pharmaceutical analysis	7	8	80	20	80	20
05	Pharmacognosy		2920105	Advanced Analytical Pharmacognosy	7	8	80	20	80	20
06	Clinical Pharmacy		2920106	Applied Pharmacotherapeutics - I	7	8	80	20	80	20
07	Pharmaceutical Analysis		2920107	Pharmaceutical Analysis - II	7	8	80	20	80	20
08	Pharmaceutics		2920102	Novel Drug Delivery System Part-I	7	8	80	20	80	20
09	Pharmaceutical Quality Assurance		2920104	Modern Pharmaceutical analysis	7	8	80	20	80	20
10	Pharmaceutical Technology		2920102	Novel Drug Delivery System Part-I	7	8	80	20	80	20
11	Pharmacology &Toxicology		2920103	Pharmacometrics and Methods of biological evaluation of drugs	7	8	80	20	80	20
12	Industrial Pharmacy		2920108	Industrial Pharmacy-III	7	8	80	20	80	20
13	Quality Assurance Technique		2920104	Modern Pharmaceutical analysis	7	8	80	20	80	20
14	Medical Chemistry		2920101	Advanced Organic Chemistry - II	7	8	80	20	80	20
15	Quality Assurance and Pharm Regulatory Affairs		1921501	Modern Pharmaceutical Analysis	7	8	80	20	80	20
16	Pharmaceutical Management and Regulatory Affairs		1921601	Regulatory Affairs-I	7	8	80	20	80	20
01	Pharm. Chemistry		2920201	Drug Design and Discovery	8	-	80	20	-	-
02	Pharmaceutical Tech. and Pharmaceutics		2920202	Global Regulatory Requirements	8	-	80	20	-	-
03	Pharmacology		2920203	Pharmacotherapeutics	8	-	80	20	-	-
04	Qual. Assurance		2920204	Regulatory Affairs and New Drug Applications	8	-	80	20	-	-

05	Pharmacognosy	**Subject of Specialization Paper IV**	2920205	Advances in Pharmaceutical Science	8	-	80	20	-	-
06	Clinical Pharmacy		2920206	Clinical Research and Regulatory Affairs	8	-	80	20	-	-
07	Pharmaceutical Analysis-I		2920207	Quality Control & Quality Assurance	8	-	80	20	-	-
08	Pharmaceutics		2920202	Global Regulatory Requirements	8	-	80	20	-	-
09	Pharmaceutical Quality Assurance		2920204	Regulatory Affairs and New Drug Applications	8	-	80	20	-	-
10	Pharmaceutical Technology		2920202	Global Regulatory Requirements	8	-	80	20	-	-
11	Pharmacology &Toxicology		2920203	Pharmacotherapeutics	8	-	80	20	-	-
12	Industrial Pharmacy		2920208	Industrial Pharmacy-IV	8	-	80	20	-	-
13	Quality Assurance Technique		2920204	Regulatory Affairs and New Drug Applications	8	-	80	20	-	-
14	Medical Chemistry		2920201	Drug Design and Discovery	8	-	80	20	-	-
15	Quality Assurance and Pharm Regulatory Affairs		1921502	GMP, GLP and Validation	8	-	80	20	-	-
16	Pharmaceutical Management and Regulatory Affairs		1921602	Pharm Management-II	8	-	80	20	-	-

Gujarat Technological University

M. Pharm.
Semester – II

Structure for Second Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme		Marking Scheme			
		Credits		Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Research Methodology	07	-	80	20	--	--
2.	Subject Specialization of Paper – III	07	08	80	20	80	20
3.	Subject Specialization of Paper – IV	08	--	80	20	--	--
	Total	**22**	**08**				

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920001

Research Methodology

(Common to all discipline)

Theory

(Four hours per week, 7 credits)

1. Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, Historical descriptive, Basic applied and Patent oriented Research) objective of Research
2. Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey.
3. Selecting a problem and preparing Research proposals
4. Methods and tools use in research –
    A. Qualities studies, quantitative studies
    B. Simple data organization descriptive data analysis,
    C. Limitation & sources of Error
    D. Inquiries in form of Questionnaire, etc.
5. Documentation-
    A. "How" of documentation
    B. Techniques of documentation
    C. Importance of documentation
    D. Use of computer packages in documentation.
6. The Research Report Paper writing/ thesis writing
    Different parts of the Research paper
    1. Title –Title of project with authors name
    2. Abstract- Statement of the problem, Background list in brief and Purpose and scope.
    3. Key Words.
    4. Methology-subject, apparatus, instrumentation & procedure.
    5. Results- tables, graphs, figures & statistical presentation
    6. Discussion support or non support of hypothesis, practical & theoretical Implications
    7. Conclusion
    8. Acknowledgements.
    9. References
    10. Errata
    11. Importance of Spell check for entire project
    12. Uses of footnotes
7. Presentation (especially for oral presentation)
    Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire
8. Cost analysis of the project – cost incurred on raw materials-
    Procedure, instrumentations and clinical trials.
9. Sources for procurement research grants – international agencies, Government and private bodies.
10. Industrial-institution interaction- Industrial projects, their, feasibility reports.
    Interaction with industries.

References Books:

1. Research in Education- John V. Best, John V. Kahn 7th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
2. Practical Introduction o copyright. - Gavin Mcfarlane
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Scientist in legal Systems- Ann labor science
5. Thesis & Assignment – Jonathan Anderson
6. Writing a technical paper- Donald Menzel
7. Effective Business Report Writing –Leland Brown
8. Protection of industrial Property rights- P. Das & Gokul Das
9. Spelling for the millions- Edna Furmess
10. Preparation for publication – King Edward Hospital Fund for London
11. Information Technology – The Hindu speaks
12. Documentation – Genesis & Development 3792.
13. Manual for evaluation of industrial projects-United Nations
14. Manual for the preparation of industrial feasibility studies

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920102
Specialization paper - III
Novel Drug Delivery System Part-I
Theory
(Six hours per week, 7 credits)

1. Recent Innovations in Conventional Dosage Forms – including site specific and time release modulation.

   e.g.: Tablets: Osmotic, Colon target, Gastro-retentive, Buccal, and Sublingual.
   Capsules: Modified release,
   Semi-solids:
   Parenterals:
   Powders: Particle coating, Taste-masking,
   Liquids:

2. Packaging components and its evaluation: factors affecting selection, Types and classification, Primary and secondary and regulatory aspects. Contribution in stability of the dosage forms.

Subject of Specialization paper - III
Novel Drug Delivery System Part-I
Practical
(Six hours per week, 8 credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

References Books:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman "**The theory and Practice of Industrial Pharmacy" 3rd edition.
3. Pharmaceutics "The Science of Dosage form design" **by Aulton**
4. Pharmaceutical dispensing **by Husa**.
5. Modern pharmaceutics **by G. S. Banker.**
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing **by Banaker.**
8. United States Pharmacopeia.
9. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920202

Specialization paper - IV

Global Regulatory Requirements

Theory

(Six hours per week, 8 credits)

1. Validation of Pharmaceutical Processes, equipments/apparatus, basic concept in analytical method development for dosage forms., Computer System validation, ERP and SAP systems.

2. Basics in Drug approval process with reference to: Orange book, Freedom of information, IIG, DMF, Historical aspects with Various phases of drug development and approval.

3. IND, NDA, ANDA , Concept of para I to IV, exclusivity: Content, format and Application.

4. Brief and comparative introduction to various regulatory agencies: USFDA, MCA, TGA, MHRA, ANVISA, CTD, WHO, ICH, SUPAC etc.

Reference Book:

The guidance documents shall be procured from the website of the respective Government.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920103
Specialization paper - III
Pharmacometrics and Methods of biological evaluation of drugs

Theory
(Six hours per week, 7 credits)

1. Biological standardization, general principles, Scope and limitation of bio-assay, bioassay of some official drugs.
2. Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.
3. Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests
4. Microbiological assay of antibiotics and vitamins.
5. Biological evaluation of drugs--Screening and evaluation (including principles of screening , development of models for diseases : In vivo models / In vitro models / cell line study) techniques of the following:
6. Parasympathomimetics, Parasympathetic blocking agents, Sympathomimetics, Sympathetic blocking agents, Ganglion stimulants and blockers, Neuromuscular stimulants and blockers.
7. General and local Anesthetics, Sedatives and Hypnotics, Antiepileptics, Psychopharmacological agents, Analgesics, Anti-inflammatory agents, Anti-Parkinson's drugs, CNS Stimulants.
8. Cardiotonics, Anti-hypertensive drugs, Anti-arrhythmic drugs, Drugs used in Ischemic Heart Diseases, Drugs used in Atherosclerosis.
9. Drugs used in Peptic Ulcer, Respiratory disorders, Hormone and Endocrine disorders. Anti fertility agents and diuretics.
10. Various models for Cataract, glaucoma, inflammatory bowel disease

Specialization paper - III
Pharmacometrics and Methods of biological evaluation of drugs
Practical
(Six hours per week, 8 credits)

1. **Bioassays of drugs**: Bioassay of agonists (Graphical, Matching, 3 Point, 4 point method) and Bioassay of antagonists using various isolated preparations.
2. **Toxicity studies**
3. **Evaluation of drugs based on theory syllabus.**

Illustrative examples

Evaluation of the antiepileptic activity of drug using maximum electro convulsive shock seizures (M. E. S.) and chemical induced convulsions methods.

1. Determination of the time required for induction and recovery from anesthesia for various volatile general anesthetics.
2. Evaluation of the effect of pentobarbitone sodium and diazepam in mice.
3. Evaluation of the effect of various tranquilizers and sedatives on motor co-ordination by rota rod test in mice.
4. Evaluation of the effects of drugs on spontaneous motor activity and to evaluate their nature as CNS stimulants or depressants.
5. Evaluation of the antiparkinsonian activity of drugs by pheno-thiazine induced catatonia.
6. Evaluation of the effect of psychotropic drugs on condition avoidance response.
7. Evaluation of the compulsive behavior (stereotypy) induced by apomorphine and its modification by chlorpromazine in mice.
8. Evaluation of anxiolytic (antianxiety) effect of diazepam in mice using elevated plus-maze apparatus.
9. Study the effect of caffeine in human volunteers.
10. Evaluation of the effect of cimetidine in drug induced gastric (peptic) and duodenal ulcers and hyper secretion of gastric acid in rats.
11. Evaluation of the antisecretory and ulcer protective effect of cimetidine in pylorus-ligated rats.
12. Evaluation of the analgesic potency of drug by thermal method.
13. Evaluation of analgesic effect of morphine in mice using hot plate method.
14. Evaluation of the analgesic effect of drugs by acetic acid induced writhing method in mice.
15. Evaluation of the anti-inflammatory property of indomethacin against carrageenan-induced acute paw oedema in rats.
16. Evaluation of the effects of various drugs (diuretics) on the output of the urine in rats.

References Books:

1. Screening methods in pharmacology (vol I & II)–R.A. Turner
2. Drug Discovery and Evaluation in Pharmacology assay: Vogel
3. Design and analysis of animal studies in pharmaceutical development, Chow, Shein, Ching.
4. Evaluation of Drug Activity: Pharmacometrics D.R. Laurence
5. Animal and Clinical pharmacologic Techniques in Drug Evaluation-Nodine and Siegler
6. Pharmacology and Toxicology- Kale S.R.
7. Fundamentals of experimental Pharmacology- Ghosh M.N.
8. Handbook of Experimental Pharmacology- Goyal R.K.
9. Handbook of Experimental Pharmacology- Kulkarni S.K.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920203
Specialization paper - IV
Pharmacotherapeutics

Theory
(Six hours per week, 8 credits)

Important disorders/conditions (etiology, pathophysiology, complications, diagnosis, Prognosis), their control and management with special emphasis on pharmacology of drugs (mechanism of action, ADME, therapeutics use, and adverse effects, toxicities and possible drug interaction) of the following:

1. Central Nervous system: Neurodegenerative Disorders (Parkinson's disease, Alzheimer's disease, Huntington's chorea, Spasticity), behavioral disorder-(Anxiety, Insomnia, Depression and Mania), Psychoses, Epilepsy, Migraine
2. Cardiovascular and hemopoeitic system ; Hypertension, Acute Coronary Syndrome, Angina Pectoris, Atherosclerosis, Congestive Heart Failure, Arrhythmias, Thromboembolic disorder, Anaemia
3. Endocrine system : Disorders of thyroid gland and Parathyroid gland, Diabetes, Adrenocortical dysfunction
4. Gastro-intestinal System :Peptic Ulcer, Inflammatory Bowel Disease, Vomiting, Achlorhydria, Constipation, Diarrhea, Liver diseases
5. Respiratory system: Bronchial Asthma, Chronic Obstructive Pulmonary Disease (COPD), Allergic Rhinitis, Common cold & Cough, Cystic fibrosis
6. Urogenital system: Renal Failure, Infertility, Benign Prostatic Hypertrophy, dysmenorrhea, Menopause
7. Disorders of eye: Glaucoma

Reference Books:

1. Principles of Pharmacology –The Pathophysiologic Basic –Golan David E.
2. Pharmacological Basis of Therapeutics-Goodman and Gilman
3. Pharmacology-Rang and Dale
4. Essentials of Pharmacotherapeutics-F.S. Barar
5. Principles of Pharmacology – Paul L. Munson
6. Pharmacology and Pharmacotherapeutics-R.S.Satoskar
7. Pharmacotherapy- A Pathophysiological Approach-Joseph T. Dipiro.
8. Lewis's Pharmacology – James Crossland – Churchil Livingston
9. Modern Pharmacology with Clinical Applications- Craig, Charles R.
10. Principles of Pharmacology--H. L. Sharma

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920101
Specialization paper - III
Advanced Organic Chemistry - II

Theory
(Six hours per week, 7 credits)

1. Detailed study of individual reactions - allylic rearrangement, Amdt ester synthesis-Bayer-Villiger rearrangement, benzillic acid rearrangement – Curtius rearrangement-Dimorth rearrangement, Heck reaction, Lossen –Schmidt rearrangement, Pinner reaction, Reformatsky reaction, Sharpless oxidation, Suzuki reaction, Sonogashira reaction, Swern oxidation, Vilsmeir Haack reaction.
2. Stereochemistry and Chiral Techniques.
    a. Principles of stereochemistry including geometric isomerism, optical isomerism and conformational isomerism.
    b. Stereochemistry of compounds with asymmetric plane.
    c. Concept of chiral drugs, resolution of racemic mixtures, racemic switches, asymmetric synthesis of following drugs: Vit.C, Nifedipine, Atenolol, Ethambutol, Omeprazole, Ampicillin and Thalidomide.
    d. Role of stereochemistry in pharmacokinetics and pharmacodynamics
3. Synthon Approach:
   Definition, terms and abbreviation, rules and guidelines used in synthesis of following drugs.
   Pyrimethamine, Ibuprofen, Diclofenac, Rosiglitazone, Cetirizine, Ciprofloxacin, Captropil, and Losartan
4. Green Chemistry:: Solvent free reaction, water as a solvent, ionic liquids, supercritical liquids, supported reagents and catalyst.
5. Introduction to microwave reactions, ultrasound reactions, nanochemistry

Specialization paper - III
Advanced Organic Chemistry - II
Practical
(Six hours per week, 8 credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

Reference Books:

1. March Jerry– Advance Organic Chemistry - Reaction Mechanism and Strucutre, McGraw-Hill International Book Company
2. F. A. Carey and R. J. Sundberg – Advance Organic Chemistry Part – A & B, Plenum Press.
3. Clayden Greeves and others – Organic Chemistry, Oxford University Press.
4. Jie Jack Li - Name Reactions, Springer
5. Eliel – Stereochemistry of Carbon Compounds
6. S. Warren - Designing Organic Synthesis, Wiley India Ltd.
7. P. T. Anastas and J. C. Warner – Green Chemistry theory and Practice, Oxford University Press.
8. C. Oliver Kappe and others – Practical Microwave Synthesis for Organic Chemist, Willey Interscience.
9. G. B. Sergeev – Nanochemistry, Elsevier publication\

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920201

Specialization paper - IV

Drug Design and Discovery

Theory
(Six hours per week, 8 credits)

1. General Introduction to drug discovery concept/process and importance of drug design approaches in drug discovery.
2. Various targets for drug action and theory of drug action –agonist, antagonism/ blockers and enzyme inhibition (IC50, EC50 concept)- an overview
3. A general study of stereochemistry and physicochemical properties of the drug/drug-like molecules and their importance in drug action. Correlation between physicochemical properties and drug action, establishing structure activity relationship (SAR) and its analysis. Isosterism and bio-isosterism as guides to structural variations and Prodrug design its application in lead optimization.
4. Various approaches to drug discovery
5. Quantitative Structure Activity Relationship QSAR- brief introduction to various methods of QSAR – Physicochemical parameters – lipophilic, electronic and steric. Detail study on Hansch LFER model, Free Wilson analysis and mixed approach. Various basic statistical methods useful in QSAR development.
    a. 3D QSAR – importance and various models (COMFA, MSA, HASL, Apex 3D, DISCO, GFA) used for it.
6. Computer Aided Drug Design (CADD) – Molecular modeling
    a. Basic concepts of computational chemistry like Quantum Mechanics, Molecular Mechanics, Force Field, Energy minimization, Conformational generation and analysis, geometry optimization, Molecular Dynamics
    b. Ligand based drug design, Analogue approach, Pharmacophore Mapping, importance of ligand shape and Excluded volume techniques, Artificial intelligence methods.
    c. Structure based drug design, requirement of SBDD, utilization of target structure derived from NMR and X-ray Crystallography techniques, understanding of drug–receptor/enzyme/target interactions, preparation of protein/target along with active site analysis, docking process, various docking methods. De-novo drug design.
    d. Drug design based on antagonism and enzyme inhibition. Various software used in CADD
7. Virtual screening of huge compound databases by using Pharmacophore mapping as well as docking methods
8. Pharmacokinetics (Absorption, Distribution, Metabolism Elimination i.e. ADME) in drug discovery.

References Books:

1. Ariens – Drug Design, vol. VII, Academic Press.
2. H Smith & H J William – Introduction to the Principal of Drug Design, John Wright & Sons Ltd.
3. Burgers Medicinal Chemistry – The Basis of Medicinal Chemistry by Manfred S. Wolff, Part – I , John Wiley & Sons

4. Copmuter assisted Drug Design by Edward C. Olson (America Chemical Society, ACD symposium series 112).
5. W. O. Foye - Principles of Medicinal Chemistry, Lipincott Williams and Wilkins.
6. C. Hansch and Leo - Comprehensive Medicinal Chemistry Vol. 4, Pergamon Press.
7. Molecular Modeling in Drug Design by Cohen N. C.
8. C. G. Wermuth - The Practice of Medicinal Chemistry, Elsevier publication.
9. E. H. Kerns and L. Di - Drug like properties, concepts, structure design and methods, Academic Press.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920104
Specialization paper - III
Modern Pharmaceutical Analysis

Theory
(Six hours per week, 7 credits)

1. Application of analytical methods to product obtained through genetic engineering , Amino acid sequence analysis, Tryptic maping, ion exchange amino acid analysis, isoelectric focusing etc.
2. Regulatory requirement in pharmaceutical analysis – US-FDA, ICH
3. Solid state analysis of drug substance including related substances, and impurities present in drugs and their effect on drug stability and therapeutic action.
4. Applications of various analytical techniques in preformulation analysis and its importance.
5. Analysis of solid oral dosage form
6. Analysis of injectable dosage form
7. Compendial testing
8. Automated analysis
9. Compendial methods for evaluation of crude drug and herbal formulation
10. Quality control of radio pharmaceuticals and radio chemical method in analysis.
11. Analysis of cosmetics

Specialization paper - III
Modern Pharmaceutical Analysis
Practical
(Six hours per week, 8 credits)

1. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
2. Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
3. Determination of Total Chloride in Thiamine Chloride Hydrochloride.
4. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
5. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
6. Determination of related substances in Albendazole, Amiloride, Metronidazole,
7. Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P. Determination of active constituents in crude drugs. E.G. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
8. Quality Control tests for some herbal formulations.
9. Quality Control tests for some cosmetics.

References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs andPharmSci.Series,Vol. 160, Taylor and Francis, 2006 N.Y.
2. S. Ahuja, Modern Pharmaceutical Analysis

3. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
4. Peptide and Protein Drug Analysis, by Reid, (Marcel Dekker).
5. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
6. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
7. Methods of sampling and test for various cosmetics as laid down by Indian Standard Institution (BIS).
8. Indian Pharmacopoeia,Vol. I and Vol. II - 1996.The Controller of Publications; New Delhi, Govt. of India,
9. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
10. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
11. Basic tests for pharmaceutical substances – WHO (1988)
12. Basic tests for pharmaceutical dosage forms – WHO (1991)
13. Phytochemical Methods by J.B.Haroborne
14. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920204
Specialization paper - IV
Regulatory Affairs and New Drug Application

Theory
(Six hours per week, 8 credits)

A) REGULATORY AFFAIRS

1. Legislation to regulate the profession of pharmacy – The Pharmacy Act 1948.
2. Legislation to regulate, import, manufacture distribution and sales of drugs, cosmetics- The Drugs & Cosmetic Act 1940 & rules 1945 with amendments.
3. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product.
4. Quality safety and legislation for cosmetic and herbal products.
5. Aims, objects and salient features of following legislations governing Pharmaceutical Industry-
6. Pollution Control Act
7. Prevention of Food Adulteration Act 1954
8. Industrial Development & Regulation Act 1951
9. Consumer Protection Act
10. Standard institutes & certification agencies like ISI, BSS, ASTM, SO, WHO, US-FDA, UK-MCA, TGA
11. Drug Master File (Case Study-3 examples)
12. Material Safety Data Sheet (MSDS) preparation
13. Industrial Safety & Health Guide lines for filing in countries like US & EU
14. Drug Regulatory Agencies-Historical perspectives, organization structure activities & responsibilities: India, US, EU, Japan, ICH
15. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP

B) Approval of New drugs:

Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.

References Books:

1. Drugs and Cosmetics Laws by Krishnan Arora, Professional Book Publishers, New Delhi
2. Mittal B.M., A Textbook of Forensic Pharmacy, 9th Ed., Vallabh Prakashan
3. Deshpande S.W., Drugs and Cosmetic Act.1940.
4. Gnarino Richard A, New Drug Approval Process, 3rd Ed., Marcel Dekker Inc.
5. P. Warayan, Intellectual Property Laws, Eastern Law House.
6 Drug and Cosmetic Act 1940, Eastern Book company by Vijay Malic, 11th Ed. Patents for Medicine, by N. B. Zareri, Indian Drug Manufacturers Association (IDMA)
7. Ira R. Bery, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
8. The Drugs and Cosmetic Act 1940 – Vijay Malik

9. Indian Pharmacopoeia, Vol. 1-3, 2007.The Indian Pharmacopoeia commission, Gahaziabad, Govt. of India.
10. The International Pharmacopoeia Vol 1, 2,3,4,5 3rd Editions
11. Pollution Control Act, 1974
12. Prevention of Food Adulteration Act 1954
13. Industrial Development & Regulation Act 1951
14. Consumer Protection Act 1986
15."WHO Expert Committee on specification on Pharmaceutical Preparation"34th report, Geneva, World Health Organisation, 1996 (WHO Technical Report Series, No. 863
16. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
17. A.C. Cartwright and Brian Mathews,"International Pharmaceutical Registration" Taylor and Francis Ltd. UK, 2002
18. United State Pharmacopoeia (USP) 32,NF27, 2009
19. Industrial Health and Safety, Dr. A.M. Sarma, Himalaya Publication.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920105
Specialization paper – III
Advanced Analytical Pharmacognosy

Theory
(Six hours per week, 7 credits)

1. Standardization of herbal medicines, traditional and folklore remedies,/ preparation and their quality, safety and efficacy assessment and intended use for acceptance by FDA.
2. Stability testing of natural products, procedures, predictable chemical and galenical changes, technical limitation, testing methods and combination products.
3. Marine Pharmacognosy
4. Principles of Ayurveda and standardization of formulation of Ayurvedic dosage form as per Ayurvedic and Herbal Pharmacopoeia.
5. Regulatory and safety measures with herbal, Ayurvedic and other drugs of traditional origin.

Specialization paper - III
Advanced Analytical Pharmacognosy
Practicals
(Six hours per week, 8 credits)

Practical exercises based on the relevant topics mentioned in theory syllabus.

References Books:

1. Evans W. C – Trease and Evans pharmacognosy (15^{th} ed)
2. Wallis T.E, Practical Pharmacognosy, J & A Churchill Ltd.
3. Wagner H., Bladt S. and Zgainski, Plant Drug Analysis Springer, Verlag, New York.
4. Peach K. and Tracey M.V., Modern Methods of Plant Analysis, 1-4, Narosa Publisher House, N.D.
5. Kalia A. N – Textbook of Industrial Pharmacognosy.
6. Handa S.S & Kaul K.L., Supplement to cultivation and utilization of medicinal plants, 1996.
7. R.D. Chaudhary, Herbal Drugs Industry, Eastern Publishers, New Delhi.
8. Clark, E.C.G., Isolation and Identification of Drugs, The Pharmaceutics Press, London.
9. Brain K.R., and Turner R.D., The Practical Evaluation of Phytopharmaceutics, Wrigth-Scientechnics Bristol.
10. WHO Publication.
11. The Ayurvedic Pharmacopoeia of India, Part I, (Vol. I–V) , part II (I & II) Govt. of India, Ministry of Health and Family Welfare, Dept. of Indian Systems of Medicine and Homeopathy, New Delhi 2008.

12. Indian Herbal Pharmacopoeia, revised new edition 2002, Published by RRL, Jammu and IDMA, Mumbai – 2002
13. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association 1996.
14. Ayurvedic Formulary of India, Vol. I and II, Ministry of Health, New Delhi.
15. Stahl E, Thin Layer Chromatography – A Laboratory Hand Book, Springer – Verlag Berlin.
16. Steimser Richard – Folk Medicines
17. Rao Ramchandra – Encyclopedia of Indian Medicine Vol. I

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920205
Specialization paper – IV
Advances in Pharmaceutical Science
Theory
(Six hours per week, 8 credits)

1. Neutraceuticals from herbal sources
2. Insecticides and pesticides from natural sources
3. Phytochemical screening technique
4. Advances drug from natural sources of following categories:
    a) Antidiabetic
    b) Cardiotonic
    c) Immunomodulators
    d) Anti-inflammatory
    e) Anti-ulcer
    f) Anti-malerial
    g) Diuretics
    h) Anti-oxidant
    i) Urolithiatics
    j) Anti-lipidemic
    k) Brain tonic
    l) Hepatoprotective
    m) Anti-cancer
    n) Anti-AIDS

References Books:

1. Chatterjee T. K – Herbal options
2. Journals-
    a. Indian Drugs
    b. Indian Journal of pharmaceutical Education
    c. Planta Medica
3. Evans W. C – Trease and Evans pharmacognosy (15^{th} ed)
4. Kalia A. N – Textbook of Industrial Pharmacognosy.
5. Handa S.S & Kaul K.L. – Supplement to cultivation and utilization of medicinal plants, 1996.
6. Govil J. N, Singh V.K, Siddiqui N. T– Recent Progress in Medicinal plants, Vol., 1-25, , Studim Press , LLC USA.
7. Brunreton J– Pharmacognosy and Phytochemistry of medicinal Plants, (2^{nd} ed.), Intercept limited, Newyork, 1999.
8. Robbers J. E, Speedie M. K, Tyler V. E– Pharmacognosy and Pharmacobiotechnology, William and wikins, USA, 2005.
9. Bhat S. V, Nagasampagi B. A, Meenakshi S– Chemistry of Natural Products, Narosa Publishing House.
10. Robbers J. E, Tyler V. E– Herbs of Choice, Haworth Press In. USA-2002.
11. Reinhold L– Progress in Phytochemistry.
12. Wealth of India,Raw Materia

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920106

Specialization paper - III

Applied Pharmacotherapeutics - I

Theory

(Six hours per week, 7 credits)

Pathophysiology, Diagnosis & Pharmacotherapeutic management of following acute and chronic diseases and disorders

Basic Concepts of Pathophysiology and Pharmacotherapeutics

1. **Cardiovascular**

   Hypertension, angina pectoris, congestive heart failure, myocardial infarction, cardiac arrhythmias.
2. **Gastrointestinal**

   Peptic ulcer disease, Inflammatory Bowel diseases, hepatitis, cirrhosis, nausea and vomiting, constipation and diarrhea.
3. **Respiratory**

   Chronic obstructive pulmonary disease, bronchial asthma, cystic fibrosis.
4. **CNS**

   Epilepsy, Parkinsonism, schizophrenia, migraine, Alzheimer disease, Huntington's chorea, Spasticity), behavioral disorder-(Anxiety, Insomnia, Depression and Mania)
5. **Endocrine**

   Endocrinal disorders including Diabetes mellitus, thyroid (hyperthyriodism and hypothyroidism), parathyroid diseases, hyperlipidemia and Adrenocortical dysfunction.

Specialization paper - III

Applied Pharmacotherapeutics - I

Practical

(Six hours per week, 8 credits)

- Each student has to undergo compulsory Hospital postings for understanding and gaining knowledge of Pathophysiology, Diagnosis & Pharmacotherapeutic management of various diseases and disorders.
- It is mandatory that each student has to maintain a record of at least 15 case studies based on the theory topics

ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

References Books:

1. Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
2. Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
3. Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/ Glasgow/ Madras.
4. Robbins Pathologic Basis of Disease. Cartran, Kumar, Collins, W.B.Saunders. Latest edition.
5. Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
6. Pharmacotherapy: A Pathophysiologic approach – Joseph T. Dipiro et al. Appleton & Lange
7. Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)
8. Davidson's Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D. Boucher ELBS with Chu0rchill Living stone. Edinburgh. Latest Edition.
9. Avery's Drug Treatment, 4th End, 1997 Adis International Limited
10. Relevant review articles from recent medical and pharmaceutical literature.

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920206

Specialization paper - IV

Clinical Research and Regulatory Affairs

Theory

(Six hours per week, 8 credits)

1. **Introduction to Drug Discovery and drug Development**
2. **Clinical trials**
   - Introduction and designing
   - Various phases of clinical trials
   - Post Marketing surveillance – methods
   - Principles of sampling
   - Inclusion and exclusion criteria
   - Methods of allocation and randomization
   - Informed consent process
   - Monitoring treatment outcome
   - Termination of trial
   - Safety monitoring in clinical trials
3. **Documents in clinical study**
   - Investigator Brochure (IB),
   - Protocol & Amendment in Protocol ,
   - Case Report Form (CRF),
   - Informed Consent Form (ICF) ,
   - Content of Clinical Trial Report
   - Essential Documents in Clinical Trial
4. **Data Management in clinical Research**
5. **Ethical guidelines in clinical research**
   - History
   - ICH-GCP & its Principles
   - Indian GCP (CDSCO Guidelines)
   - ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects
   - Schedule Y
6. **Roles & Responsibility of various clinical trial personnel as per ICH GCP**
   - Sponsor
   - Investigator
   - Monitor
   - Auditors
7. **Institution Ethics Committee / Independent Ethics Committee**
8. **Quality Assurance in clinical Research**
9. **BA/BE studies: Introduction, Regulatory requirements and methodology**
10. **Clinical Trial Application in India**
    Import & Export of Drug in India
11. **Investigational New Drug application (IND)**
12. **Abbreviated New Drug Application (ANDA)**
13. **New Drug Application (NDA)**

ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

References Books:

1. Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004
2. Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002
3. Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002
4. Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006
5. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002
6. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication
7. Bert Spilker. Guide to Clinical Trials.
8. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009
9. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006
10. Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
11. Principals of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
12. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications.
13. Various Guidelines like:
    - ✓ ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996.
    - ✓ ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.
    - ✓ Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.

    Schedule Y

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920107

Specialization paper – III

PHARMACEUTICAL ANALYSIS SPECIALISATION

PHARMACEUTICAL ANALYSIS II

Theory

(Six hours per week, 7 credits)

1. Preparation of drug samples for analysis: Pharmaceutical samples, fundamental theories controlling preparation techniques, specific sample preparation techniques. **04 Hrs**

2. A detailed study of the principles, instrumentations and applications in drug analysis of: GC-MS, LC-MS with reference to drug metabolism, toxicologic and forensic studies, diagnosis of disease state, quantification of drugs in biological samples, counter current chromatography; Super critical fluid chromatography and size exclusion chromatography **20Hrs**

3. Analytical methods for the analysis of protein and its product: Amino acid sequence analysis, HPLC,Tryptic maping, ion exchange amino acid analysis, isoelectric focusing and other electrophoretic techniques. **7 Hrs**

4. A detailed study of the various principles and procedure involved in the quantitative analysis of pharmaceutical preparations and dosage forms containing the following groups of drugs included in I.P. (Biological and microbiological methods excluded)
   (a) Analgesics and Antipyretics (b) Sedatives & Tranquillizers
   (c) Antihypertensives (d) Antihistaminics
   (e) Cardiovascular drugs (f) Antidiabetics **7 Hrs**

5. Solid state analysis of drug substance including a detailed study on related substances and impurities present in drugs and their effect on drug stability and therapeutic action.
   ICH guidelines for impurity and related substances determination in drugs. **6Hrs**

6. Methods of systematic phytochemical analysis including extraction and identification of plant constituents using chromatographic techniques.
   Quality control of crude drugs : proximate analysis including ash and extractive values, crude fibre content, U.V. and fluorescence analysis of powdered drugs.
   WHO guidelines for the quality control of raw materials used in herbal formulations.
   Analysis of official formulations derived from crude drugs including some Ayurvedic preparations. **14 Hrs**

7. Automated analysis **02Hrs**

Specialization paper – III
Pharmaceutical Analysis II
Practical
(Six hours per week, 8 credits)

1. Determination of active constituents in crude drugs. e.g. Caffiene from tea powder, curcumin from curcuma longa, quinine from cinchona bark etc.
2. Determination of extractive values of crude drugs.
3. Determination of Rf values of different amino acids and alkaloids.
4. Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and Ferrous Fumerate I.P.
5. Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
7. Determination of related substances in Albendazole, Amiloride, Metronidazole, Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol, Eucalyptus oil, Phenylbarbitone and Sulphafurazone, Rifampicin as per I.P.
8. Quality Control tests for some herbal formulations.

References Books:

1. Harry G Brittain, Spectroscopy of Pharmaceutical Solids, Drugs and Pharm Sci.Series, Vol. 160, Taylor and Francis, 2006 N.Y.
2. Lena Ohannesian and Anthony J. Streeter, Hand Book of Pharmaceutical Analysis, Pharm Sci. series, Vol. 117, Maarcel Dekker Inc., N.Y
3. Peptide and Protein Drug Analysis, by Reid,(Marcel Dekker).
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
5. A text book of Pharmaceutical analysis by K.A.Conners (John Wiley)
6. Indian Pharmacopoeia,Vol. I and Vol. II - 2010.The Controller of Publications; New Delhi, Govt. of India,
7. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
8. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
9. Basic tests for pharmaceutical substances – WHO (1988)
10. Basic tests for pharmaceutical dosage forms – WHO (1991)
11. Phytochemical Methods by J.B.Haroborne
12. Pharmacopoeial standards for Ayurvedic Formulation (Council of Research in Indian
13. Medicine & Homeopathy)
14. ICH guideline for impurity determination and stability studies.
15. WHO guide lines for the quality control of Herbal plant materials.
16. The Practical evaluation of phytopharmaceutical by Brain & Turner.
17. Indian Herbal Pharmacopoeia, Vol.1&2, RRL, IDMA, 1998, 2000.
18. Ayurvedic Formulary of India.
19. British Herbal Pharmacopoeia.

Gujarat Technological University

Master of Pharmacy

Semester – II

Paper code -2920207

Specialization paper – IV

PHARMACEUTICAL ANALYSIS SPECIALISATION

QUALITY CONTROL & QUALITY ASSURANCE

Theory

(Six hours per week, 8 credits)

1) **Drug Regulatory Affairs)-** Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

15 Hrs

2) **Stability Testing-** Role of stability testing, stability test guidelines and Regulatory requirements. Protocol of stability testing including testing under different climatic zones and conditions. Conduct of stability testing. Presentation and recording of stability data, Interpretation of data, determination of shelf life. Stability test equipment and recent developments in this area. **15 Hrs**

3) **Documentation-** Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents. **2 Hrs**

4) **GMP of Pharmaceuticals-** Current GMP in manufacturing, processing, packaging of drugs. GMP for finished products. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, container and closures, production and process, packaging and labeling, laboratory and control of records and reports. **15 Hrs**

5) **Good Laboratoy Practice-** Current GLP in manufacturing, responsibilities. General provision, organization and personnel, building and facilities, equipment, control of components and drug product, laboratory and control of records and reports, Non-clinical testing, Controls on animal house, Application of Computers in Quality control Laboratory. **10 Hrs**

6) Regulatory aspects of Pharmaceuticals and Bulk Manufacturing, WHO Certification Globalization of Drug Industry, Patent regime. **3 Hrs**

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. S. Weinberg, "Good Laboratory Practice Regulation" Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
3. WHO's "Drug" Bulletins
4. GMP practices for pharmaceutical-James Swarbrick.

5. Gnarino Richard A, New Drug Approval Process, 3 rd Ed., Marcel Dekker Inc.
6. Ira R. Bery, "Introduction to the Pharmaceutical Regulatory Process", Drugs and Pharm Sci. Series, Vol. 144, Marcel Dekker Inc., N.Y.
7. ICH guide lines
8. Drug stability: Principles and practices by Jens T. Carstensen
9. Stability Testing of Drug Products by W.Grimm. .
10. Stability of Drugs and Dosage Forms by Yoshioka and Stella.
11. A.C. Cartwright and Brian Mathews,"International Pharmaceutical Registration" Taylor and Francis Ltd. UK, 2002

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920108
Subject of Specialization paper –III
Industrial Pharmacy Paper-III
Theory
(Six hours per week, 7 Credits)

1) **Legislative requirements** as per drug & cosmetic act for obtaining manufacturing licenses for different categories of pharmaceutical products. Approval formalities as per factory act, excise and WHO GMP certification scheme, etc. **10 Hrs.**
2) Aims, objects and salient features of following legislations governing Pharmaceutical Industry-Pollution control act, Prevention of Food Adulteration Act 1954, Industrial Development & Regulation Act 1951, Consumer Protection Act **12 Hrs.**
3) **Packaging components and its evaluation**: **10 Hrs.**
   Factors affecting selection, Types and classification, Primary and secondary and regulatory aspects, Contribution in stability of the dosage forms
   Films for Flexible Packages: Types of films, materials used for film production, production and evaluation of *Oriented and Non-oriented, Stretchable films and Laminates.*
   Strip Packaging: Significance of Strip Packing, advantages, economics and limitation of Strip Packing, Strip Packing machinery, films employed in Strip Packing (including composites and laminates) and evaluation of films and strips packs.
   Blister Packaging: Blister packing materials, significance of Blister packing, advantages, economics and limitation of blister packing, blister packing machinery, various types of blister packages, and evaluation of blister package.
   Sterile Product Packaging: General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages.
   In-process quality control tests for various dosage forms including packaging and labeling operations.
4) **Disperse systems:** General consideration and recent advances in disperse system technology with main emphasis on pharmaceutical suspensions and emulsions, Quality control of disperse systems
   Aerosols: General considerations, recent developments, study of various components of aerosol system, formulation, aerosol filling processes and machinery, Quality control of aerosols.
   Parenterals: General considerations, recent developments, formulation, stabilization and manufacturing of small and large volume parenterals, production of injectable grade water, environmental controls and design consideration for parenteral production facility, freeze drying. In process quality control.
   Semisolid dosage forms: General considerations, recent developments, formulation and large scale production of various types of semi solid dosage forms, factors affecting release of drugs from semisolid dosage forms. Quality control of semisolid dosage forms. **08 Hrs.**
5) **Stability Study as per** I.P., ICH, other regulatory requirements **12 Hrs.**

6) **SUPAC guidelines** for different dosage forms like; Immediate release, Modified release, semisolid, etc. including equipments amendment. BACPAC guidelines for active pharmaceutical ingredients. **08 Hrs.**

Reference Books:

1. Pharmaceutics "The Science of Dosage Form Design" by Aulton.
2. Encyclopedia of Pharmaceutical Technology Volumes: 1 to 19.
3. Remington's Pharmaceutical Sciences 19th edition.
4. Modern Pharmaceutics by G.S.Banker
5. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc .N.Y.
6. The Theory and Practice of Industrial Pharmacy by Leon Lachman.
7. Pharmaceutical Production Facilities, Design and applications by Graham C. Cole.
8. International Pharmaceutical Product Registration by Anthony C. Cartwright.
9. Encyclopedia of Controlled Drug Delivery Volumes 1 and 2 by Banker Gilbert
10. Pharmaceutical dosage forms, Parenterals medications: Vol. 1 & 2 by Avis Kenneth
11. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
12. Stability of drug and dosage forms by Yoskioka.
13. Pharmaceutical dosage forms, Aerosol systems by Lachman L., Liberman H.
14. Pharmaceutical dosage forms, Disperse systems by Lachman L., Liberman H.

Practicals
(Six hours per week, 8 Credits)

Practical exercises formulated bases on the topics mentioned in the theory such as Accelerated stability analysis, Packaging testing and evaluation, Case studies of different acts, Disperse system, parentrals, semisolids etc.

Gujarat Technological University
Master of Pharmacy
Semester – II
Paper code -2920208
Subject of Specialization paper –IV
Industrial Pharmacy Paper-IV
Theory
(Six hours per week, 8 Credits)

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, OHSAS 14000, Quality audits etc. **08 Hrs.**
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development. **04 Hrs.**
3. Brief introduction to general requirements of health regulatory agencies such as USFDA, MCC, TGA, MHRA, ANVISA, eCTD, WHO, ICH **12 Hrs.**
4. Preparation of documents for new drug application and export registration. Clinical study and basic concepts of Good clinical practice. **03 Hrs.**
5. Concepts in validation, validation of manufacturing and analytical equipments. Process validation in production of pharmaceuticals.
   Electronic records (21CFR11) **10 Hrs.**
6. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER. **08 Hrs.**
7. Regulatory aspects of pharmaceutical and bulk drug manufacture and biotechnology derived product. **08 Hrs.**
8. Study of compendia – Evolution, Study of parts of compendia like: Policies, General notices, Monographs, Comparative picture of IP, USP, BP, EP&GP **07 Hrs.**

Reference Books:

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Marcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Marcel Dekker Inc., N.Y.
5. The guidance documents shall be procured from the website of the respective Government.

Gujarat Technological University

Subject Codes/ Teaching/Evaluation Scheme for M. Pharm.

Semester III-(Revised from July-2013)

Branch Code	Branch Name/Specialization	Subject	Subject Code	Subject Name	Teaching Scheme		Evaluation Scheme			
					Credits		Theory		Practical	
					Theory	Practical	External	Internal	External	Internal
00	GENERAL	**Modern Analytical Techniques**	930001	Exprimental design and patents	7	0	80	20	0	0
01	Pharm. Chemistry	**Subject of specialization Paper V**	930101	Advanced Medicinal Chemistry	7	8	80	20	80	20
02	Pharmaceutical Tech. and Pharmaceutics		930102	Novel Drug Delivery System: Part – II	7	8	80	20	80	20
03	Pharmacology		930103	Clinical Research and Pharmacy Practice	7	8	80	20	80	20
04	Qual. Assurance		930104	Validation and Product Development	7	8	80	20	80	20
05	Pharmacognosy		930105	Traditional Drugs	7	8	80	20	80	20
06	Clinical Pharmacy		930106	Applied Pharmacotherapeutics - II	7	8	80	20	80	20
07	Pharmaceutical Analysis		930107	Pharmaceutical and Cosmetic Analysis	7	8	80	20	80	20
08	Pharmaceutics		930102	Novel Drug Delivery System: Part – II	7	8	80	20	80	20
09	Pharmaceutical Quality Assurance		930104	Validation and Product Development	7	8	80	20	80	20
10	Pharmaceutical Technology		930102	Novel Drug Delivery System: Part – II	7	8	80	20	80	20
11	Pharmacology &Toxicology		930103	Clinical Research and Pharmacy Practice	7	8	80	20	80	20
12	Industrial Pharmacy		930108	Industrial Pharmacy-V	7	8	80	20	80	20
13	Quality Assurance Technique		930104	Validation and Product Development	7	8	80	20	80	20
14	Medical Chemistry		930101	Advanced Medicinal Chemistry	7	8	80	20	80	20
15	Quality Assurance and Pharm Regulatory Affairs		1931501	Drug Regulation and Regulatory Authority	7	8	80	20	80	20
16	Pharmaceutical Management and Regulatory Affairs		1931601	Regulatory Affairs-II	7	8	80	20	80	20
01	Pharm. Chemistry		930201	Introduction to Dissertation	0	8	-	-	80	20
02	Pharmaceutical Tech. and Pharmaceutics		930202	Introduction to Dissertation	0	8	-	-	80	20
03	Pharmacology		930203	Introduction to Dissertation	0	8	-	-	80	20
04	Qual. Assurance		930204	Introduction to Dissertation	0	8	-	-	80	20

05	Pharmacognosy	**Introduction to Dissertation**	930205	Introduction to Dissertation	0	8	-	-	80	20
06	Clinical Pharmacy		930206	Introduction to Dissertation	0	8	-	-	80	20
07	Pharmaceutical Analysis-I		930207	Introduction to Dissertation	0	8	-	-	80	20
08	Pharmaceutics		930202	Introduction to Dissertation	0	8	-	-	80	20
09	Pharmaceutical Quality Assurance		930204	Introduction to Dissertation	0	8	-	-	80	20
10	Pharmaceutical Technology		930202	Introduction to Dissertation	0	8	-	-	80	20
11	Pharmacology &Toxicology		930203	Introduction to Dissertation	0	8	-	-	80	20
12	Industrial Pharmacy		930208	Introduction to Dissertation	0	8	-	-	80	20
13	Quality Assurance Technique		930204	Introduction to Dissertation	0	8	-	-	80	20
14	Medical Chemistry		930201	Introduction to Dissertation	0	8	-	-	80	20
15	Quality Assurance and Pharm Regulatory Affairs		1931502	Introduction to Dissertation	0	8	-	-	80	20
16	Pharmaceutical Management and Regulatory Affairs		1931602	Introduction to Dissertation	0	8	-	-	80	20

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm.

Semester – III

Structure for Third Semester of Master of Pharmacy Course

Sr. No.	Subject	Teaching Scheme		Marking Scheme			
		Credits		Theory		Practical	
		Theory	Practical	Ext	Intl	Ext	Intl
1.	Experimental Design and Patents	07	-	80	20	--	--
2.	Subject Specialization of Paper – V	07	08	80	20	80	20
3.	Introduction to Dissertation	--	08	--	--	80	20
	Total	**14**	**16**				

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Semester – III

Paper code -930001

Common Subject for all

Experimental Design and Patents

(Theory only)

(Four hours per week, 7 credits)

1. **Experimentals Designs**
   Introduction to full and fractional factorial designs, Central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subject mentioned under Pharmacoinformatics, Introduction to contour plots.
2. **Patents**
   Definition, Need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search,
   The essential elements of patents, Guidelines for preparations of laboratory notebook, non-obviousness in patents, Drafting of patent claims, important patent related websites.
3. **Brief introduction to trademark protection and WO patents,**
   Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application.

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Semester – III

Paper code -930102

Subject of Specialization Paper – V (Pharmaceutics)

Novel Drug Delivery System: Part – II

Theory

(Four hours per week, 7 credits)

1. Polymer Science Application: Classification, Properties, IIG status and impurity profile, Mechanisms of biodegradation and application in dosage forms.
2. Basic Techniques for development of NDDS: Nanotechnology, Bioadhesive systems, Insitu gels, intelligent drug delivery, and tailor made medicines, Strips, Disketts and film products. Liposomes/neosomes. Ionto and sonophoretic systems.
3. Use of Spherical Techniques, Super and sub-critical fluids, PEGylations. Biotech based products, Proteins and peptides, Immunomoduated molecules. Prodrug approach.

Subject of Specialization Paper – V (Pharmaceutics)

Novel Drug Delivery System: Part – II

Practical

(Six hours per week, 8 credits)

Development of NDDS using novel polymers and technologies studied in theory (as described above)

Reference Books:

1. Encyclopedia of pharmaceutical technology; volume 9 Metered dose inhalers
2. Praveen Tyle , Drug delivery devices: fundamentals and applications, Marcel Dekker.
3. Robinson & Lee, controlled drug delivery: fundamentals and applications, 2nd edition
4. Chien Y.W., Novel fundamentals, developmental concepts, biomedical assessments.
5. Lachman L., Liberman H. A., Kanig J. L., The theory and practise of industrial pharmacy. 2nd Edition 1991, Varghese publishing house,
6. Remington:the science and practice of pharmacy.
7. James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Marcel Dekker, III.
8. G.S.Banker, Modern Pharmaceutics, 3rd edition.
9. Delivery of Protein Therapeutics, Ajay K.Banga, Pharmatech 2003.
10. Encyclopedia of pharmaceutical technology – volume –16
11. "Computers in Pharmaceutical Technology", Encyclopedia of Pharmaceutical Technology, Volume 3.

12. The theory & practice of industrial. Pharmacy by L.Lachman J.L. Kanning 3rd edition. New Drug Approval Process, Fifth Edition, edited by Richard A. Guarino
13. Protein Formulation and Delivery, Second Edition, edited by Eugene J. McNally and Jayne E. Hastedt
14. Oral-Lipid Based Formulations: Enhancing the Bioavailability of Poorly Water-soluble Drugs, edited by David J. Hauss
15. Microencapsulation: Methods and Industrial Applications, Second Edition, edited by Simon Benita.
16. Supercritical fluid technology for drug product development edited by peter york, uday b. kompella, and boris y. shekunov,drug and the pharmaceutical sciences. Vol 138
17. Polymeric drug delivery systems, edited by glen s. kwon drug and the pharmaceutical sciences. Vol 148
18. Transdermal drug delivery system: 2nd edition, revised and expanded, edited by Richard h.guy and jonathan hadgraft. Drug and the pharmaceutical sciences. Vol 123
19. Bioadhesive drug delivery system, fundamental novel approaches and development, edited by edith mathiowitz, Donald.e, chickering III, claus michael lehr. Drug and the pharmaceutical sciences. Vol 98.

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M. Pharm.

Semester – III

Paper code -930101

Advanced Medicinal Chemistry

Subject of Specialization Paper- V (Pharmaceutical Chemistry)

Theory

(Four hours per week, 7 credits)

Combinatorial Chemistry

Introduction, combinatorial approaches, applications, methodology, combinatorial organic synthesis, Peptide and small molecule libraries, assays and screening of combinatorial libraries, introduction to High Throughputs Screening (HTS)

1. **Peptides as a Drug**
   Chemistry, structure and stability, Reactivity of proteins and peptides. Different methods of synthesis. Study of Insulin, Relaxin, Somatostatin, Interferon, Peptidomimetics

2. **Microorganisms in Drug Synthesis and Development**
   Microbial conversions of drugs like steroids, prostaglandin, antibiotics, enzyme immobilization Techniques.

3. **Recent advances in therapy of following**
   - **a.** Neurodegenerative diseases: Alzheimer's and Parkinsonism
   - **b.** CVS disorders: Hypertension, Arrhythmia,Atherosclerosis.
   - **c.** Hormonal disorder: hypoglycemic agents and steroidal agents
   - **d.** Disorders of immune system: NSAID's, antihistamines, immunomodulators
   - **e.** Chemotherapeutic agents: antituberculer, antimalarial, antiviral, anti-cancer, antifungal, antibacterials

Advanced Medicinal Chemistry
Subject of Specialization Paper- V (Pharmaceutical Chemistry)

Practical
(Six hours per week, 8 credits)

Practical exercises based on the relevant topics. Synthesis of some drug and drug intermediate falls under therapeutic class mentioned in theory syllabus.

Reference Books:

1. Corwin Hansch, Peter G. Sammes, John B. Taylor; Comprehensive Medicinal Chemistry Vol. 4, Pergamon.
2. John H. Block, John M. Beale; Wilson & Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 11th edition, Lippincott Williams and Wilkins.
3. Davis A. Williams, Thomas L. Lemke; Foye: Principles of Medicinal Chemistry, 5th edition, Lippincott Williams Wilkins.
4. Bernard Testa, Walter Fuhrer – Perspectives in Medicinal Chemistry.
5. Donald J. Abraham; Berger's Medicinal Chemistry and Drug Discovery, 6th edition, John Wiley and Sons.
6. Daniel Lednicer; the Organic Chemistry of Drug Synthesis, Vol. 1-6, Wiley Interscience.
7. Richard B. Silverman: The Organic Chemistry of Drug Design and Drug action; 2nd edition, Elsevier.

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M. Pharm.

Semester – III

Paper code -930103

Clinical Research and Pharmacy Practice

Subject of Specialization Paper- V (Pharmacology)

Theory

(Four hours per week, 7 credits)

1. **Clinical development of drug**

   Introduction to clinical trials, various phases of clinical trials,
   IND applications, ANDA, NDA, Investigator Brochure
   Ethical guidelines in clinical research, Inform consent process,
   Composition, responsibility, procedures of IRB/IEC
   Role and responsibility of clinical trials personals as per ICH GCP guidelines.

2. **Clinical Pharmacy Practice**

   Concept of essential and Rational Drug use.
   General principles of clinical pharmacokinetics
   General principle of clinical toxicology
   Drug induced diseases, adverse drug reaction; their monitoring and reporting (Pharmacovigilance)
   Drug interaction- Prescription monitoring, documentation and other methods for minimizing clinically relevant drug interaction.
   Therapeutic drug monitoring and dosage adjustment in renal and hepatic disorders
   Drug treatment for special category of patients: pediatric and Geriatric consideration for drug treatment, drug treatment for pregnancy and lactation.
   Racial, ethnic and gender differences in response to drug (Pharmacogenetics)
   Principles of Pharmacoepidemilogy, and Pharmacoeconomics
   Interpretation of clinical laboratory test: Hematological, pathological and Biochemical investigations as markers of Disease/organ damage and their impact on drug therapy decision.
   Critical care: Critical care therapy and Transplantation

Clinical Research and Pharmacy Practice

Subject of Specialization Paper- V (Pharmacology)

Practicals

(Six hours per week, 8 credits)

Practical scenario on essentiality concept and skill for clinical pharmacy practice (2 cases each)
Rational drug use and essential drug concept
Medication adherence
Interpreting laboratory data –biochemistry and hematology
Interpreting laboratory data –infectious disease
Patient Counseling
Ward round participation
Therapeutic drug monitoring
Drug therapy review
Drug Interaction
Adverse drug reaction
Geriatric pharmacy practice
Pediatric pharmacy practice
Pharmacy practice for pregnant women

Evaluation of drug formulation (based on essentiality and rationality-50 formulations):
Illustrated Examples
Rational drug therapy for nutritional anemia
Rational drug therapy for Cough
Rational drug therapy for diarrhea
Prescription audit (10)
Protocol preparation for submission to IRB

Reference Books:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Pharmacy and Therapeutics Roger walker and Clive Edwards,Churchill Livingstone Edinburgh
7. Davidson's Principle and Practice of Medicine, EDs Christopher, Haslett, Edwin R.Chilvers.
8. Harrison's Principles of Internal medicine- Vol 1 and 2 Braunwald, Eugene & Others.
9. Textbook of Therapeutics Drug Disease Management- Eric T.Herfindal and Dick R.Gourley.
10. Comprehensive Pharmacy Review- Shargel Leon
11. Melmon and Morrells Clinical Pharmacology 4th Edition – S George Carrythers
12. A textbook of Clinical pharmacy practice- Parthasarthi G.

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M. Pharm.

Semester – III

Paper code -930106

Applied Pharmacotherapeutics – II

Subject of Specialization Paper- V (Clinical Pharmacy)

Theory

(Four hours per week, 7 credits)

Pathophysiology, Diagnosis & Pharmacotherapeutic management of acute and chronic diseases

1. **Haemopoetic:**Anemias, Coagulation diseases.
2. **Joint and Connective Tissue:** Rheumatoid arthritis, osteoarthritis, gout and hyperuricemia
3. **Neoplastic:** Acute leukemias, Hodgkins disease, carcinoma of breast, Liver tumors, gastrointestinal cancers, lung cancer, prostate cancer, pediatric solid tumors, gynecological cancers and skin cancers.
4. **Infections**: Various infectious diseases including Tuberculosis, urinary tract infections, enteric infections, upper respiratory tract infections, Pneumonia, Intraabdominal infections, gastrointestinal infections, bone and joint infections, sepsis, parasitic infections, sexually transmitted diseases and AIDS
5. **Renal:** Acute renal failure, chronic renal failure.
6. **Diseases of skin:** Contact dermatitis, Acne Vulgaris, psoriasis, warts, burns.
7. **Eye:** Glaucoma & Conjunctivitis
8. **Reproductive System:** Male and Female reproductive system and their hormones. Physiology of menstruation, coitus and fertilization. Sex differentiation, spermatogenesis, pregnancy its maintenance and parturition
9. **Managing ICUs, T.P.N. and Emergencies**
10. **Concept of acute care medicine**
11. **General treatment guideline for: Pediatric patients, geriatric patients, pregnancy & lactating mother**

Applied Pharmacotherapeutics – II

Subject of Specialization Paper- V (Clinical Pharmacy)

Practical

(Six hours per week, 8 credits)

Each student has to undergo compulsory Hospital postings for understanding and gaining knowledge of Pathophysiology, Diagnosis & Pharmacotherapeutic management various diseases and disorders.

It is mandatory that each student has to maintain a record of at least 15 case studies based on the theory topics

Assignments: The students are required to submit a minimum of two written assignments selected from the topics given to them.

Reference Books:

1. Clinical Pharmacy and Therapeutics. Roger Walker and Clive Edwards, Churchill Livingstone publication
2. Text Book of Therapeutics: Drug and Disease Management. 7th Edition. Editors: Eric T. Herfindal and Dick R. Gourley, Williams and Wilkins
3. Pathology & Therapeutics for Pharmacists. Russel. J. Greene and Normal F. Harris. Chapman & Hall, London/ Glasgow/ Madras.
4. Robbins Pathologic Basis of Disease. Cartran, Kumar, Collins, W.B.Saunders. Latest edition.
5. Applied Therapeutics: The Clinical Use or Drugs Eds. Brian S.Katcher, Lioyd Yee Young, Marry Anne Koda-Kimble, Applied Therapeutics Inc. Spokane. Latest Edition.
6. Pharmacotherapy: A Pathophysiologic approach – Joseph T. Dipiro et al. Appleton & Lange
7. Harrisons Principles of Internal Medicine. Medical Toxicology (Ellen Horns)
8. Davidson's Principle and Practice of Medicine, Eds. Christopher R. W., Edwards & Ian A.D. Boucher ELBS with Chu0rchill Living stone. Edinburgh. Latest Edition.
9. Avery's Drug Treatment, 4th End, 1997 Adis International Limited
10. Relevant review articles from recent medical and pharmaceutical literature.

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Semester – III

Paper code -930105

Traditional Drugs

Subject of Specialization Paper – V (Pharmacognosy)

Theory

(Four hours per week, 7 credits)

1. Distribution and chemotaxonomy of volatile oil in plants. Role of volatile oils in medicine, their industry and industrial importance in India.
2. Biodiversity conservation, economic development and drug discovery from traditional medicinal plants of India.
3. Plant growth regulators.
4. Methods of isolation, purification, identification, estimation, conversion to useful derivatives and importance of following phytopharmaceuticals:
   a. Vinca alkaloids
   b. Morphine
   c. Reserpine
   d. Quinine
   e. Diosgenin
   f. Solasodine
   g. Glycyrrhizin
   h. Picroside
   i. Rutin
   j. Vasicine
   k. Ephedrine
   l. Anthraquinones
5. Herbal medicine information sources, books, journals, online databases.

Traditional Drugs

Subject of Specialization Paper – V (Pharmacognosy)

Practical

(Six hours per week, 8 credits)

Practical exercises based on the relevant topics mentioned in theory syllabus.

Reference Books:

1. Stephen K. Sim, Medicinal Plant Glycosides, University of Toronto Press, Canada.
2. Stephen K. Sim, Medicinal Plant Alkaliods, University of Toronto Press, Canada.

3. Olayiwola Akerele, Vernon Heywood and Hugh Synge (Editors), The Conservation of Medicinal Plants, Printed by Cambridge University Press, Cambridge.
4. Atal C.K. and Kapur B.M., Cultivation and Utilization of Medicinal Plants, Published by RRL, Jammu-Tawi, 1982.
5. Handa S.S & Kaul K.L., Supplement to cultivation and utilization of medicinal plants, 1996.
6. R.D. Chaudhary, Herbal Drugs Industry, Eastern Publishers, New Delhi.
7. Wagner H., Bladt S. and Zgainski, Plant Drug Analysis Springer, Verlag, New York.
8. Peach K. and Tracey M.V., Modern Methods of Plant Analysis, 1-4, Narosa Publisher House, N.D.
9. Indian Herbal Pharmacopoeia, Vol. I and II, Jointly published by RRL, Jammu and IDMA, Mumbai – 1998 and 1999.
10. British Herbal Pharmacopoeia, Published by British Herbal Medicines Association 1996.
11. Trease E and Evan's W.C., Pharmacognosy, 15th edition, Balliere Tindall. Eastbourne, U.K., 2002.
12. James E. Robbers, Varro E. Tyler, Herbs of Choice – The Therepeutic Use of Phytomedicinals.
13. Guenther, The Essential Oils, Vol. I and II, Published by D.Van Nostrand Company Inc., 1948.
14. R. H. F. Manske, The Alkaloids-Chemistry and Physiology, Published by Academic Press, London.
15. Zechmeister, Progress in the Chemistry of Organic Natural Products, Published by Springler-Verlag Wien, Austria.

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M. Pharm.

Semester – III

Paper code -930104

Validation and Product Development

Subject of Specialization Paper – V (Quality Assurance)

Theory

(Four hours per week, 7 credits)

1. **Introduction to Pharmaceutical Validation:**
   Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master Plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.
2. **Calibration Master plan**
   Validation of Equipment
   Concept of URS, DQ, IQ, OQ & PQ,
   Validation of following equipment
   - Dry Powder Mixers
   - Fluid Bed and Tray dryers.
   - Tablet Compression (Machine)
   - Dry Heat Sterilization/Tunnels
   - Autoclaves
   - Membrane filtration
   - Capsule filling machines.
   - Validation of Integrated lines by media fill test.
   - Validation of existing equipment.
3. **Vendor Certification**
4. **Utilities Validation**
   a. Validation of Pharmaceutical Water System & pure steam,
   b. Validation of HVAC system
   c. Validation of Compressed air
5. **Cleaning Validation:** Cleaning of Equipment, Cleaning of Facilities
6. **Analytical Method Validation**
   General principles of analytical method validation.
   Validation of following analytical Instruments
   - HPLC
   - Dissolution test apparatus
   - U.V./Visible spectrophotometers
7. **Process Validation**
   Prospective, concurrent, retrospective & revalidation, Process validation of following formulations
   - Coated tablets
   - Capsules
   - Ointment/Creams

- Liquid Orals

8. **Computer System Validation**
9. **Product development**
   a. In-process controls in manufacturing process design and development of:
   Tablets,
   Capsule
   Liquid orals
   Ophthalmic applications
   Aerosols
   Sterile parenteral
   b. Scale up operations, SUPAC guide line.

Validation and Product Development

Subject of Specialization Paper – V (Quality Assurance)

Practical

(Six hours per week, 8 Credits)

1. Validation of following equipment
   a. Autoclave b. Hot air oven c. Powder Mixer (Dry)
   c. Tablet Compression Machine
2. Pre-formulation studies of a model Drug.
3. Validation of analytical method (minimum four exercises).
4. Validation of a processing area.
5. Validation of at least two analytical instruments.
6. Cleaning validation of one equipment.

Reference Books:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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M. Pharm.

Semester – III

Introduction to Dissertation (For all branches)

16 Hour/week

Instructions:

1. Student must complete literature search and preliminary experimental work of his/her research project and submit the synopsis, dully signed by Research Guide and Principal of Institute to University on completion of Semester – III.
2. Utmost care should be taken in selection of research topic so that repetition of research work is avoided.
3. For change in research topic, written permission of institute level research committee should be taken.
4. Candidates work will be evaluated by the external examiner through viva-voce.

Gujarat Technological University

M. Pharm. Semester III

Paper code -930107

Paper V (Pharmaceutical Analysis)

PHARMACEUTICAL AND COSMETIC ANALYSIS

THEORY

(Four hours per week, 7 credits)

1. STABILITY OF DRUGS AND DRUG PRODUCTS. **15 Hours.**

a. Drug decomposition mechanisms:

(i) Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
(ii) Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
(iii) Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

b. Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:
(1) Solids – tablets, capsules, powder and granules
(2) Disperse systems
(3) Microbial decomposition
(4) Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

2. Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation. **5 Hours.**

3. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs. **5 Hours.**

4. General method of analysis to determine the quality of raw materials used in cosmetic industry. **7 Hours.**

5. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards. **7 Hours.**

6. Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. **15 Hours.**

7. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products. **6 Hours.**

M. Pharm. Semester III

Paper V (Pharmaceutical Analysis)

PHARMACEUTICAL AND COSMETIC ANALYSIS

Practical

(Six hours per week, 8 Credits)

1. Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
2. Physical stability testing of dosage forms:
   (1) Solids – tablets, capsules, powder and granules
   (2) Disperse systems
3. Analysis of drugs in biological fluid: Plasma, urine, saliva etc
4. Testing of raw materials used in cosmetic industry.
5. Analysis of cosmetics in the finished forms.

Reference Books :

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.
3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
4. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 2010.
5. J. B. Wilkinson and R. J. Moore : Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
6. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
7. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
8. Cosmetic and toilet goods – methods of sampling IS 3958 of Indian Standards Institution (BIS).
9. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
10. Drug stability: Principles and practices by Jens T. Carstensen
11. Stability Testing of Drug Products by W.Grimm.
12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

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M. Pharm.

Semester III

Paper-V

Paper code: 930108

Industrial Pharmacy Paper-V

Theory

(Four hours per week, 7 credits)

1. Advances in pharmaceutical process technology including lyophillization, extrusion spheronization, FFS/BFS, prefilled syringes, Electrostatic coating, fluid bed granulating and coating, ALU-ALU packaging, laser printing
2. Novel formulation process technology; concepts and systems design on bases of flow chart of manufacturing of rate controlled drug delivery, liposome, niosomes, TDDS, mucoadhesive, osmotic, floating, micro and nanoparticulate drug delivery etc.
3. Good engineering practice, maintenance and cleaning in industrial pharmacy

Reference Books:

1. Pharmaceutics "The Science of Dosage Form Design" by Aulton.
2. Encyclopedia of Pharmaceutical Technology Volumes: 1 to 19.
3. Remingtons Pharmaceutical Sciences 19th edition.
4. Modern Pharmaceutics by G.S.Banker
5. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc.N.Y.
6. Encyclopedia of pharmaceutical technology; volume 9 Metered dose inhalers
7. Praveen Tyle , Drug delivery devices: fundamentals and applications, Marcel Dekker.
8. Robinson & Lee, controlled drug delivery: fundamentals and applications, 2nd edition
9. Chien Y.W., Novel fundamentals, developmental concepts, biomedical assessments.
10. G.S.Banker, Modern Pharmaceutics, 3rd edition.
11. Protein Formulation and Delivery, Second Edition, edited by Eugene J. McNally and Jayne E. Hastedt
12. Oral-Lipid Based Formulations: Enhancing the Bioavailability of Poorly Water-soluble Drugs, edited by David J. Hauss
13. Microencapsulation: Methods and Industrial Applications, Second Edition, edited by Simon Benita.

Practical

(Six hours per week, 8 Credits)

Practical design formulated based on the topics such as Lab Level development of Novel pharmaceutical processes, Pharmaceutical process technology etc.

Gujarat Technological University

Subject Codes/ Teaching/Evaluation Scheme for M. Pharm.

Semester IV-(Revised from Jan-2014)

Branch Code	Branch Name/Specialization	Subject	Subject Code	Subject Name	Teaching Scheme	Evaluation Scheme			
					Credit	External		Internal	Total Marks
						Thesis Progress Review	Final Dissertation	Internal Thesis Evaluation	
01	Pharm. Chemistry	Dissertation	940101	Dissertation	30	60	100	40	200
02	Pharmaceutical Tech. and Pharmaceutics		940102		30	60	100	40	200
03	Pharmacology		940103		30	60	100	40	200
04	Qual. Assurance		940104		30	60	100	40	200
05	Pharmacognosy		940105		30	60	100	40	200
06	Clinical Pharmacy		940106		30	60	100	40	200
07	Pharmaceutical Analysis		940107		30	60	100	40	200
08	Pharmaceutics		940102		30	60	100	40	200
09	Pharmaceutical Quality Assurance		940104		30	60	100	40	200
10	Pharmaceutical Technology		940102		30	60	100	40	200
11	Pharmacology &Toxicology		940103		30	60	100	40	200
12	Industrial Pharmacy		940108		30	60	100	40	200
13	Quality Assurance Technique		940104		30	60	100	40	200
14	Medical Chemistry		940101		30	60	100	40	200
15	Quality Assurance and Pharm Regulatory Affairs		1941501		30	60	100	40	200
16	Pharmaceutical Management and Regulatory Affairs		1941601		30	60	100	40	200