17BP101T SEMESTER-I

HUMAN ANATOMY AND PHYSIOLOGY-I (Theory) 4H 4C

Instruction hours/ week: L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total: 100
External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To know various homeostatic mechanisms and their imbalances
- Students can Illustrate the body fluids coagulation, blood grouping, Rh factors and disorders of blood
- Knows about bones, Joints and their functions in the human body

Course Outcomes (CO's): On successful completion of the course the student will

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. Illustrate the body fluids coagulation, blood grouping, Rh factors and disorders of blood.
5. Appreciate coordinated working pattern of different organs of each system.
6. Explain all the bones, Joints and their functions in the human body

Course Content:

UNIT-I

Introduction to human body: Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeo stasis, 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.

UNIT- II

Integumentary system: Structure and functions of skin.

Skeletal system: Divisions of skeletal system, types of bone, salient features and function of bones of axial and appendicular skeletal system Organization of skeletal muscle, physiology of muscle contraction, neuro muscular junction.

Joints - Structural and functional classification, type of joints movements and its articulation.

UNIT-III

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 anddisordersofblood,Reticuloendothelial system.

Lymphatic system: Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system.

UNIT-IV

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.

UNIT-V

Cardio vascular system: Heart– anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electro cardiogram and disorders of heart.

Reference Books (Latest Editions):

1. Physiological basis of Medical Practice-Best and Tailor. Williams &Wilkins Co, Riverview, MIUSA.
2. Text book of Medical Physiology-Arthur.C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol1 and2) by Dr.C.C. Chatterrje, Academic Publishers Kolkata.

17BP107P SEMESTER-I

HUMAN ANATOMY AND PHYSIOLOGY-I (Practical) 4H 2C

Instruction hours/week: L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- 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.
- To Identify epithelial, connective tissue, muscular, nervous tissues Microscopically and the axial, appendicular bones.
- Know about the bleeding time and clotting time.
- Know to Record the heart rate, pulse rate, blood pressure.
- Understand the WBC count and RBC count

Course Outcomes (CO's): On successful completion of the course the student will

1. Identify epithelial, connective tissue, muscular, nervous tissues Microscopically and the axial, appendicular bones.
2. Determine the bleeding time, clotting time.
3. Record the heart rate, pulse rate, blood pressure.
4. Demonstrate the WBC count and RBC count.
5. Identify the axial, appendicular bones.
6. Estimate the blood group and erythrocyte sedimentation rate.

Content:

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 clottingtime
11. Estimation of hemoglobincontent
12. Determination of bloodgroup.
13. Determination of erythrocytesedimentationrate (ESR).
14. Determination of heart rate and pulserate.
15. Recording of blood pressure.

Suggested Readings:

1. Essentials of Medical Physiology by K.Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiologyin 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, MIUSA
4. Text book of Medical Physiology-ArthurC,Guytonand John.E.Hall Miamisburg,OH, U.S.A
5. Principles of Anatomy and Physiology by TortoraGrabowski.Palmetto, GA, U.S.A.
6. Text book of Human Histology by InderbirSingh, Jaypee brother's medical publishers, NewDelhi.
7. Text book of Practical Physiology by C.L.Ghai, Jaypee brother's medical publishers, NewDelhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, NewDelhi.

Reference Books (Latest Editions):

1. Physiological basis of Medical Practice-Best and Tailor. Williams &Wilkins Co, Riverview, MIUSA
2. Text book of Medical Physiology-ArthurC, GuytonandJohn.E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol1 and2) by Dr.C.C. Chatterrje, Academic Publishers Kolkata

17BP102T SEMESTER - I

PHARMACEUTICAL ANALYSIS (Theory) **4H 4C**

Instruction hours/week: L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs
- To Understand the basic concepts and Pharmacopeial standards of pharmaceutical analysis
- To Identify the errors in analysis
- To Understand the principles of volumetric analysis
- To Understand the principles of electrochemical analysis
- Know the applications of volumetric analysis.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the basic concepts and Pharmacopeial standards of pharmaceutical analysis
2. Identify the errors in analysis
3. Understand the principles of volumetric analysis
4. Understand the principles of electrochemical analysis
5. Applications of volumetric analysis.
6. Applications of electrochemical analysis.

Course Content:

UNIT-I

(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, sodiumthio sulphate , sulphuric acid ,potassium permanganate and cericammoniumsulphate.

(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.

UNIT-II

Acid base titration: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acid sand bases, neutralization curves.

Nonaqueous titration: Solvents ,acid imetry and alkalimetry titration and estimation of Sodiumbenzoate and Ephedrine HCl.

UNIT-III

Precipitation titrations: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodiumchloride.

Complexometrictitration: Classification, metalion indicators, masking and dem asking reagents, estimation of Magnesium sulphate, and calcium gluconate.
Gravimetry: Principle and steps involved in gravimetric analysis.
Purity of the precipitate: co-precipitationandpostprecipitation, Estimation of barium sulphate. Basic Principles, methods and application of diazotisationtitration.

UNIT-IV
Redoxtitrations: (a)Concepts of oxidation and reduction (b)Types of red oxtitrations (Principles and applications) Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry,Titration with potassiumiodate.

UNIT-V
Electrochemical methods of analysis Conductometry: Introduction, Conductivity cell, Conductometric titrations, applications.
Potentiometry-Electrochemical cell, construction and working of reference (Standard hydrogen, silverchloride electrode and calomelelectrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine endpoint of potentiometric titration and applications.
Polarography - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications.

Suggested Readings:
1. A.H.Beckett& J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I&II, Stahlone Press of University of London.
2. A.I.Vogel, TextBook 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.

17BP108P SEMESTER – I

PHARMACEUTICAL ANALYSIS (Practical) 4H 2C

Instruction hours/week: L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To Analyze the limit test for samples.
- Understand how to prepare the solutions for volumetric and electro-analytical methods.
- To Standardize the solutions by volumetric and electro-analytical methods.
- Know how to Perform the assay for chemical substances.
- To Standardize the titrant used for the assay.
- To Determine the strength of the solutions by electro-analytical methods.

Course Outcomes (CO's): On successful completion of the course the student will

1. Analyze the limit test for samples.
2. Prepare the solutions for volumetric and electro-analytical methods.
3. Standardize the solutions by volumetric and electro-analytical methods.
4. Perform the assay for chemical substances.
5. Standardize the titrant used for the assay.
6. Determine the strength of the solutions by electro-analytical methods.

Content:

I **Limit Test of the following:**

(1) Chloride.
(2) Sulphate.
(3) Iron.
(4) Arsenic.

II **Preparation and standardization of:**

(1) Sodium hydroxide.
(2) Sulphuric acid.
(3) Sodiumthio sulfate.
(4) Potassium permanganate.
(5) Cericammonium sulphate.

III **Assay of the following compounds along with Standardization of Titrant:**

(1) Ammoniumchloride by acid basetitration.
(2) Ferroussulphate by Cerimetry.
(3) Coppersulphate by Iodometry.
(4) Calciumgluconate by complexometry.
(5) Hydrogenperoxide by Permanganometry.
(6) Sodiumbenzoate by non-aqueoustitration.
(7) SodiumChloride by precipitationtitration.

IV **Determination of Normality by electro-analytical methods:**

(1) Conducto metric titration of strong acid against strong base.

(2) Conducto metric titration of strong acid and weak acid against strong base.

(3) Potentio metric titration of strong acid against strong base.

Suggested Readings:

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.GunduRao, Inorganic Pharmaceutical Chemistry.
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry.
5. John H.Kennedy, Analytical chemistry principles.
6. Indian Pharmacopoeia.

17BP103T SEMESTER - I

PHARMACEUTICS (Theory) 4H 4C

Instruction hours/week: L: 3 T: 1 P:0 Marks: Internal: 25 External: 75 Total: 100

s External Semester Exam: 3 Hours

Course Objectives:

- This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.
- Students can Understand the history of profession of pharmacy
- To know the basics of different dosage forms.
- To Understand the professional way of handling the prescription
- Students will know how to Prepare various conventional dosage forms
- Students will develop a clear idea about Pharmaceutical incompatibility and different pharmaceutical calculations in pharmacy.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the history of profession of pharmacy
2. Understand the basics of different dosage forms.
3. Understand the professional way of handling the prescription
4. Prepare various conventional dosage forms
5. Develop a clear idea about Pharmaceutical incompatibility and different pharmaceutical calculations in pharmacy.
6. Predict the instability problems in semi sold dosage forms

Course Content:

UNIT– I

Historical background and development of profession of pharmacy: History of profession of Pharmacy in India in relation to Pharma cyeducation, 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, bodyweight and body surface area.

UNIT– II

Pharmaceutical calculations: Weights and measures – Imperial & Metric system, Calculations involving percentagesolutions,alligation,proofspirit 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 disadvantage soft liquid dosage forms. Excipients used in formulation of liquid dosage forms.Solubility enhacement Techniques.

UNIT– III

Monophasic liquids: Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.

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 of Emulsion, Methods of preparation &stability problems and methods to overcome.

UNIT– IV

Suppositories: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.

Pharmaceutical in compatibilities: Definition, classification, physical, chemical and therapeutic in compatibilities with examples.

UNIV– V

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.

Suggested Readings:

1. H.C. Anseletal, 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, NewDelhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Living stone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
7. AlfonsoR. Gennaro Remingt on .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. DilipM.Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, NewYork.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC New York.

17BP109P SEMESTER-I

PHARMACEUTICS (Practical) 4H 2C

Instruction hours/week: L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To Understand the professional way of preparing a prescription
- To know various liquid dosage forms preparations.
- To Prepare various solid dosage forms
- To Perform quality control tests for various dosage forms
- To Acquire the knowledge of using equipment's in pharmaceutical industry

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the professional way of preparing a prescription
2. Prepare various liquid dosage forms
3. Prepare various solid dosage forms
4. Perform quality control tests for various dosage forms
5. Acquire the knowledge of using equipment's in pharmaceutical industry

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) TerpinHydrateLinctusIP'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) Divided powders

8. Suppositories

a) Glycero gelatin suppository
b) Coca butter suppository
c) Zinc Oxide suppository

9. Semisolids

a) Sulphur Ointment
b) Non staining Iodine ointment with methyl salicylate
c) Carbopal gel

10. Gargles and Mouth Washes

a) Iodine gargle
b) Chlorhexidine Mouthwash

Suggested Readings:

1. H.C.Anseletal., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott William sand 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. AlfonsoR. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, NewDelhi.
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. DilipM.Parikh: Hand book 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.

17BP104T SEMESTER-I

PHARMACEUTICAL INORGANIC CHEMISTRY (Theory) 4H 4C

Instruction hours/week: L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total: 100
External Semester Exam: 3 Hours

Course Objective:

- This subject deals with the monographs of inorganic drugs and pharmaceuticals.
- To Understand the sources of impurities.
- Knowing the methods to determine the impurities
- Explain the medicinal and pharmaceutical importance of buffers, electrolytes and dental products
- Know about medicinal and pharmaceutical importance of gastrointestinal agents
- To Discuss the medicinal and pharmaceutical importance of expectorants, hematinics, emetics, antidotes and astringents.

Course Outcomes(CO's): On successful completion of the course the student will

1. Understand the sources of impurities.
2. Explain the methods to determine the impurities in inorganic drugs and pharmaceuticals
3. Explain the medicinal and pharmaceutical importance of buffers, electrolytes and dental products
4. Describe the medicinal and pharmaceutical importance of gastrointestinal agents
5. Discuss the medicinal and pharmaceutical importance of expectorants, hematinics, emetics, antidotes and astringents.
6. Elaborate the medicinal and pharmaceutical importance of Radiopharmaceuticals.

Course Content:

UNIT - I

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.

UNIT - II

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 isotonic city.

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 eugenolcement.

UNIT - III

Gastro intestinal 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.

UNIT - IV

Miscellaneous compounds Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartarate.

Haematinics: Ferrous sulphate*, Ferrous gluconate.

Poison and Antidote: Sodiumthio sulphate*, Activated charcoal, Sodium nitrite333.

Astringents: Zinc Sulphate, Potash Alum.

UNIT - V

Radio Pharmaceuticals: Radio activity, Measurement of radioactivity, Properties of α,β,γ radiations, Half life, radio isotope sand study of radio isotopes - Sodium iodide I131, Storage conditions, precautions & pharmaceutical application of radio active substances.

Suggested Readings:

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.GunduRao, Inorganic Pharmaceutical Chemistry, 3rdEdition.
4. M.L Schroff, Inorganic Pharmaceutical Chemistry.
5. Bentley and Driver's Text book of Pharmaceutical Chemistry.
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry.
7. Indian Pharmacopoeia.

17BP110P SEMESTER - I

PHARMACEUTICAL INORGANIC CHEMISTRY (Practical) 4H 2C

Instruction hours/week: L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- Know how to Perform Limit test for ions
- To Perform Limit test for metals
- Know how to Identify inorganic pharmaceuticals
- To Test the inorganic sample for its purity.
- To determine the physical properties of inorganic pharmaceuticals.
- Understand inorganic pharmaceuticals preparation.

Course Outcomes (CO's): On successful completion of the course the student will

1. Perform Limit test for ions
2. Perform Limit test for metals
3. Identify inorganic pharmaceuticals
4. Test the inorganic sample for its purity.
5. Determine the physical properties of inorganic pharmaceuticals.
6. Prepare inorganic pharmaceuticals.

Course content:

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 Heavymetals.
- Limit test for Lead.
- Limit test for Arsenic.

II **Identification test:**

- Magnesium hydroxide, Ferrous sulphate, Sodium bicarbonate, Calcium gluconate and Copper sulphate.

III **Testforpurity:**

- 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.

Suggested Reading:

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.GunduRao, Inorganic Pharmaceutical Chemistry, 3rdEdition.
4. M.L Schroff, Inorganic Pharmaceutical Chemistry.
5. Bentley and Driver's Text book of Pharmaceutical Chemistry.
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry.
7. Indian Pharmacopoeia.

17BP105T SEMESTER – I

COMMUNICATION SKILLS (Theory) 2H 2C

Instruction hours/week: L:2 T:0 P:0 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 2 Hours

Course Objectives:

- This course will prepare the young pharmacy student to interact effectively withdoctors, 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.
- Students will develop interview skills
- Understand Leadership qualities and essentials
- They Develop presentation and group discussion skills

Course Outcomes (CO's): On successful completion of the course the student will

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
6. Develop presentation and group discussion skills

Course content:

UNIT– I

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

UNIT– II

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.

UNIT– III

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 Writte Communication-Complexity of the Topic, Amount of Discussion's Required, Shadeso Meaning, Formal Communication.

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience Organization of the Message.

UNIT– IV

Interview Skills: Purpose of an interview, Do's and Don'ts of an interview.

Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery.

UNIT– V

Group Discussion: Introduction, Communication skills in group discussion, Do's and Don'ts of group discussion

Suggested Readings:

1. Basic communication skills for Technology, Andreja.J.RutherFord, 2nd Edition, Pearson Education, 2011
2. Communication skills, SanjayKumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen.P.Robbins, 1st Edition, Pearson, 2013
4. Brilliant-Communication skills, GillHasson, 1st Edition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, 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,Konarnira,2nd Edition,Newarrivals–PHI,2011
8. Personality development and soft skills,Barun KMitra,1st Edition, Oxford Press,2011
9. Soft skill for everyone, Butter Field,1st Edition,Cengage Learning india pvt.ltd,2011
10. Soft skills and professional communication, rancis Peters SJ, 1st Edition, McGraw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan,2009.
12. Bringing out the best in people,Aubrey Daniels, 2nd Edition, McGraw Hill,1999.

17BP111P SEMESTER-I

COMMUNICATION SKILLS (Practical) 2H 1C

Instruction hours/week: L:0 T:0 P:2 Marks: Internal: 10 External: 15 Total:25

External Semester Exam: 2 Hours

Course Objectives:

- Students can able to communicate effectively to meet the people, ask question and make friends
- To Understand the do's and don't's of effective communication.
- Know about Pronunce the sounds effectively.
- To Explain the figures of speech and direct/indirect speech.
- Know to Write effectively mails and other written communications.
- Will be able to Present a topic in a gathering.

Course Outcomes: On successful completion of the course the student will

1. Communicate effectively to meet the people, ask question and make friends
2. Understand the do's and don't's of effective communication.
3. Pronunce the sounds effectively.
4. Explain the figures of speech and direct/indirect speech.
5. Write effectively mails and other written communications.
6. Present a topic in a gathering.

Course Content

Basic communication covering the following topics:

MeetingPeople
AskingQuestions
MakingFriends
Whatdidyoudo? Do'sand
Dont's

Pronunciationscoveringthefollowingtopics

Pronunciation (ConsonantSounds)
PronunciationandNouns
Pronunciation (VowelSounds)

AdvancedLearning

ListeningComprehension/ DirectandIndirectSpeech
FiguresofSpeech
EffectiveCommunication
WritingSkills
EffectiveWriting
InterviewHandlingSkills
E-Mailetiquette PresentationSkills

Suggested Readings:

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

17BP106RBT SEMESTER-I

REMEDIAL BIOLOGY (Theory) 2H 2C

Instruction hours/week: L: 2 T:0 P: 0 Marks: Internal: 15 External: 35 Total:50
External Semester Exam: 3 Hours

Course Objectives:

- To learn and understand the components of living world, structure and functionalsystem of plant and animal kingdom.
- To know the classification and salient features of five kingdoms of life and morphology of flowering plants.
- To understand the circulatory, digestive and respiratory systems.
- To know the Nervous, Excretory and reproductive systems.
- To Understand the photosynthesis and plant and mineral nutrition.
- Will be able to know the respiration, growth of plants

Course Outcomes: On successful completion of the course the student will

1. Explain the classification and salient features of five kingdoms of life and morphology of flowering plants.
2. Describe the circulatory, digestive and respiratory systems.
3. Discuss the Nervous, Excretory and reproductive systems.
4. Understand the photosynthesis and plant and mineral nutrition.
5. Discuss the respiration, growth of plants
6. Elaborate the cell and tissues of plant and animal.

UNIT-I

Livingworld: 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, in florescence, flower, leaf, fruit,seed. General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.

UNIT-II

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, cardiacoutput and ECG

Digestion and Absorption:

- Human alimentary canal and digestive glands
- Role of digestive enzymes

- Digestion, absorption and as simulation 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

UNIT-III

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
- Parts of male reproductivesystem
- Spermatogenesis and Oogenesis
- Menstrualcycle

UNIT-IV

Plants and mineral nutrition:

- Essential mineral,macro and micro nutrients
- Nitrogen metabolism,Nitrogencycle,biological nitrogen fixation

Photosynthesis:

- Autotrophic nutrition,photosynthesis, Photosynthetic pigments,Factors affecting photosynthesis.

UNITV

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 andcell organelles cell division.

Tissues:

Definition, types of tissues, location and functions.

Suggested Readings:

1. Text book of Biology by S.B. Gokhale.
2. A Text book of Biology by Dr.Thulajappa and Dr.Seetaram.
3. A Text book of Biology by B.V.Sreenivasa Naidu.
4. A Text book of Biology by Naidu and Murthy.
5. Botany for Degree students ByA.C.Dutta.
6.Outlines of Zoology by M.Ekambaranathaayyer and T.N. Ananthakrishnan.
7. Amanual for pharmaceutical biology practical by S.B. Gokhale and C.K.Kokate.

17BP112RBP SEMESTER-I

REMEDIAL BIOLOGY (Practical) 2H 1C

Instruction hours/week: L: 0 T:0 P: 2 Marks: Internal: 10 External: 15 Total:25
External Semester Exam: 2 Hours

Course Objectives :

- Students will be able to Understand the microscope, cutting sections, mount, stain and slide preparation.
- To know about cell and its organelles
- To understand the parts of plant and their modifications
- Able to know the system using software
- Able to Identify types of bones.
- To Determine blood group, blood pressure and tidal volume.

Course Outcomes(CO's): On successful completion of the course the student will

1. Understand the microscope, cutting sections, mount, stain and slide preparation.
2. Study cell and its organelles
3. Study the parts of plant and their modifications
4. Study the system in from using software
5. Identify types of bones.
6. Determine blood group, blood pressure and tidal volume.

Course Content

1. Introduction to experiments in biology
   a) StudyofMicroscope
   b) Sectioncuttingtechniques
   c) Mountingandstaining
   d) Permanentslidepreparation
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

Suggested readings:

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 corecurriculum. Biology forum of Karnataka.Prof.M.J.H.Shafi

17BP106RMT SEMESTER-I

REMEDIAL MATHEMATICS 2H 2C

Instruction hours/week: L:2 T:0 P: 0 Marks: Internal: 15 External: 35 Total:50
External Semester Exam: 2 Hours

Course Objectives:

- This is an introductory course in mathematics.
- This subject deals with the ntroduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.
- Able to Perform calculations using matrices and determinants.
- Able to Solve problems using differential and integral calculus.
- To Calculcate the equation for straight line and coordinates.
- Students can able to pply differential equations and Laplace transformation for solving problems

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the partial fration, logarithms, function and limits.
2. Perform calculations using matrices and determinants.
3. Solve problems using differential and integral calculus.
4. Calculcate the equation for straight line and coordinates.
5. Apply differential equations and Laplace transformation for solving problems
6. Appreciate the important application of mathematics in Pharmacy

Content

UNIT- I

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(ε-δ definition), $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1$,

UNIT- II

Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transposeofa matrix, MatrixMultiplication,Determinants, Propertiesof determinants, Product of determinants, Minorsandco-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverseofamatrix, Solution of system of linear of equations using matrix method, Cramer'srule, Characteristic equation and roots of a square matrix, Cayley Hamilton theorem,Application of Matrices in solving Pharmacokinetic equations.

UNIT- III

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 (Quotientformula)–**WithoutProof**, Derivativeofx^n $w.r.t$x,where n is any rational number, Derivative of e^x,, Derivative of $\log_e x$, Derivative of a^x,Derivative of trigonometric functions from

first principles **(without Proof)**, Successive Differentiation, Conditions maximum or a minimum at a point.

UNIT -IV

AnalyticalGeometry:

Introduction: Signs of the Coordinates, Distance formula.

Straight Line : Slope or gradient of a straight line, Conditions for Parallel is and perpendicular ity of twolines, Slope of a line joining two points, Slope–intercept form of a straight line.

Integration:

Introduction,Definition, Standard formulae,Rules of integration,Method of substitution, Method of Partial fractions, Integration by parts, definite integrals,application.

UNIT -V

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.**

Suggested Readings:

1. Differential Calculus by Shanthi narayan.
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.

17BP201T SEMESTER - II

HUMAN ANATOMY AND PHYSIOLOGY-II (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total: 100

External Semester Exam: 3 Hours

Course Objectives:

- This subject is designed to impart fundamental knowledge on the structure andfunctions 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.
- To 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.
- It also gives coordinated working pattern of different organs of each system
- Able to the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Outcomes: On successful completion of the course the student will

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.

Course Content:

UNIT - I

Nervous system: Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerveimpulse, 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)

UNIT - II

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, peps in role in prote in digestion) small in testine and large in testine, 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.

UNIT - III

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 formation, micturitionre flex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

UNIT - IV

Endocrine system: Classification of hormones, mechanism of hormoneaction, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

UNIT - V

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.

Suggeted Readings:

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,MIUSA.

4. Text book of Medical Physiology-Arthur C,Guyton and John. E.Hall. Miamisburg, OH, U.S.A.

5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA,U.S.A.

6. Text book of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.

7. Text book 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, NewDelhi.

17BP207P SEMESTER - II

HUMAN ANATOMY AND PHYSIOLOGY (Practical) 4H 2C

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- 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**.**
- To Determine the tidal volume, vital capacity and total blood count by cell analyzer.
- Able to Record the body temperature, basal mass index.
- Will understand how to demonstrate positive and negative feedback mechanism.

Course Outcomes: On successful completion of the course the student will

1. Identify nervous system, endocrine system, digestive, respiratory with the help of specimens, charts and models.
2. Identify the cardiovascular systems, urinary and reproductive systems with the help of specimens, charts and models.
3. Demonstrate the function of olfactory nerve, visual acuity, reflex activity, and different types of taste
4. Determine the tidal volume, vital capacity and total blood count by cell analyzer.
5. Record the body temperature, basal mass index.
6. Demonstrate positive and negative feedback mechanism.

Course Content:

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 activity.

8. To demonstrate the reflex activity.

9. Recording of body temperature.

10. To demonstrate positive and negative feed back mechanism.

11. Determination of tidal volume and vital capacity.

12. Study of digestive, respiratory, cardio vascular 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.

Suggested Readings:

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,MIUSA.

4. Text book of Medical Physiology-Arthur C,Guyton and John. E.Hall. Miamisburg, OH, U.S.A.

5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA,U.S.A.

6. Text book of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.

7. Text book 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, NewDelhi.

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 Kolkata

17BP202T SEMESTER - II

PHARMACEUTICAL ORGANIC CHEMISTRY–I (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject deals with classification and nomenclature of simple organiccompounds, 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.
- Know how to schematize the reaction/reaction mechanism and name the reaction
- Able to explain the orientation of reactions.
- Understand the reactivity/stability of compounds.
- To Identify/confirm the organic compounds.

Course Outcomes(CO's): On successful completion of the course the student will

1. Understand the classification and nomenclature of organic compounds, and the concepts of isomerism.
2. Write the structure, name and the type of isomerism of the organic compound.
3. Schematize the reaction/reaction mechanism and name the reaction
4. Explain the orientation of reactions.
5. Account for reactivity/stability of compounds.
6. Identify/confirm the organic compounds.

Course Content:

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

UNIT-I

Classification, nomenclature and isomerism: Classification of Organic Compounds Common and IUPAC systems of nomenclature of organic compounds. (up to 10Carbons open chain and carbocyclic compounds) Structural isomerisms inorganic compounds.

UNIT-II

Alkanes*, Alkenes*and Conjugateddienes*: SP3hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP2hybridization in alkenes E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and vidences. E1 verses E2 reactions, Factors affecting E1 andE2 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, allylicre arrangement.

UNIT-III

Alkyl halides: SN1 andSN2 reactions-kinetics, orderofre activity of alkyl halides, stereochemistry and rearrangement of carbocations. SN1versusSN2reactions, Factors affecting SN1 and SN2 reactions Structure and uses of ethyl chloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodo form.

Alcohols*: Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol.

UNIT- IV

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 Formal dehyde, Paraldehyde, Acetone, Chloralhydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V

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, Methylsalicylate and Acetylsalicylic acid.

Aliphatic amines*: Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine.

Suggested Readings:

1. Organic Chemistry by Morrison and Boyd.

2. Organic Chemistry by I.L.Finar , Volume-I.

3. Text book 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, Lampmanand Kriz.

17BP208P SEMESTER-II

PHARMACEUTICAL ORGANIC CHEMISTRY-I (Practical) **4H** **2C**

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- Students will able to perform qualitative analysis of unknown organic compounds.
- Will be able to detect special elements in an organic sample.
- Understand how to Confirm unknown compounds by m.p./b.p.
- Will be able to Prepare derivatives of organic compounds.
- To know how to prepare the solid derivatives from organic compounds.
- Able to Construct molecular models.

Course Outcomes (CO's): On successful completion of the course the student will

1. Systematically perform qualitative analysis of unknown organic compounds.
2. Detect special elements in an organic sample.
3. Confirm unknown compounds by m.p./b.p.
4. Prepare derivatives of organic compounds.
5. Prepare the solid derivatives from organic compounds.
6. Construct molecular models.

Course Content:

1. Systematic qualitative analysis of unknown organic compounds like preliminary test:

   1. Color, odour, aliphatic / aromatic compounds, saturation and un saturation ,etc.

   2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test.

   3. Solubilitytest.

   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.

2. Preparation of suitable olid derivatives from organic compounds.

3. Construction of molecular models.

Suggested Readings:

1. Organic Chemistry by Morrison and Boyd.

2. Organic Chemistry by I.L.Finar , Volume-I.

3. Text book 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, Lampmanand Kriz.

17BP203T SEMESTER-II

BIOCHEMISTRY (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- Biochemistry deals with complete understanding of the molecular levels of thechemical 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.
- Will be able to know bioenergetics and energy rich compounds.
- To know the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the types and importance of biomolecules
2. Explain the bioenergetics and energy rich compounds.
3. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
4. Elaborate the biological oxidation emphasizing electron transport chain and oxidative phosphorylation.
5. Describe the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.
6. Discuss the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

Course Content:

UNIT-I

Biomolecule: Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

Bioenergetic: 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.

UNIT-II

Carbohydrate metabolism: Glycolysis– Pathway, energetic 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 Oxidative phosphorylation &its mechanism and substrate phosphorylation Inhibitors ETC and oxidative phosphorylation / Un couplers level.

Biological oxidation
Electron transport chain (ETC) and its mechanism,Oxidative phosphorylation & its mechanism and substrate level phosphorylation Inhibitors ETC and oxidative phosphorylation/Uncouplers.

UNIT-III

Lipid metabolism: β- Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization of ketone bodies; ketoacidosis Denovo synthesis of fatty acids (Palmitic acid) Biological significance of cholesterol and conversion of cholesterol in to bile acids, steroid or mone and vitamin D Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

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.

UNIT-IV

Nucleic acid metabolism and genetic information transfer: Biosynthesis of purine and pyrimidinenucleotides Catabolism of purinenucleotides 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.

UNIT-V
Enzymes Introduction, properties, nomenclature and IUB classification of enzymes Enzyme kinetics(Michaeli splot, Line Weaver Burkeplot) Enzymeinhibitors 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.

Suggested Readings

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

17BP209P SEMESTER - II

BIOCHEMISTRY (Practical) **4H** **2C**

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To know the Qualitative analysis of the biomolecules.
- Will be able to Quantitatively analyze biochemical parameters and their importance in diagnosis of disease.
- To understand how to analyse the urine for abnormal constituents.
- Understand how to identify the biomolecules using chemical tests.
- To Determine the enzymatic activity.
- To Study the effect of physical parameters on the enzymatic activity.

Course Outcomes(CO's): On successful completion of the course the student will

1. Qualitatively analyze the biomolecules.
2. Quantitatively analyze biochemical parameters and their importance in diagnosis of disease.
3. Systematically analyse the urine for abnormal constituents.
4. Identify the biomolecules using chemical tests.
5. Determine the enzymatic activity.
6. Study the effect of physical parameters on the enzymatic activity.

Course Content:

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 orab normal 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.

Suggested Readings:

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

17BP204T SEMESTER-II

PATHOPHYSIOLOGY (Theory) **4H** **4C**

Instruction hours/week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Ojectives:

- 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
- Understanding of basic pathophysiological mechanisms
- Hence it will not only help to study the syllabus of pathology,
- To get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.
- To Understand the etiology and pathogenesis of diseases.

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the description about the types of system and related disorders
2. Name the signs and symptoms of the diseases.
3. Mention the complications of the diseases.
4. Describe the mechanism of the diseases.
5. Understand the etiology and pathogenesis of diseases.
6. Discuss about the Sexually transmitted diseases.

Course content:

UNIT-I

Basic principles of Cell injury and Adaptation: Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury**,** Pathogenesis (Cellmembranedamage, Mitochondrial damage, Ribo some damage, Nuclear damage)**,** Morphology of cell injury–Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia)**,** Cell swelling, Intracellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance.

Basic 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.

UNIT-II

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.

UNIT-III

Haematological Diseases: Irondeficiency, megaloblasticanemia (VitB12 and folic acid), sicklecellanemia, 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.

Gastrointestinal system: Peptic Ulcer.

UNIT- IV

Inflammatoryboweldiseases,jaundice,hepatitis(A,B,C,D,E,F)alcoholicliver disease.

Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout.

Principles of cancer: classification, etiology and pathogenesis of cancer.

Diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis, Gout.

Principles of Cancer: Classification, etiology and pathogenesis of Cancer.

UNIT-V

Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections.

Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea.

Suggested Readings:

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.; Good man 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 edition; united states;
5. William and Wilkins, Baltimore; 1991[1990 printing].
6. NickiR. Colledge, BrianR. Walker, Stuart H.Ralston; Davidson's Principles and Practice of Medicine; 21stedition; London; ELBS / Churchill Living stone;2010.

7. Guyton A,John. EHall; Text book of Medical Physiology; 12th edition; WBS aunders Company;2010.

8. Joseph DiPiro,Robert L. Talbert,Gary Yee,Barbara Wells,L. Michael Posey; Pharmacotherapy:APathophysiologicalApproach; 9th edition;London;McGraw-Hill Medical;2014.

9. V.Kumar,R.S.Cotran and S.L.Robbins; Basic Pathology; 6th edition;Philadelphia; WBSaunders Company;1997.

10.Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Living stone publication;2003.

Reference Books (Latest Editions):

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 JournalofPathologyand Microbiology.ISSN-0377-4929.

17BP205T SEMESTER-II

COMPUTER APPLICATIONS IN PHARMACY (Theory) 3H 3C

Instruction hours/week : L: 3 T:0 P:0 Marks: Internal: 25 External:50 Total:75

External Semester Exam: 3 Hours

Course Objectives:

- This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.
- To Describe the various types of application of computers in pharmacy
- To Understand the various types of databases
- Able to know the applications of databases in pharmacy
- To Understand the concept of bioinformatics and explain the data analysis in Preclinical development
- Able to elaborate the applications of bioinformatics in Vaccine Discovery

Course Outcomes: On successful completion of the course the student will

1. Describe the various types of application of computers in pharmacy
2. Understand the various types of databases
3. Discuss the applications of databases in pharmacy
2. Understand the concept of bioinformatics
3. Explain the data analysis in Preclinical development
4. Elaborate the applications of bioinformatics in Vaccine Discovery

Course content:

UNIT– I

Number system: Binary number system, Decimal number system, Octal number system, Hexa decimal 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: Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/ output design, process life cycle, planning and managing the project

UNIT–II

Web technologies: Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MSACCESS, Pharmacy Drug database.

UNIT– III

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.

UNIT– IV

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V

Computers as data analysis in Preclinical development: Chromatographic data analysis (CDS), Laboratory Information management System (LIMS) and Text Information Management System (TIMS).

Suggested Readings:

1. Computer Application in Pharmacy– WilliamE.Fassett–LeaandFebiger,600 South Washington Square, USA,(215)922-1330.
2. Computer Application in Pharmaceutical Research and Development–Sean Ekins– Wiley-Inter science, A John Willey and Sons, INC., Publication, USA.
3. Bioinformatics (Concept, Skills and Applications)– S.C.Rastogi- CBS Publisher sand Distributors, 4596/1-A,11DaryaGani, NewDelhi – 110002(INDIA).
4. Microsoft office Access -2003,Application Development Using VBA, SQL Server, DAP and Infopath– Cary N.Prague– Wiley Dream tech India(P)Ltd.,4435/7, Ansari Road, Daryagani, NewDelhi-110002.

17BP210P SEMESTER-II

COMPUTER APPLICATIONS IN PHARMACY (Practical) 2H 1C

Instruction hours/week : L: 0 T:0 P:2 Marks: Internal: 10 External:15 Total:25

External Semester Exam: 2 Hours

Course Outcomes (CO's): On successful completion of the course the student will

1. Describe the various types of application of computers in pharmacy
2. Understand the various types of databases
3. Information about online tools for drug interaction
4. Work in MS Office
5. Create database for patients
6. Know Drug information storage and retrieval using MS Access.

Course content:

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 MSWORD.
5 Create a data base 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 in voice 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

Suggested Readings

1. Computer Application in Pharmacy– WilliamE.Fassett–LeaandFebiger,600 South Washington Square, USA,(215)922-1330.
2. Computer Application in Pharmaceutical Research and Development–Sean Ekins– Wiley-Inter science, A John Willey and Sons, INC., Publication, USA.
3. Bioinformatics (Concept, Skills and Applications)– S.C.Rastogi- CBS Publisher sand Distributors, 4596/1-A,11DaryaGani, NewDelhi – 110002(INDIA).
4. Microsoft office Access -2003,Application Development Using VBA, SQL Server, DAP and Infopath– Cary N.Prague– Wiley Dream tech India(P)Ltd.,4435/7, Ansari Road, Daryagani, NewDelhi-110002.

17BP206T SEMESTER-II

ENVIRONMENTAL SCIENCES (Theory) 3H 3C

Instruction hours/week : L: 3 T:0 P:0 Marks: Internal: 25 External:50 Total:75

External Semester Exam: 1 Hours

Course Objectives:

- Environmental Sciences is the scientific study of the environmental system andthe 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.
- Able to Develop an attitude of concern for the environment.
- To Motivate learner to participate in environment protection and environment improvement.
- Understand the skills to help the concerned individuals in identifying and solving environmental problems.
- Able to Strive to attain harmony with Nature.

Course Outcomes (CO's): On successful completion of the course the student will

1. Create 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.

Course content:

UNIT-I

The Multi disciplinary 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) Food resources ;e)Energy resources; f)Land resources: Role of an individual in conservation of natural resources.

UNIT-II

Ecosystems:

i) Concept of an ecosystem.

ii)Structure and function of an ecosystem.

Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grass land ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries).

UNIT-III

Environmental Pollution: Air pollution; Water pollution; Soil pollution.

Suggested Readings:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore.
2. Agarwal, K.C.2001Environmental Biology, Nidi Publ.Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380013,India.
4. BrunnerR.C.,1989, Hazardous Waste Incineration, McGrawHillInc. 480p.
5. ClarkR.S., Marine Pollution, Clanderson PressOxford.
6. Cunningham, W.P. Cooper, T.H. Gorhani, E &Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ.House, Mumbai,1196p.
7. DeA.K., Environmental Chemistry,Wiley Eastern Ltd.
8. Down of Earth,Centre for Science and Environment.

SEMESTER III

17BP301T SEMESTER-III

PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory) 4H 4C

Instruction hours/week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- Students can Emphasize the synthesis, reactions and uses of Polynuclear hydrocarbons and its derivatives.
- Students can able to explain the synthesis, reactions and stability of cycloalkanes.

Course Outcomes: On successful completion of the course the student will

1. Account for the structure, stability, orientation, reaction and its mechanism of Benzene.
2. Understand the acidic/basic properties, qualitative tests, structure and uses of Phenols, Aromatic amines, Aromatic acids and its derivatives.
3. Explan the effect of substituents on acidity and basicity of phenols, aromatic acids and aromatic amines.
4. Describe the Definition/difference, properties and analytical constants pertaining to Fats and Oils.
5. Emphasize the synthesis, reactions and uses of Polynuclear hydrocarbons and its derivatives.
6. Explain the synthesis, reactions and stability of cycloalkanes.

Course Content:

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

UNIT- I

Benzene and its derivatives:

A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule.

B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel crafts alkylation- reactivity, limitations, Friedel crafts acylation.

C. Substituent's, effect of substituent's on reactivity and orientation of mono substituted benzene compounds towards electro philic substitution reaction.

D. Structure and uses of DDT, Saccharin, BHC and Chloramine.

UNIT- II

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 substituent's on basicity, and synthetic uses of aryl diazonium salts.

Aromatic Acids* –Acidity, effect of substituent's on acidity and important reactions of benzoic acid.

UNIT- III

Fats and Oils:

a. Fatty acids – reactions.

b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT- IV

Poly nuclear hydrocarbons:

a. Synthesis, reactions.

b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives.

UNIT- V

Cyclo alkanes*: Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Couls on and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only.

Suggested Readings:

1. Organic Chemistry by Morrison and Boyd.
2. Organic Chemistry by I.L. Finar , Volume-I.
3. Text book of Organic Chemistry b y 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.

17BP305P SEMESTER-III

PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical) 4H 2C

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- Students able to Demonstrate recrystallization and its applications.
- Students able to Demonstrate steam distillation and its applications.
- To Determine the qualitative parameters of oil.
- To Prepare few compounds using basic chemical reactions.
- Able to Synthesize organic compounds using named reactions.
- To Understand the use and application of synthesized organic compounds.

Course Outcomes(CO's): On successful completion of the course the student will

1. Demonstrate recrystallization and its applications.
2. Demonstrate steam distillation and its applications.
3. Determine the qualitative parameters of oil.
4. Prepare few compounds using basic chemical reactions.
5. Synthesize organic compounds using named reactions.
6. Understand the use and application of synthesized organic compounds.

I Experiments involving laboratory techniques:

i) Recry stallization

ii) Steam distillation

II Determination of following oil values (including standardization of reagents):

i) Acid value

ii) Saponification value

iii) Iodine value

III Preparation of compounds:

i) Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.

ii) 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/Acetanilide by halogenation (Bromination) reaction.

iii) 5-Nitro salicylic acid/Meta dinitro benzene from Salicylic acid / Nitro benzene by nitration reaction.

iv) Benzoic acid from Benzyl chloride by oxidation reaction.

v) Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.

vi) 1-Phenylazo-2-napthol from Aniline by diazotization and coupling reactions.

vii) Benzil from Benzoin by oxidation reaction.

viii) Dibenzal acetone from Benzal dehyde by Claison Schmidt reaction

ix) Cinnammic acid from Benzal dehyde by Perkin reaction

x) *P*-Iodo benzoic acid from *P*-amino benzoic acid

Suggested Readings:

1. Organic Chemistry by Morrison and Boyd.
2. Organic Chemistry by I.L. Finar , Volume-I.
3. Text book 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.

17BP302T SEMESTER-III

PHYSICAL PHARMACEUTICS-I (Theory) 4H 4C

Instruction hours/week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- To understand the physicochemical properties, and principles involved in dosage forms/formulations.
- To get a better insight into various areas of formulation research and development,
- To know stability studies of pharmaceutical dosage forms.
- To gain a clear idea about solubilisation and techniques for identifying the phenomenon.
- To understand complexation and protein binding and its effect in the formulation of new dosage forms.
- To Identify the importance of pH and buffers in pharmaceutical systems.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand various physicochemical properties of drug molecules in the design of dosage forms.
2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations.
3. Develop a clear idea about solubilisation and techniques for identifying the phenomenon.
4. Discover the term complexation and protein binding and its effect in the formulation of new dosage forms.
5. Identify the importance of pH and buffers in pharmaceutical systems.
6. Achieve a better insight into various areas of formulation, research and development.

Course Content:

UNIT-I

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.

UNIT-II

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapor 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.

UNIT-III

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.

UNIT-IV

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermo dynamic treatment of stability constants.

UNIT-V

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.

Suggested Readings:

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 Ramasam y 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 Pharmacy, by Gaurav Jain & Roop K. Khar

17BP306P SEMESTER-III

PHYSICAL PHARMACEUTICS – I (Practical) 4H 2C

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Ojectives:

- To Understand the physicochemical parameters of a drug.
- To Identify methods to enhance solubility of a new drug moiety
- To Know the importance of stability in pharmaceutical preparations.
- To build practical skills for new drug development process.
- To determine the physicochemical parameters for drug formulation.
- To determine the physical constants of a drug.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the physicochemical parameters of a drug.
2. Identify methods to enhance solubility of a new drug moiety
3. Discover the importance of stability in pharmaceutical preparations.
4. Build practical skills for new drug development process.
5. Determine the physicochemical parameters.
6. Determine the physical constants of a drug.

1. Determination the solubility of drug at room temperature.
2. Determination of pKa value by Half Neutralization/ Henderson Hassel balch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water.
4. Determination of Partition co- efficient of Iodine in CCl4 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.

Suggested Readings:

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 Ramasam y 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 Pharmacy, by Gaurav Jain & Roop K. Khar

17BP303T SEMESTER-III

PHARMACEUTICAL MICROBIOLOGY (Theory) 4H 4C

Instruction hours/week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Ojectives:

- To study of all categories of microorganisims especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc.
- To understand methods of identification, cultivation and preservation of various microorganisms.
- To understand the importance and implementation of sterilization in pharmaceutical processing and Industry.
- To Learn sterility testing of pharmaceutical products.
- To Carry out microbiological standardization of Pharmaceuticals.
- To understand the cell culture technology and its applications in pharmaceutical industries.

Course Outcomes: On successful completion of the course the student will

1. Understand methods of identification, cultivation and preservation of various microorganisms.
2. To understand the importance and implementation of sterilization in pharmaceutical processing and Industry.
3. Learn sterility testing of pharmaceutical products.
4. Carry out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.
6. Develop knowledge on different types of microscopes in pharmaceutical industry.

Course content:

UNIT -I

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 contrast microscopy, dark field microscopy and electron microscopy.

UNIT -II

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.

UNIT- III

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 bacterio static and bactericidal actions Evaluation of bactericidal & Bacterio static. Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP , BP and USP.

UNIT -IV

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.

UNIT- V

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. 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.

Suggested Readings:

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 Hilledn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdilletal: 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

17BP307P SEMESTER-III

PHARMACEUTICAL MICROBIOLOGY (Practical) 4H 2C

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To discuss about the instruments used in experimental microbiology
- To understand the sterilization methods followed in laboratory.
- To know the staining techniques used in microbiology.
- To carry out assay of different antibiotics
- To understand the mechanism of action opf antibiotics.
- To perform different sterility tests and bacteriological analysis of water

Course Outcomes (CO's): On successful completion of the course the student will

1. Discuss about the instruments used in experimental microbiology
2. Understand the sterilization methods followed in laboratory.
3. Discover the staining techniques used in microbiology.
4. Carry out assay of different antibiotics
5. Understand the mechanism of action opf antibiotics.
6. Execute different sterility tests and bacteriological analysis of water

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.

Suggester Readings:

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 Hilledn.
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.

17BP304 T SEMESTER-III

PHARMACEUTICAL ENGINEERING (Theory) 4H 4C

Instruction hours/week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.
- To understand the material handling techniques.
- To perform various processes involved in pharmaceutical manufacturing process.
- To appreciate and comprehend significance of plant lay out design for optimum use of resources.
- To know the various preventive methods used for corrosion control in Pharmaceutical industries.
- To execute various tests to prevent environmental pollution.

Course Outcomes (CO's): On successful completion of the course the student will

1. Know various unit operations used in Pharmaceutical industries.
2. Understand the material handling techniques.
3. Perform various processes involved in pharmaceutical manufacturing process.
4. Appreciate and comprehend significance of plant lay out design for optimum use of resources.
5. Appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.
6. Execute various tests to prevent environmental pollution.

Course content:

UNIT-I

Flow of fluids: Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitottube 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.

UNIT-II

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.

UNIT- III

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 blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silvers on Emulsifier,

UNIT-IV

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 Seitz 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.

UNIT- V

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.

Suggeted Readings:

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 b y 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.

17BP308P SEMESTER-III

PHARMACEUTICAL ENGINEERING (Practical) **4H** **2C**

Instruction hours/week : L: 0 T:0 P:4 Marks: Internal: 15 External:35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To Understand different methods like moisture content, drying curve.
- To Identify different techniques like filtration, size reduction, crystallization.
- To Know about distillation and steps to be followed in steam distillation.
- To Summarize different instruments handled for engineering operations.
- To Determine the physical constants for a formulation.
- To Demonstrate the various machines used in pharmaceutical industry.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand different methods like moisture content, drying curve.
2. Identify different techniques like filtration, size reduction, crystallization.
3. Know about distillation and steps to be followed in steam distillation.
4. Summarize different instruments handled for engineering operations.
5. Determine the physical constants for a formulation.
6. Demonstrate the various machines used in pharmaceutical industry.

I. Determination of radiation constant of brass, iron, unpainted and painted glass.

II. Steam distillation – To calculate the efficiency of steam distillation.

III. To determine the overall heat transfer coefficient by heat exchanger. IV. Construction of drying curves (for calcium carbonate and starch).

V. Determination of moisture content and loss on drying.

VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.

VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.

VIII. Size analysis b y sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.

IX. 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.

X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.

XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ Viscosity.

XII. To stud y the effect of time on the Rate of Crystallization.

XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

Suggested Readings:

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 b y 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.

SEMESTER -IV

17BP401T SEMESTER-IV

PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory) 4H 4C

Instruction hours/week : L: 3 T:1 P:0 Marks: Internal: 25 External:75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject imparts knowledge on stereo-chemical aspects of organic compoundsand organic reactions, important named reactions, chemistry of important hetero cyclic compounds.
- It also emphasizes on medicinal and other uses of organic compounds.
- To understand the methods of preparation organic compounds.
- To understand the properties of organic compounds.
- To know the medicinal uses and other applications of organic compounds.
- To elaborate the reactions of synthetic importance.

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the stereo chemical aspects of organic compounds and stereo chemical reactions.
2. Discuss heterocyclic compounds based on nomenclature, classification, synthesis and reactions.
3. Understand the methods of preparation organic compounds.
4. Understand the properties of organic compounds.
5. Know the medicinal uses and other applications of organic compounds.
6. Elaborate the reactions of synthetic importance.

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications:

UNIT-I

Stereo isomerism: Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds elements of symmetry, chiral and achiral molecules DL s ystem 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.

UNIT-II

Geometrical isomerism: Nomenclature of geometrical isomers (Cis Trans, EZ, Synthesis 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.

UNIT-III

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.

UNIT-IV

Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrazole, Imidazole, Oxazole and Thiazole. Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicit y of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives.

UNIT-V

Reactions of synthetic importance: Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction. Oppenauer-oxidation and Dakin reaction. Beckmanns rearrangement and Schmidt rearrangement. Claisen-Schmidt condensation.

Suggested Readings:

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 by Morrison and Boyd.
5. Heterocyclic Chemistry by T.L. Gilchrist.

17BP402T SEMESTER-IV

MEDICINAL CHEMISTRY – I (Theory) 4H 4C

Instruction hours/week : L: 3 T:1 P:0 Marks:Internal:25 External:75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- Describe the Classification, therapeutic value and chemistry of cholinergic agonist and antagonist drugs.
- Brief the Classification, Synthesis, therapeutic value and Structural activity relationship of drugs acting on Central nervous system particularly sedatives, hypnotics, antipsychotics and anticonvulsants.
- Enlight the Classification, and chemical aspects including structural activity relationship of drugs acting on Central nervous system particularly general anesthetics and analgesics.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the drug metabolic pathways.
2. State the chemistry of drugs with respect to their biological activity.
3. Explain the Classification, Synthesis, therapeutic value and Structural activity relationship of adrenergic agonist and antagonist drugs.
4. Describe the Classification, therapeutic value and chemistry of cholinergic agonist and antagonist drugs.
5. Brief the Classification, Synthesis, therapeutic value and Structural activity relationship of drugs acting on Central nervous system particularly sedatives, hypnotics, antipsychotics and anticonvulsants.
6. Enlight the Classification, and chemical aspects including structural activity relationship of drugs acting on Central nervous system particularly general anesthetics and analgesics.

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 selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I

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.

UNIT- II

Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters:

i) Biosynthesis and catabolism of catecholamine.

ii) 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, Ox ymetazoline and Xylometazoline.

1. Indirect acting agents: Hydrox yamphetamine, Pseudoephedrine, Propylhexedrine.
2. Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenox ybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III

Cholinergic neurotransmitters:

1. Biosynthesis and catabolism of acetylcholine.
2. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Para sympathomimetic 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.

UNIT- IV

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*, Mephen ytoin, Ethotoin **Oxazolidine diones:** Trimethadione, Paramethadione **Succinimides:** Phensuximide, Methsuximide, Ethosuximide.

Urea and monoacylureas: Phenacemide, Carbamazepine.

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate

UNIT – V

Drugs acting on Central Nervous System General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal 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.

Suggested Readings:

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 Chemistr y 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.

17BP406P SEMESTER-IV

MEDICINAL CHEMISTRY – I (Practical) 4H 2C

Instruction hours/ week : L:0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- Synthesize few drugs and their intermediates.
- Synthesize drug intermediates.
- Synthesize some basic nucleus of drug candidates.
- Estimate the purity of drugs.
- Estimate the quantity of drugs present in tablet.
- Determine the partition coefficient of the drugs.

Course Outcomes (CO's): On successful completion of the course the student will

1. Synthesize few drugs and their intermediates.
2. Synthesize drug intermediates.
3. Synthesize some basic nucleus of drug candidates.
4. Estimate the purity of drugs.
5. Estimate the quantity of drugs present in tablet.
6. Determine the partition coefficient of the drugs.

I Preparation of drugs/ intermediates:

- 1,3-pyrazole
- 1,3-oxazole
- Benzimidazole
- Benztriazole
- 2,3-diphenylquinoxaline
- Benzocaine
- Phenytoin
- Phenothiazine
- Barbiturate

II Assayofdrugs:

- Chlorpromazine
- Phenobarbitone
- Atropine
- Ibuprofen
- Aspirin
- Furosemide

III Determination of Partition coefficient for any two drugs

Suggested Readings:

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 Chemistr y 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.

17BP403T SEMESTER-IV

PHYSICAL PHARMACEUTICS-II (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations.
- Theory 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.
- To demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.
- To understand the stability enhancement techniques in pharmaceutical industry.
- To discover the importance of accelerated stability testing in new drug formulation.
- To achieve a better insight into various areas of formulation, research and development.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms.
2. Demonstrate the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations.
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.
4. Understand the stability enhancement techniques in pharmaceutical industry.
5. Discover the importance of accelerated stability testing in new drug formulation.
6. Achieve a better insight into various areas of formulation, research and development.

Course Content:

UNIT-I

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.

UNIT-II

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.

UNIT-III

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.

UNIT-IV

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.

UNIT-V

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

Suggested Readings:

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.

17BP407P SEMESTER-IV

PHYSICAL PHARMACEUTICS- II (Practical) 4H 2C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total: 50

External Semester Exam: 4 Hours

Course Objectives:

- To Understand the Preformulation parameters to be carried out in a new drug.
- To Discover different reaction rates.
- To Interpret the values from accelerated stability studies.
- To Build practical skills for new drug development process.
- To Demonstrate the sedimentation rate of various drug products.
- To Express the evaluation methods used in rheology.

Course Outcomes(CO's): On successful completion of the course the student will

1. Understand the Preformulation parameters to be carried out in a new drug.
2. Discover different reaction rates.
3. Interpret the values from accelerated stability studies.
4. Build practical skills for new drug development process.
5. Demonstrate the sedimentation rate of various drug products.
6. Express the evaluation methods used in rheology.

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 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.

Suggseted Readings:

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.

17BP404T SEMESTER-IV

PHARMACOLOGY-I (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To Illustrate the Adverse drug reactions, Drug interactions, Pharmacovigilance and Drug discovery cycle.
- To demonstrate the Organization, function of ANS, classification of neurotransmitters and the drugs acting on it.
- To summarize the Pharmacology of drugs acting on various CNS diseases.
- To describe the Local anesthetic agents and the drugs used in myasthenia gravis, glaucoma.

Course Outcomes: On successful completion of the course the student will

1. Explain the basics of pharmacology such as scope, historical landmarks of, drugs concept, Agonists, antagonists, spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy and various pharmacokinetic parameters.
2. Defend the Pharmacodynamics, Principles, various types of receptors and mechanisms of drugs on it, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
3. Illustrate the Adverse drug reactions, Drug interactions, Pharmacovigilance and Drug discovery cycle.
4. Demonstrate the Organization, function of ANS, classification of neurotransmitters and the drugs acting on it.
5. Summarize the Pharmacology of drugs acting on various CNS diseases.
6. Describe the Local anesthetic agents and the drugs used in myasthenia gravis, glaucoma.

Course Content:

UNIT-I

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 non competitive), 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.

UNIT-II

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 discover y and clinical evaluation of new drugs -Drug discover y phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

UNIT-III

2. Pharmacology of drugs acting on peripheral nervous system:

a. Organization and function of ANS.

b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.

c. Para sympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma.

UNIT-IV

3. Pharmacology of drugs acting on central nervous system:

a. Neuro humoral 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.

UNIT-V

3. Pharmacology of drugs acting on central nervous system:

a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

b. Drugs used in Parkinson's disease and Alzheimer's disease. c. CNS stimulants and no tropics.

d. Opioid analgesics and antagonists.

e. Drug addiction, drug abuse, tolerance and dependence.

Suggested Readings:

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,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan.

17BP408P SEMESTER-IV

PHARMACOLOGY-I (Practical) 4H 2C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To understand the instruments used in experimental pharmacology.
- To maintain the laboratory animals as per CPCSEA guidelines.
- To demonstrate the Blood withdrawal, serum and plasma separation, anesthetics.
- To administer the drugs in different routes.
- To explain the euthanasia used for animal studies.
- To screen the drugs with the use of various pharmacological instruments.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the instruments used in experimental pharmacology.
2. Maintain the laboratory animals as per CPCSEA guidelines.
3. Demonstrate the Blood withdrawal, serum and plasma separation, anesthetics.
4. Administer the drugs in different routes.
5. Explain the euthanasia used for animal studies.
6. Screen the drugs with the use of various pharmacological instruments.

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 phenobarbit one 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 b y MES 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

Suggested Readings:

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.

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.

10.Kulkarni SK. Hand book of experimental pharmacology. Vallabh Prakashan.

17BP405T SEMESTER-IV

PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- The subject involves the fundamentals of Pharmacognosy like scope, classification ofcrude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.
- To explain the classification of crude drugs, Quality control of Drugs of Natural Origin, Quantitative microscopy of crude drugs.
- To elaborate the techniques in the cultivation and production of crude drugs.
- To demonstrate the plant tissue culture.
- To understand the traditional system of medicine.
- To explain the Plant Products Primary metabolites Proteins, Enzymes, Lipids, Marine drugs.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the history, scope and development of Pharmacognosy.
2. Explain the classification of crude drugs, Quality control of Drugs of Natural Origin, Quantitative microscopy of crude drugs.
3. Elaborate the techniques in the cultivation and production of crude drugs.
4. Demonstrate the plant tissue culture.
5. Understand the traditional system of medicine.
6. Explain the Plant Products Primary metabolites Proteins, Enzymes, Lipids, Marine drugs.

Course Content:

UNIT-I

Introduction to Pharmacognosy:

(a) Definition, history, scope and development of Pharmacognosy.

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture.

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilage's, 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.

UNIT-II

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.

UNIT-III

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.

UNIT- IV

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.

UNIT- V

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

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.

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.

Suggested Readings:

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. Text Book of Pharmacognosy by T.E. Wallis

4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae.
9. Anatomy of Crude Drugs by M.A. Iyengar.

17BP409P SEMESTER-IV

PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical) 4H 2C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- Analyze the crude drugs by chemical tests.
- Determine the stomatal number and index and vein islet number, vein islet termination and palisade ratio.
- Determine the starch grains, calcium oxalate crystals by eye piece micrometer.
- Perfrom the Fiber length and width starch grains by Lycopodium spore method.
- Analyze the purity of crude drugs by ash value and extractive value.
- Determine the moisture content, swelling index and foaming index.

Course Outcomes(CO's): On successful completion of the course the student will

1. Analyze the crude drugs by chemical tests.
2. Determine the stomatal number and index and vein islet number, vein islet termination and palisade ratio.
3. Determine the starch grains, calcium oxalate crystals by eye piece micrometer.
4. Perfrom the Fiber length and width starch grains by Lycopodium spore method.
5. Analyze the purity of crude drugs by ash value and extractive value.
6. Determine the moisture content, swelling index and foaming index.

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.

Suggested Readings:

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. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae.
9. Anatomy of Crude Drugs by M.A. Iyengar.

SEMESTER V

17BP501T SEMESTER – V

MEDICINAL CHEMISTRY – II (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs.
- To Know the Structural Activity Relationship of different class of drugs.
- To study the chemical synthesis of selected drugs.

Course Outcomes(CO's): On successful completion of the course the student will

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

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 selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I

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 sodiu

H2-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neo plastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, C ytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleom ycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II

Anti-anginal:

Vasodilators: Amyl nitrite, Nitrogl ycerin*, 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, 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.

UNIT- III

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.

UNIT- IV

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.

UNIT – V

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, Propox ycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Suggested Readings:

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.

17BP502T SEMESTER V

INDUSTRIAL PHARMACY-I (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To discover various formulation considerations in development of pharmaceutical dosage forms like tablets, capsules, etc.
- To Understand the quality control tests for the dosage forms.
- To know parenterals, stringent procedures in the preparation and its evaluation.
- To Understand clearly about packaging and cosmetic preparations.
- To Interpret the various pharmaceutical additives to be included in all dosage forms.

Course Outcomes(CO's): On successful completion of the course the student will

1. Aquire knowledge about the various pharmaceutical dosage forms and their manufacturing techniques.
2. Discover various formulation considerations in development of pharmaceutical dosage forms like tablets, capsules, etc.
3. Understand the quality control tests for the dosage forms.
4. Detail on parenterals, stringent procedures in the preparation and its evaluation.
5. Understand clearly about packaging and cosmetic preparations.
6. Interpret the various pharmaceutical additives to be included in all dosage forms.

Course content:

UNIT-I

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.

UNIT-II

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

UNIT-III

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

UNIT-IV

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity.

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

UNIT-V

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.

Suggested Readings:

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 b y 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. Theory and Practice of Industrial Pharmac y b y Liberman & Lachman.
7. Pharmaceutics- The science of dosage form design b y 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.

17BP506P SEMESTER V

INDUSTRIAL PHARMACY-I (Practical) **4H** **2C**

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To manufacture tablets.
- To understand the strict formulation considerations in parenteral and ophthalmic manufacturing.
- To demonstrate the evaluations of different packaging materials in pharmaceutical industry.
- To achieve skills in making a pharmaceutical product.
- To demonstrate the manufacturing of capsules.
- To exploit the formulation of various cosmetics.

Course Outcomes (CO's): On successful completion of the course the student will

1. Manufacture tablets.
2. Understand the strict formulation considerations in parenteral and ophthalmic manufacturing.
3. Demonstrate the evaluations of different packaging materials in pharmaceutical industry.
4. Achieve skills in making a pharmaceutical product.
5. Demonstrate the manufacturing of capsules.
6. Exploit the formulation of various cosmetics.

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).

Suggested Readings:

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 b y 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. Theory and Practice of Industrial Pharmac y b y Liberman & Lachman.
7. Pharmaceutics- The science of dosage form design b y 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,Vol107.

17BP503T SEMESTER V

PHARMACOLOGY-II (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To demonstrate the Pharmacology of drugs acting on various cardio vascular disease.
- To explain the drug used in the therapy of shock, Pharmacology of coagulants, anticoagulants, Fibrinolytics, anti-platelet drugs, Diuretics and Anti-diuretics.
- To Illustrate the Pharmacology of Autocoids, Non-steroidal anti-inflammatory agents, Anti-gout drugs and Antirheumatic drugs.
- To know the Pharmacology of drugs acting on endocrine system.
- To describe the Principles, applications of bioassay and bioassay of various drugs.

Course Outcomes: On successful completion of the course the student will

1. Demonstrate the Pharmacology of drugs acting on various cardio vascular disease.
2. Explain the drug used in the therapy of shock, Pharmacology of coagulants, anticoagulants, Fibrinolytics, anti-platelet drugs, Diuretics and Anti-diuretics.
3. Illustrate the Pharmacology of Autocoids, Non-steroidal anti-inflammatory agents, Anti-gout drugs and Antirheumatic drugs.
4. Outline the Pharmacology of drugs acting on endocrine system.
5. Describe the Principles, applications of bioassay and bioassay of various drugs.
6. Summarize the drugs acting on the uterus and oral contraceptives.

Course Content:

UNIT-I

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.

UNIT-II

1. Pharmacology of drugs acting on cardio vascular system:

a. Drug used in the therapy of shock.

b. Hematinics, coagulants and anticoagulants.

c. Fibrinol ytics and anti-platelet drugs.

d. Plasma volume expanders.

2. Pharmacology of drugs acting on urinary system:

a. Diuretics.

b. Anti-diuretics.

UNIT-III

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.

UNIT-IV

5. 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.

d. Insulin, Oral H ypogl ycemic agents and glucagon.

e. ACTH and corticosteroids.

UNIT-V

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.

6. 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.

Suggested Readings:

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., Bradle y 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.

17BP507P SEMESTER V

PHARMACOLOGY-II (Practical) **4H** **2C**

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To explain the in-vitro pharmacology, PA2 and PD2 values.
- To Record the Effect of drugs on frog, dog heart and blood pressure.
- To Record the DRC of acetylcholine, estimate the Bioassay of histamine, oxytocin, serotonin by interpolation bioassay method.
- To Estimate the Bioassay of histamine, oxytocin, serotonin by matching bioassay.
- To demonstrate the Anti-inflammatory activity and Analgesic activity in animal models.
- To explain the three point and four-point bioassay

Course Outcomes(CO's): On successful completion of the course the student will

1. Explain the in-vitro pharmacology, PA2 and PD2 values.
2. Record the Effect of drugs on frog, dog heart and blood pressure.
3. Record the DRC of acetylcholine, estimate the Bioassay of histamine, oxytocin, serotonin by interpolation bioassay method.
4. Estimate the Bioassay of histamine, oxytocin, serotonin by matching bioassay.
5. Demonstrate the Anti-inflammatory activity and Analgesic activity in animal models.
6. Explain the three point and four-point bioassay

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 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 b y 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

Suggested Readings:

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Living stone 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., Bradle y 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.

17BP504T SEMESTER - V

PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- The main purpose of subject is to impart the students the knowledge of how thesecondary 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
- To explain the modern extraction techniques, characterization and identification of the herbal drugs and Phytoconstituents
- To understand the preparation and development of herbal formulation.
- To understand the herbal drug interactions.
- To isolate and identify the Phytoconstituents.

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the Composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications.
2. Metabolic pathways in higher plants and their determination
3. Explain the modern extraction techniques, characterization and identification of the herbal drugs and Phytoconstituents
4. Understand the preparation and development of herbal formulation.
5. Understand the herbal drug interactions.
6. Isolate and identify the Phytoconstituents.

Course Content:

UNIT-I

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.

UNIT-II

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

UNIT-III

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

UNIT-IV

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V

Basics of Phytochemistry: Modern methods of extraction, application of latest techniques like Spectroscopy.

Suggested Readings:

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.

17BP508P SEMESTER - V

PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical) 4H 2C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To Perform the histology and powder characteristics & extraction & detection of Phytoconstituents.
- To Isolate and detect the active principles.
- To Separate the sugars by Paper chromatography.
- To Perform TLC of herbal extract
- To Distillate the volatile oils and detects the Phytoconstituents by TLC.
- To Analysis of crude drugs by chemical tests.

Course Outcomes (CO's): On successful completion of the course the student will

1. Perform the histology and powder characteristics & extraction & detection of Phytoconstituents.
2. Isolate and detect the active principles.
3. Separate the sugars by Paper chromatography.
4. Perform TLC of herbal extract
5. Distillate the volatile oils and detects the Phytoconstituents by TLC.
6. Analysis of crude drugs by chemical tests.

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.

Suggseted Readings:

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.

17BP505T SEMESTER – V

PHARMACEUTICAL JURISPRUDENCE (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.
- To demonstrate various Indian pharmaceutical Acts and Laws.
- To understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
- To elicit the code of ethics during the pharmaceutical practice.
- To acquire clear idea on drug price control order and its implication in India.
- To acquire information regarding the licenses to be achieved for a new drug discovery process.

Course Outcomes (CO's): On successful completion of the course the student will

1. Exploit the Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Demonstrate various Indian pharmaceutical Acts and Laws.
3. Understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals.
4. Elicit the code of ethics during the pharmaceutical practice.
5. Acquire clear idea on drug price control order and its implication in India.
6. Acquire information regarding the licenses to be achieved for a new drug discovery process.

Course Content:

UNIT-I

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.

UNIT-II

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 penaltiesLabeling & 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.

UNIT-III

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.

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.

UNIT-IV

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 Essential Medicines (NLEM)

UNIT-V

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquir y 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)

Suggseted Readings:

1. Forensic Pharmacy by B. Suresh.

2. Text book of Forensic Pharmacy by B.M. Mithal.

3. Hand book of drug law-by M.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).

SEMESTER - VI

17BP601T SEMESTER-VI

MEDICINAL CHEMISTRY – III (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- 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)
- To understand the prodrug concept, combinatorial chemistry and Computer aided drug design (CADD).
- The subject also emphasizes on the chemistry, mechanism of action, metabolism,
- To know adverse effects, Structure Activity Relationships (SAR) and therapeutic uses
- To synthesis of important drugs.

Course Outcomes(CO's): On successful completion of the course the student will

1. Illustrate the classification of drugs.
2. Explain the mechanism of action of drugs.
3. Understand the chemistry of drugs with respect to their biological activity.
4. Know the metabolism, adverse effects and therapeutic value of drugs.
5. Discuss the importance of SAR of drugs.
6. Understand the importance of drug design and different techniques of drug design.

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 selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I

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

UNIT – II

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.

UNIT – III

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, 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.

UNIT – IV

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, N ystatin, 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*.

UNIT – V

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 chemistry: solid phase and solution phase synthesis.

Suggested Readings:

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 b y Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

17BP607P SEMESTER-VI

MEDICINAL CHEMISTRY- III (Practical) 4H 2C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To prepare drugs and medicinally important compounds by traditional and microwave method.
- To prepare drug intermediates by traditional and microwave method.
- To perform assay of drug substances.
- To draw structures of chemicals using softwares.
- To determine physicochemical properties for drugs using software.
- To screen drug likeliness.

Course Outcomes(CO's): On successful completion of the course the student will

1. Prepare drugs and medicinally important compounds by traditional and microwave method.
2. Prepare drug intermediates by traditional and microwave method.
3. Perform assay of drug substances.
4. Draw structures of chemicals using softwares.
5. Determine physicochemical properties for drugs using software.
6. Screen drug likeliness.

I Preparation of drugs and intermediates:

1 Sulphanilamide

2 7-Hydrox y, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

II Assay of drugs:

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

III. Preparation of medicinally important compounds or intermediates by Microwave 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 like liness screening (Lipinskies RO5)

Suggested Readings:

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 S ynthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

17BP602T SEMESTER-VI

PHARMACOLOGY-III (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases.
- Comprehend the principles of toxicology and treatment of various poisonings.
- Appreciate correlation of pharmacology with related medical sciences.
- Enlight the chemotherapy of drugs on various Urinary tract infections and sexually transmitted diseases and Chemotherapy of malignancy.
- Explain about Immunopharmacology, Protein drugs, monoclonal antibodies, target drugs to antigen and biosimilars.

Course Outcomes (CO's): On successful completion of the course the student will

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 poisonings.
3. Appreciate correlation of pharmacology with related medical sciences.
4. Enlight the chemotherapy of drugs on various Urinary tract infections and sexually transmitted diseases and Chemotherapy of malignancy.
5. Explain about Immunopharmacology, Protein drugs, monoclonal antibodies, target drugs to antigen and biosimilars.
6. Describe Chronopharmacology, Biological clock and its significance.

Course Content:

UNIT-I

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

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.

UNIT-II

3. Chemotherapy:

a. General principles of chemotherapy.

b. Sulfonamides and cotrimoxazole.

c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminogl ycosides

UNIT-III

3. Chemotherapy:

a. Antitubercular agents

b. Antileprotic agents

c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV

3. Chemotherapy:

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology:

a. Immunostimulants

b. Immunosuppressant Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

5. Principles of toxicology:

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicit y 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.

6. Chronopharmacology:

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

Suggested Readings:

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., Bradle y 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 Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
8. 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.

17BP608P SEMESTER-VI

PHARMACOLOGY-III (Practical) 4H 4C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To Calculate the dose in pharmacological experiments.
- To Perform various pharmacological screening studies.
- To Demonstrate the toxicity studies in animal models.
- To know the student's t test, ANOVA, Chi square test, Wilcoxon Signed Rank test.
- To determine the pharmacokinetic parameters by using the data.
- To evaluate the acute skin irritation, acute eye irritation and corrosion of a test substance.

Course Outcomes (CO's): On successful completion of the course the student will

1. Calculate the dose in pharmacological experiments.
2. Perform various pharmacological screening studies.
3. Demonstrate the toxicity studies in animal models.
4. Describe the student's t test, ANOVA, Chi square test, Wilcoxon Signed Rank test.
5. Determine the pharmacokinetic parameters by using the data.
6. Evaluate the acute skin irritation, acute eye irritation and corrosion of a test substance.

1. Dose calculation in pharmacological experiments.
2. Antiallergic activity by mast cell stabilization assay.
3. Study of anti-ulcer activity of a drug using pyloruslig and (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- auto analyser.
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**

Suggested Readings:

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., Bradle y 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 Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
8. 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.

17BP603T SEMESTER-VI

HERBAL DRUG TECHNOLOGY (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject gives the student the knowledge of basic understanding of herbal drugindustry, 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
- To elaborate the herbal cosmetics, natural sweeteners, Nutraceuticals
- To explain the patenting of herbal drugs, Herbal drugs industry.
- To demonstrate the GMP.
- To understand the study of Herbal cosmetics, excipients and formulations.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand raw material as source of herbal drugs from cultivation to herbal drug product.
2. Explain the WHO and ICH guidelines for evaluation of herbal drugs.
3. Elaborate the herbal cosmetics, natural sweeteners, Nutraceuticals
4. Explain the patenting of herbal drugs, Herbal drugs industry.
5. Demonstrate the GMP.
6. Understand the study of Herbal cosmetics, excipients and formulations.

Course content:

UNIT-I

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.

UNIT-II

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.

UNIT-III

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.

Herbal formulations : Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes.

UNIT- IV

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.

UNIT-V

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 – Good Manufacturing 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.

Suggested Readings:

1. Text book of Pharmacognosy by Trease & Evans.
2. Text book 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 Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

17BP609P SEMESTER-VI

HERBAL DRUG TECHNOLOGY (Practical) **4H** **2C**

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To perform the preliminary phytochemical screening of crude drugs.
- To determine the alcohol content of Asava and Arista.
- To evaluate the excipients of natural origin.
- To prepare and standardize the creams, lotions and shampoos and syrup.
- To explain the Monograph analysis of herbal drugs.
- To determine the aldehyde content, Phenol content and total alkaloids.

Course Outcomes(CO's): On successful completion of the course the student will

1. Perform the preliminary phytochemical screening of crude drugs.
2. Determine the alcohol content of Asava and Arista.
3. Evaluate the excipients of natural origin.
4. Prepare and standardize the creams, lotions and shampoos and syrup.
5. Explain the Monograph analysis of herbal drugs.
6. Determine the aldehyde content, Phenol content and total alkaloids.

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.

Suggested Readings:

1. Text book of Pharmacognosy by Trease & Evans.
2. Text book 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 Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

17BP604T SEMESTER-VI

BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
- To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- To understand various pharmacokinetic parameters, their significance & applications.
- To demonstrate a clear information on compartmental models and methods to assess the models.
- To describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Explain the use of plasma drug concentration-time data to calculate the pharmacokinetic parameters.
3. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.
5. Demonstrate a clear information on compartmental models and methods to assess the models.
6. Describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

Course Content:

UNIT-I

Introduction to Biopharmaceutics 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.

UNIT- II

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.

UNIT- III

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.

UNIT- IV

Multi compartment models: Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings.

UNIT- V

Nonlinear Pharmacokinetics:

a. Introduction,

b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Suggseted Readings:

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: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; B y Swarbrick.
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm 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, By Mack Publishing Company, Pennsylvnia

17BP605T SEMESTER-VI

PHARMACEUTICAL BIOTECHNOLOGY (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- 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 technology makes 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.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries.
2. Explain Genetic engineering applications in relation to production of pharmaceuticals.
3. Understand the Importance of Monoclonal antibodies in Industries.
4. Appreciate the use of microorganisms in fermentation technology.
5. Discover different blotting techniques in pharmaceutical biotechnology.
6. Acquire scientific application in the field of genetic engineering, medicine and fermentation technology.

UNIT -I

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 Enz ymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

f) Basic principles of genetic engineering.

UNIT- II

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.

UNIT- III

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.

f) Hybridoma technology- Production, Purification and Applications.

g) Blood products and Plasma Substituties.

UNIT -IV

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.

UNIT -V

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 Substitutes.

Suggested Readings:

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.Society of Chemistr y.

2. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

3. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.

4. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi.

17BP606T SEMESTER –VI

PHARMACEUTICAL QUALITY ASSURANCE (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100
External Semester Exam: 3 Hours

Course Objectives:

- This course deals with the various aspects of quality control and qualityassurance aspects of pharmaceutical industries.
- It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.
- To discuss the scope of quality certifications applicable to pharmaceutical industries.
- To elaborate the responsibilities of QA and QC departments.
- To understand the GLP and its importance
- To describe the warehouse and good warehouse practice.

Course Outcomes(CO's): On successful completion of the course the student will

1. Understanding the cGMP aspects in a pharmaceutical industry.
2. Explain the importance of documentation.
3. Discuss the scope of quality certifications applicable to pharmaceutical industries.
4. Elaborate the responsibilities of QA and QC departments.
5. Understand the GLP and its importance
6. Describe the warehouse and good warehouse practice.

Course content:

UNIT – I

Quality Assurance and Quality Management concepts: Definition and concept of Qualit y 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

UNIT - II

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.

UNIT – III

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.

UNIT – IV

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.

UNIT – V

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, 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

Suggested Readings:

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh.
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – 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.

SEMESTER VII

17BP701T SEMESTER – VII

INSTRUMENTAL METHODS OF ANALYSIS (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject deals with the application of instrumental methods in qualitative andquantitative 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.
- To discuss the applications of analytical techniques.
- To perform quantitative analysis of drugs using various analytical instruments.
- To perform qualitative analysis of drugs using various analytical instruments

Course Outcomes: On successful completion of the course the student will

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
2. Describe the instrumentation of spectroscopy techniques.
3. Understand the chromatographic separation and analysis of drugs.
4. Discuss the applications of analytical techniques.
5. Perform quantitative analysis of drugs using various analytical instruments.
6. Perform qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I

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.

UNIT –II

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.

UNIT –III

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.
Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications.

UNIT –IV

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications.
High performance liquid chromatography (HPLC)-Introduction, theory, Instrumentation, advantages and applications.

UNIT –V

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.

Suggested Readings:

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 by William 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.

17BP705P SEMESTER – VII

INSTRUMENTAL METHODS OF ANALYSIS (Practical) 4H 2C

Instruction hours/ week : L: 0 T:0 P:4 Marks: Internal: 15 External: 35 Total:50

External Semester Exam: 4 Hours

Course Objectives:

- To estimate the samples using analytical instruments.
- To perform assay of drug samples using analytical intruments
- To determine the effect of solvents on absorption maxima.
- To separate the mixtures of sample using chromatographic techniques.
- To demonstrate HPLC.
- To demonstrate gas chromatography.

Course Outcomes (CO's): On successful completion of the course the student will

1. Estimate the samples using analytical instruments.
2. Perform assay of drug samples using analytical intruments
3. Determine the effect of solvents on absorption maxima.
4. Separate the mixtures of sample using chromatographic techniques.
5. Demonstrate HPLC.
6. Demonstrate gas chromatography.

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.

Suggested Readings:

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 by William 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.

17BP702T SEMESTER –VII

INDUSTRIAL PHARMACY - II (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market
- To understand the process of technology transfer from lab scale to commercial batch.
- To elicit different Laws and Acts that regulate pharmaceutical industry.
- To understand the approval process and regulatory requirements for drug products.
- To detailed description on regulatory requirements followed in India.
- To exploit knowledge on pharmaceutical product development and translation from laboratory to market.

Course Outcomes (CO's): On successful completion of the course the student will

1. Identify 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. Elicit different Laws and Acts that regulate pharmaceutical industry.
4. Understand the approval process and regulatory requirements for drug products.
5. Detailed description on regulatory requirements followed in India.
6. Exploit knowledge on pharmaceutical product development and translation from laboratory to market.

Course Content:

UNIT-I

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.

UNIT-II

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), Granularit y of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, anal ytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BC IL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues.

UNIT-III

Regulatory affairs: Introduction, Historical overview of Regulator y Affairs, Regulator y authorities, Role of Regulatory affairs department, Responsibility of Regulator y 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.

UNIT-IV

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Qualit y 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

UNIT-V

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.

Suggested Readings:

1. Regulator y 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 Regulator y Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulator y Affairs brought b y learning plus, inc. available at http.//www.cgmp.com/ra.htm.

17BP703T SEMESTER -VII

PHARMACY PRACTICE (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- Students will effectively apply principles of drug store management and inventory control to medication use.
- Students will provide patient-centered care to diverse patients using the best available evidence and monitor drug therapy of patient through medication chart review, obtain medication history interview and counsel the patients, identify drug related problems.
- Students will engage in innovative activities by making use of the knowledge of clinical trials
- Students will exhibit professional ethics by producing safe and appropriate medication use throughout society

Course Outcomes: On successful completion of the course the student will

1. Students will demonstrate knowledge and ability to use principles of therapeutics, health behavior, social and administrative aspects in the practice of pharmacy.
2. Students will use knowledge of drug distribution methods in hospital and apply it in the practice of pharmacy.
3. Students will effectively apply principles of drug store management and inventory control to medication use.
4. Students will provide patient-centered care to diverse patients using the best available evidence and monitor drug therapy of patient through medication chart review, obtain medication history interview and counsel the patients, identify drug related problems.
5. Students will engage in innovative activities by making use of the knowledge of clinical trials
6. Students will exhibit professional ethics by producing safe and appropriate medication use throughout society

UNIT- I

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, idiosyncras y, 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, t ypes 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.

UNIT- II

a) Drug distribution system in a hospital: 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 Drug Monioring, 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.

UNIT III

a) 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 emergencey 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.

UNIT- IV

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.

UNIT- V

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: Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests: Blood chemistry, hematology, and urinalysis

Suggested Readings:

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.

Suggesting 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.Pharmacytimes(Monthlymagazine).

17BP704T SEMESTER – VII

NOVEL DRUG DELIVERY SYSTEMS (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject is designed to impart basic knowledge on the area of novel drug delivery systems.
- To demonstrate the criteria for selection of drugs for the development of Novel drug delivery systems.
- To understand the criteria for selection of polymers for the development of Novel drug delivery systems.
- To express the Formulation characteristics of a new drug delivery systems.
- To explain the evaluation techniques followed in each drug delivery systems.
- To exploit new technologies to already existing drugs for enhancing the therapeutic effect.

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand various approaches for development of novel drug delivery systems.
2. Demonstrate the criteria for selection of drugs for the development of Novel drug delivery systems.
3. Understand the criteria for selection of polymers for the development of Novel drug delivery systems.
4. Express the Formulation characteristics of a new drug delivery systems.
5. Explain the evaluation techniques followed in each drug delivery systems.
6. Exploit new technologies to already existing drugs for enhancing the therapeutic effect.

Course content:

UNIT-I

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.

UNIT-II

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.

UNIT-III

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 systems: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

UNIT-IV
Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications.

UNIT-V
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.

Suggested Readings:

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 Wileyand 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, Vallabhrakashan, New Delhi, First edition 2002.

Suggested 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).

SEMESTER VIII

17BP801T SEMESTER-VIII

BIOSTATISITC AND RESEARCH METHODOLOGY (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- To understand the applications of Biostatics in Pharmacy.
- This subject deals with descriptive statistics, Graphics, Correlation, Regression and logistic regression Probability theory
- To know sampling technique, Parametric tests, Non Parametric tests and ANOVA
- To know Introduction to Design of Experiments, Phases of Clinical trials
- To understand observational and experimental studies, SPSS, R and MINITAB statistical software's,
- To analyse the statistical data using Excel**.**

Course Outcomes (CO's): On successful completion of the course the student will

1. Measure the central tendency, dispersion and correlation.
2. Calculate regression analyse and probability.
3. Perform parametric and non-parametric tests.
4. Design methodology for research and draw graphs.
5. Design and analyse experiments.
6. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)

Course content:

UNIT-I

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.

UNIT-II

Regression: Curve fitting b y 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.

UNIT-III

Non Parametric tests: Wilcox on 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.

UNIT-IV

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels **Introduction to Practical components of Industrial and Clinical Trials Problems**: Statistical Analysis Using Excel, SPSS, MINITAB®, DES IGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach.

UNIT-V

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques.

Suggested Readings:

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
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.

17BP 802T SEMESTER-VIII

SOCIAL AND PREVENTIVE PHARMACY (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To evaluate alternative ways of solving problems related to health and pharmaceutical issues
- To understand general principles of prevention and control of diseases
- To Know the functions of Primary Health Centres.

Course Outcomes (CO's): On successful completion of the course the student will

1. Measure the central tendency, dispersion and correlation.
2. Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
3. Have a critical way of thinking based on current healthcare development.
4. Evaluate alternative ways of solving problems related to health and pharmaceutical issues
5. General principles of prevention and control of diseases
6. Know the functions of Primary Health Centres.

Course content:

UNIT I:

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.

UNIT II:

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.

UNIT III:

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.

UNIT IV:

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

UNIT V:

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.

Suggested Readings:

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 Ro y 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, IS BN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Suggested Journals:

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

17BP803ET SEMESTER-VIII

PHARMA MARKETING MANAGEMENT (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people
- It 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.
- To demonstrate the new products decision like labeling, packaging etc.
- To discover promotion criteria's to be followed in Indian market.
- To exploit new technologies to already existing drugs for enhancing the therapeutic effect

Course Outcomes (CO's): On successful completion of the course the student will

1. Understand the market concepts.
2. Demonstrate the new products decision like labeling, packaging etc.
3. Discover promotion criteria's to be followed in Indian market.
4. Explain the role of professional sales representative.
5. Interpret the merging concepts in the ever-developing market.
6. Exploit new technologies to already existing drugs for enhancing the therapeutic effect

UNIT -I

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.

UNIT -II

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.

UNIT- III

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.

UNIT- IV

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.

UNIT- V

Pricing: Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authorit).

Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Suggested Readings:

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.

17BP804ET SEMESTER-VIII

PHARMACEUTICAL REGULATORY SCIENCE (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- 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.
- To know the process of drug discovery, development and generic product development
- To understand the regulatory approval process and registration procedures for API and drug products in various countrie
- To learn the basic understanding of regulations of India with other global regulated markets
- It gives basic understanding of developing clinical trial protocols

Course Outcomes(CO's): On successful completion of the course the student will

1. Explain the process of drug discovery, development and generic product development
2. Describe the regulatory approval process and registration procedures for API and drug products in various countrie
3. Learn the basic understanding of regulations of India with other global regulated markets
4. Understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
5. Explain basic understanding of developing clinical trial protocols
6. Understand the concept of pharmacovigilance and its significance

Course content:

UNIT I

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.

UNIT II

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)

UNIT III

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.

UNIT IV

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 - safety monitoring in clinical trials.

UNIT V

Regulatory Concepts: Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

Suggested Readings:

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berr y 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. 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.

17BP 805ET SEMESTER-VIII

PHARMACOVIGILANCE (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science
- To know basic terminologies used in pharmacovigilance,
- To understand global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization
- To learn various methods that can be used to generate safety data and signal detection.
- This paper also develops the skills of classifying drugs, diseases.
- Learn to write effectively case narratives of adverse events and their quality.

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the importance of safety monitoring.
2. Discuss the History and development of pharmacovigilance, National and international scenario of pharmacovigilance, Dictionaries, coding and terminologies used in pharmacovigilance, Detection of new adverse drug reactions and their assessment, Adverse drug reaction reporting systems and communication in pharmacovigilance, Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India.
3. Understand the International standards for classification of diseases and drugs
4. Generate and describe the safety data during pre clinical, clinical and post approval phases of drugs' life cycle, Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
5. Elaborate the ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning, CIOMS requirements for ADR reporting
6. Write effectively case narratives of adverse events and their quality.

Course Content

UNIT I

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.

UNIT II

Drug and disease classification:

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- 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.

UNIT III

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.

UNIT IV

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.

UNIT V

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
- Differences in Indian and global pharmacovigilance requirements

Suggested Readings:

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 Mann
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn 3=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

17BP806ET SEMESTER-VIII

QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory) 4H 4C

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- In this subject the student learns about the various methods
- To understand 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.
- To know regulatory approval process and their registration in Indian and international markets.
- To understand Drugs and Cosmetic Act Provision for herbal drug preparation and marketing
- To learn basic tests for drugs to obtain dosage form for pharmaceutical substances and medicinal plants

Course Outcomes(CO's): On successful completion of the course the student will

1. Explain basic tests for drugs to obtain dosage form for pharmaceutical substances and medicinal plants
2. Explain methods for evaluation of pharmaceutical substances, medicinal plants and commercial crude drugs along with WHO guidelines for quality control for herbal drugs
3. Describe guidelines for cGMP, GAP, GMP and GLP for quality assurance of herbal drugs in industry
4. Describe guidelines for quality control of herbal drugs and evaluation of safety and efficacy of herbal medicines.
5. Explain regulatory approval process and their registration in Indian and international markets.
6. Explain Drugs and Cosmetic Act Provision for herbal drug preparation and marketing

UNIT- I

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

UNIT- II

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.

UNIT -III

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

UNIT- IV

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.

UNIT-V

Regulator y 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.

Suggested Readings:

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.

17BP807ET SEMESTER-VIII

COMPUTER AIDED DRUG DESIGN (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.
- To know the various stages of drug discover
- To Learn the concept of bioisosterism and drug resistance
- To understand physicochemical Properties and the techniques involved in QSAR
- To Learn Bioinformatics and Cheminformatics
- To know methods in molecular and quantum mechanics

Course Outcomes(CO's): On successful completion of the course the student will

1. Explain the various stages of drug discover
2. Learn the concept of bioisosterism and drug resistance
3. Describe physicochemical Properties and the techniques involved in QSAR
4. Learn introduction to Bioinformatics and Cheminformatics
5. Learn methods in molecular and quantum mechanics
6. Explain various structure based drug design methods (Molecular docking, Denovo drug design)

Course Content:

UNIT-I

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.

UNIT-II

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.

UNIT-III

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.

UNIT-IV

Informatics & Methods in drug design: Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Suggested Readings:

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" John Wiley & 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.

17BP808ET SEMESTER-VIII

CELL AND MOLECULAR BIOLOGY (Elective subject)

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- To understand cell and molecular biology history 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,
- To learn specialized cells in multi-cellular organisms such as humans, plants, and sponges.
- To know basic molecular genetic mechanisms
- To understand protein structure and functions

Course Outcomes(CO's): On successful completion of the course the student will

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

Course content:

UNIT I

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).

UNIT II

a) DNA and the Flow of Molecular Information.
b) DNA Functioning.
c) DNA and RNA.
d) Types of RNA.
e) Transcription and Translation.

UNIT III

a) Proteins: Defined and Amino Acids.
b) Protein Structure.
c) Regularities in Protein Pathways.
d) Cellular Processes.
e) Positive Control and significance of Protein Synthesis.

UNIT IV

a) Science of Genetics.
b) Transgenics and Genomic Analysis.
c) Cell Cycle analysis.
d) Mitosis and Meiosis.
e) Cellular Activities and Checkpoints.

UNIT V

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

Suggested Readings:

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 Goldshyet. al., : Kuby Immunology.

17BP809ET SEMESTER-VIII

COSMETIC SCIENCE (Theory) **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total: 100

External Semester Exam: 3 Hours

Course Objectives:

- To know the cosmetics in day to day life.
- To understand the formulation characteristics of cosmetic preparations
- To understand the role of herbs in cosmetic science
- To Demonstrate the evaluation procedures in the formulation of cosmetics
- To Identify the problems encountered during the usage of cosmetics
- To illustrate the role of nutraceuticals in day to day life

Course Outcomes(CO's): On successful completion of the course the student will

1. Discover the cosmetics in day to day life.
2. Formulation characteristics of cosmetic preparations
3. Understand the role of herbs in cosmetic science
4. Demonstrate the evaluation procedures in the formulation of cosmetics
5. Identify the problems encountered during the usage of cosmetics
6. Illustrate the role of nutraceuticals in day to day life

UNIT I

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, rheology modifiers, 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**.**

UNIT II

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.

UNIT III

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, skin- cream and toothpaste**.**

UNIT IV

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.

UNIT V

Oily and dr y skin, causes leading to dr y 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

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) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

17BP810ET SEMESTER-VIII

PHARMACOLOGICAL SCREENING METHODS **4H** **4C**

Instruction hours/ week : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject is designed to impart the basic knowledge of preclinical studies inexperimental animals including design, conduct and interpretations of results.
- To study blood withdrawal techniques and drug administration in animals.
- To know dose, dose calculations grouping of animals, species selection, sex in conducting the animal experimentation.
- To understand the research Study of screening animal models for Diuretics, no-tropics, anti-Parkinson's, anti asthmatics.
- To learn screening methods of CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti parkinsonism, alzheimer's diseaseExplain screening methods of for CVS activity- anti hypertensives, diuretics, anti arrhythmic, anti dyslepidemic
- To know screening methods of Research methodology and Bio-statistics

Course Outcomes(CO's): On successful completion of the course the student will

1. Describe the applications of common laboratory animals, explain CPCSEA and OECD guidelines governing the for maintenance, breeding and conduct of experiments on laboratory animals.
2. Explain blood withdrawal techniques and drug administration in animals.
3. Explain dose, dose calculations grouping of animals, species selection, sex in conducting the animal experimentation.
4. Describe the research Study of screening animal models for Diuretics, no-tropics, anti-Parkinson's, anti asthmatics.
5. Explain screening methods of CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti parkinsonism, alzheimer's diseaseExplain screening methods of for CVS activity- anti hypertensives, diuretics, anti arrhythmic, anti dyslepidemic
6. Explain screening methods of Research methodology and Bio-statistics

UNIT –I

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.

UNIT –II

Preclinical screening models:

a. Introduction: 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.

b. Study of screening animal models: Diuretics, nootropics, anti-Parkinson's, antiasthmatics. **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antips ychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease.

UNIT –III

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, para sympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on e ye, local anaethetics.

UNIT –IV

Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregator y, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

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.

Suggested Readings:

1. Fundamentals of experimental Pharmacology-by M.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

17BP 811ET SEMESTER-VIII

ADVANCED INSTRUMENTATION TECHNIQUES 4H 4C

Instruction hours/ wee : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject deals with the application of instrumental methods in qualitative andquantitative 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.
- To Learn basic principles and instrumentation of thermal analysis
- To know general principles and procedures involved in extraction techniques.
- To Learn basic instrumentation and applications of hyphenated techniques.

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain theoretical principles of, MASS and NMR spectroscopy.
2. Learn basic instrumentation of NMR and mass spectrometer.
3. Explain theoretical principles of x-rays, instrumentation and identification of organic compounds.
4. Learn basic principles and instrumentation of thermal analysis
5. Describe general principles and procedures involved in extraction techniques.
6. Learn basic instrumentation and applications of hyphenated techniques.

Course Content:

UNIT-I

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, Anal yzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II

Thermal Methods of Analysis: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC).

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X- ray Crystallograph y, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT-III

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.

UNIT-IV

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.

UNIT-V

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Suggested Readings:

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 by William 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.

17BP 812 ET SEMESTER-VIII

DIETARY SUPPLEMENTS AND NUTRACEUTICALS **4H** **4C**

Instruction hours/ wee : L: 3 T:1 P:0 Marks: Internal: 25 External: 75 Total:100

External Semester Exam: 3 Hours

Course Objectives:

- This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.
- To know about effect of nutrition to maintain healthy life of public included maternal and child health and effects of education about nutrition in community.
- To understand source, chemistry and uses of several natural nutraceuticals.
- To know occurrence, chemical nature and medicinal benefits of natural nutraceuticals belong to different phytochemical categories.
- To learn about different free radical which generate in body and their effects and different dietary fibres and complex carbohydrate as functional food ingredients.
- To understand the role of free radicals in development of different diseases and aging

Course Outcomes (CO's): On successful completion of the course the student will

1. Explain the definition, classification of nutraceuticals, functional foods and dietary supplements and role of nutraceuticals in prevention or cure various diseases.
2. Explain about effect of nutrition to maintain healthy life of public included maternal and child health and effects of education about nutrition in community.
3. Describe about source, chemistry and uses of several natural nutraceuticals.
4. Describe occurrence, chemical nature and medicinal benefits of natural nutraceuticals belong to different phytochemical categories.
5. Explain about different free radical which generate in body and their effects and different dietary fibres and complex carbohydrate as functional food ingredients.
6. Explain the role of free radicals in development of different diseases and aging

UNIT I **07 hours**

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

UNIT II **15 hours**

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.

UNIT III **07 hours**

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, nucleicac

b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV **10 hours**

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, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin

Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention

UNIT V **06 hours**

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.

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 FunctionalFoods* 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

17BP 813ET SEMESTER-VIII

Elective course on Pharmaceutical Product Development (Theory) 4H 4C

No of Hours: 3 **Tutorial: 1** **Credit points:4**

Course Objectives:

- To Learn the regulatory principles and requirements of drug discovery and developments
- To Understand the concept of preformulation studies for various formulations
- To understand concept and designing of pilot plants and product scale up
- To Learn various pharmaceutical packaging systems and their quality testing
- To Learn the concept of technology transfer from R&D to production plant
- To Discuss on the new era opportunities and challenges in the pharmaceutical market

Course Outcomes (CO's): On successful completion of the course the student will

1. Learn the regulatory principles and requirements of drug discovery and developments
2. Understand the concept of preformulation studies for various formulations
3. Concept and designing of pilot plants and product scale up
4. Learn various pharmaceutical packaging systems and their quality testing
5. Learn the concept of technology transfer from R&D to production plant
6. Discuss on the new era opportunities and challenges in the pharmaceutical market

Course content

Unit I

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

Unit II

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 sorbitols
v. Suspending and emulsifying agents
vi. Semi solid excipients

Unit-III

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

Unit-IV

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.

Unit-V

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

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E.Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz

17BP 814PW SEMESTER-VIII

PROJECT WORK **12H 6C**

Instruction hours/ week : L: 0 T:0 P:12 Marks: Internal: 0 External: 150 Total:150

External Semester Exam: 4 Hours

No. of hours: 12 **Tutorial:0** **Credit point: 6**

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 semesterVIII. 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 internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shallbeevaluated in groups for four hours (i.e., about half an hour for a group of five students).