

19PD101T

FIRST YEAR

HUMAN ANATOMY AND PHYSIOLOGY (THEORY)**4H****4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory: 4 Hrs / Week****Course Objectives:**

- This course is designed to impart a fundamental knowledge on the structure and functions of the human body.
- It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems.
- Since medicament, which is produced by pharmacist, is used to correct the deviations in human body
- It enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
- To appreciate coordinated working pattern of different organs of each system; and
- To understand the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Outcome (CO's):

1. Describe the structure (gross and histology) and functions of various organs of the human body;
2. Describe the various homeostatic mechanisms and their imbalances of various systems;
3. Identify the various tissues and organs of the different systems of the human body;
4. Perform the hematological tests and also record blood pressure, heart rate, pulse and respiratory volumes;
5. Appreciate coordinated working pattern of different organs of each system; and
6. Appreciate the interlinked mechanisms in the maintenance of normal Functioning (homeostasis) of human body.

Course Content:**UNIT I**

- Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
- Structure of cell – its components and their functions.
- Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

UNIT II

- Osseous system - structure, composition and functions of the skeleton

- Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

UNIT III

Haemopoetic System

- Composition and functions of blood
- Haemopoiesis and disorders of blood components (definition of disorder)
- Blood groups
- Clotting factors and mechanism
- Platelets and disorders of coagulation

Lymph

- Lymph and lymphatic system, composition, formation and circulation.
- Spleen: structure and functions, Disorders
- Disorders of lymphatic system (definition only)

UNIT IV

Cardiovascular system

- Anatomy and functions of heart
- Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
- Electrocardiogram (ECG)
- Cardiac cycle and heart sounds
- Blood pressure – its maintenance and regulation
- Definition of the following disorders
- Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

Respiratory system

- Anatomy of respiratory organs and functions
- Mechanism / physiology of respiration and regulation of respiration
- Transport of respiratory gases
- Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

UNIT V

Digestive system

- Anatomy and physiology of GIT

- Anatomy and functions of accessory glands of GIT
- Digestion and absorption
- Disorders of GIT (definitions only)

UNIT VI

Nervous system

- Definition and classification of nervous system
- Anatomy, physiology and functional areas of cerebrum
- Anatomy and physiology of cerebellum
- Anatomy and physiology of mid brain
- Thalamus, hypothalamus and Basal Ganglia
- Spinal cord: Structure & reflexes – mono-poly-planter
- Cranial nerves – names and functions
- ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

UNIT VII

Urinary system

- Anatomy and physiology of urinary system
- Formation of urine
- Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
- Clearance tests and micturition

Endocrine system

- Pituitary gland
- Adrenal gland
- Thyroid and Parathyroid glands
- Pancreas and gonads

UNIT VIII

Reproductive system

- Male and female reproductive system
- Their hormones – Physiology of menstruation
- Spermatogenesis & Oogenesis
- Sex determination (genetic basis)
- Pregnancy and maintenance and parturition
- Contraceptive devices

UNIT IX**Sense organs**

- Eye
- Ear
- Skin
- Tongue & Nose

Skeletal muscles

- Histology
- Physiology of Muscle contraction
- Physiological properties of skeletal muscle and their disorders (definitions)

UNIT X**Sports physiology**

- Muscles in exercise, Effect of athletic training on muscles and muscle performance,
- Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
- Drugs and athletics

Suggested Readings:

1. Tortora Gerard J. and Nicholas P. Principles of Anatomy and Physiology Publisher Harpercollins College New York.
2. Wilson, K.J.W. Ross and Wilson's foundations of Anatomy and Physiology Publisher: Churchill Livingstone, Edinburg.

Reference Books (Latest Editions):

1. Guyton Arthur, C. Physiology of human body. Publisher: Holtsaunders.
2. Chatterjee C C. Human physiology. Volume 1&11. Publisher: Medical Allied Agency, Calcutta.
3. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
4. Gray's Anatomy. Publisher: Churchill Livingstone, London.

HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs/Week****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.

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book (100pages), Stationary items, Blood lancet.**List of Experiments:**

1. Study of tissues of human body
 - (a) Epithelial tissue
 - (b) Muscular tissue
2. Study of tissues of human body
 - (a) Connective tissue
 - (b) Nervous tissue
3. Study of appliances used in hematological experiments
4. Determination of W.B.C. count of blood
5. Determination of R.B.C. count of blood
6. Determination of differential count of blood
7. Determination of
 - (a) Erythrocyte Sedimentation Rate
 - (b) Hemoglobin content of Blood

- (c) Bleeding time & Clotting time
- 8. Determination of
 - (a) Blood Pressure
 - (b) Blood group
- 9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton
 - (b) Skeleton system part II- appendicular skeleton
 - (c) Cardiovascular system
 - (d) Respiratory system
 - (e) Digestive system
 - (f) Urinary system
 - (g) Nervous system
 - (h) Special senses
 - (i) Reproductive system
- 10. Study of different family planning appliances.
- 11. To perform pregnancy diagnosis test.
- 12. Study of appliances used in experimental physiology.
- 13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
- 14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
- 15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
- 16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
- 17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Suggested Readings:

1. Goyal, R. K, Natvar M.P, and Shah S.A, Practical Anatomy, Physiology and Biochemistry, Latest Edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

1. Ranade VG, Text Book of Practical Physiology, Latest Edition, Publisher: PVG, Pune.
2. Anderson Experimental Physiology, Latest Edition, Publisher: NA

19PD102T

FIRST YEAR

PHARMACEUTICS (THEORY)**3H 3C**

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 3 Hrs /Week****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**

- Introduction to dosage forms - classification and definitions
- Prescription: definition, parts and handling

UNIT II

Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.

UNIT III

Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

UNIT IV

- Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

- Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

UNIT V

Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.

UNIT VI

Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavors with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

UNIT VII

Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.

UNIT VIII

- Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

UNIT IX

- Pharmaceutical calculations.
- Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.

UNIT X

Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

Suggested Readings:

1. Cooper and Gunn's Dispensing for pharmacy students.
2. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference Books (Latest Editions):

1. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
2. Remington's Pharmaceutical Sciences. Register of General Pharmacy by Cooper and Gunn.
3. General Pharmacy by M.L.Schroff.

19PD108P

FIRST YEAR

PHARMACEUTICS (PRACTICAL)**3H 2C**

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs./Week****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
- 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 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
6. Develop a clear idea about Pharmaceutical incompatibility and different pharmaceutical calculations in pharmacy.

List of Experiments:**Syrups**

- Simple Syrup I.P
- Syrup of Ephedrine Hcl NF
- Syrup Vasaka IP
- Syrup of ferrous Phosphate IP
- Orange Syrup

Elixir

- Piperizine citrate elixir BP
- Cascara elixir BPC
- Paracetamol elixir BPC

Linctus

- Simple Linctus BPC
- Pediatric simple Linctus BPC

Solutions

- Solution of cresol with soap IP
- Strong solution of ferric chloride BPC
- Aqueous Iodine Solution IP
- Strong solution of Iodine IP
- Strong solution of ammonium acetate IP

Liniments

- Liniment of turpentine IP*
- Liniment of camphor IP

Suspensions*

- Calamine lotion
- Magnesium Hydroxide mixture BP

Emulsions*

- Cod liver oil emulsion
- Liquid paraffin emulsion

Powders[#]

- Eutectic powder
- Explosive powder
- Dusting powder
- Insufflations

Suppositories[#]

- Boric acid suppositories
- Chloral suppositories

Incompatibilities

- Mixtures with Physical
- Chemical & Therapeutic incompatibilities

* Colorless bottles required for dispensing

Paper envelope (white), butter paper and white paper required for dispensing.

Suggested Readings:

3. Cooper and Gunn's Dispensing for pharmacy students.
4. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference Books (Latest Editions):

4. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
5. Remington's Pharmaceutical Sciences. Register of General Pharmacy by Cooper and Gunn.
6. General Pharmacy by M.L.Schroff.

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week

Course Objectives:

- Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells.
- Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.
- To understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- To know the metabolic process of biomolecules in health and illness (metabolic disorders);
- To understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- To know the biochemical principles of organ function tests of kidney, liver and endocrine gland

Course Outcome (CO's):

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

1. Understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
2. Know the metabolic process of biomolecules in health and illness (metabolic disorders);
3. Understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
4. Know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
5. Do the qualitative analysis and determination of biomolecules in the body fluids.
6. To know energy rich compounds; ATP, Cyclic AMP and their biological significance

Course content:

UNIT I

• **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

- **Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

UNIT II

- **Carbohydrate metabolism:** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.
- **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).

UNIT III

Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

UNIT IV

Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

UNIT V

Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

UNIT VI

Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory.

UNIT VII

The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

- Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
- Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)

- Urine concentration test
- Urinary tract calculi. (stones)

UNIT VIII

Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

- Test for hepatic dysfunction-Bile pigments metabolism.
- Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
- Dye tests of excretory function.
- Tests based upon abnormalities of serum proteins.

UNIT IX

- **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases. Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

UNIT X

Electrolytes: Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

Suggested Readings:

1. Harpers Review of Biochemistry – Martin
2. Text book of Biochemistry – D. Satyanarayana
3. Text book of Clinical Chemistry- Alex Kaplan & Laverve L.Szabo

Reference Books (Latest Editions):

1. Principles of Biochemistry -- Lehninger
2. Text book of Biochemistry -- Ramarao
3. Practical Biochemistry-David T.Plummer
4. Practical Biochemistry-Pattabhiraman

MEDICINAL BIOCHEMISTRY (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs./Week****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.

Title of the Experiment:

- 1 Qualitative analysis of normal constituents of urine.*
- 2 Qualitative analysis of abnormal constituents of urine.*
- 3 Quantitative estimation of urine sugar by Benedict's reagent method.**
- 4 Quantitative estimation of urine chlorides by Volhard's method.**
- 5 Quantitative estimation of urine creatinine by Jaffe's method.**
- 6 Quantitative estimation of urine calcium by precipitation method.**
- 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
- 8 Preparation of Folin Wu filtrate from blood.*
- 9 Quantitative estimation of blood creatinine.**
- 10 Quantitative estimation of blood sugar Folin-Wu tube method.**
- 11 Estimation of SGOT in serum.**
- 12 Estimation of SGPT in serum.**
- 13 Estimation of Urea in Serum.**
- 14 Estimation of Proteins in Serum.**
- 15 Determination of serum bilirubin**

- 16 Determination of Glucose by means of Glucoseoxidase.**
- 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
- 18 Study of factors affecting Enzyme activity. (pH & Temp.)**
- 19 Preparation of standard buffer solutions and its pH measurements (any two)*
- 20 Experiment on lipid profile tests**
- 21 Determination of sodium,calcium and potassium in serum.**

** Indicate major experiments & * Indicate minor experiments

Assignments:

Format of the Assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Suggested Readings:

1. Harpers Review of Biochemistry – Martin
2. Text book of Biochemistry – D. Satyanarayana
3. Text book of Clinical Chemistry- Alex Kaplan & Laverve L.Szabo

Reference Books (Latest Editions):

1. Practical Biochemistry-David T.Plummer
2. Practical Biochemistry-Pattabhiraman

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory : 4 Hrs. /Week

Course Objectives:

This course is designed to impart a very good knowledge about

- IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
- Some important physical properties of organic compounds;
- Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
- Some named organic reactions with mechanisms; and
- Methods of preparation, test for purity, principle involved in the assay
- To know important medicinal uses of some important 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.

UNIT I

Structures and Physical properties:

- Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P,
- Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
- Acids and bases, Lowry bronsted and Lewis theories
- Isomerism.

Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines,

Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And cycloalkanes.

Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability

UNIT II

- **Alicyclic compounds** : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- **Nucleophilic aliphatic substitution mechanism:** Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN₂ reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN₁ reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN₁ reaction, Ion dipole bonds, SN₂ versus SN₁ solvolyses, nucleophilic assistance by the solvents.

UNIT III

Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E₂ and E₁ mechanism, elimination via carbocation, evidence for E₂ mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E₂ versus E₁, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

UNIT IV

Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, Heat of hydrogenation and stability of alkenes, Markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, Halohydrin formation, mechanism of free radicals addition, Mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, Additions of carbene to alkene, cyclo addition reactions.

UNIT V

- **Carbon-carbon double bond as substituents:** Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- **Theory of resonance:** Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN₁ reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN₂ nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated

dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

UNIT VI

Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.

UNIT VII

Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution. Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

UNIT VIII

- **Hoffman rearrangement:** Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

UNIT IX

- **Nucleophilic aromatic substitution:** Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
 - Oxidation reduction reaction.

UNIT X

- Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

Suggested Readings:

1. T.R.Morrison and R. Boyd - Organic chemistry
2. Bentley and Driver-Text book of Pharmaceutical chemistry
3. I.L.Finar- Organic chemistry, the fundamentals of chemistry

Reference Books (Latest Editions):

1. Organic chemistry – J.M.Cram and D.J.Cram
2. Organic chemistry- Brown
3. Advanced organic chemistry- Jerry March, Wiley
4. Organic chemistry- Cram and Hammered, Pine Hendrickson

PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P: 3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs./Week****Course Objectives:**

- Students will be 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.

Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid

13. Preparation of O-chlorobenzoic acid from O-chlorotoluene

14. Preparation of cyclohexanone from cyclohexanol

Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Suggested Readings:

1. T.R.Morrison and R. Boyd - Organic chemistry
2. Bentley and Driver-Text book of Pharmaceutical chemistry
3. I.L.Finar- Organic chemistry, the fundamentals of chemistry

Reference Books (Latest Editions):

1. Organic chemistry – J.M.Cram and D.J.Cram
2. Organic chemistry- Brown
3. Advanced organic chemistry- Jerry March, Wiley
4. Organic chemistry- Cram and Hammered, Pine Hendrickson

PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY) 3H 3C

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory : 3 Hrs. /Week

Course Objectives:

- This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
- 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

Course Outcome (CO's):

1. Understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
2. Know the analysis of the inorganic pharmaceuticals their applications; and
3. Appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.
4. Identify the errors in analysis
5. Understand the principles of volumetric analysis and electrochemical analysis
6. Applications of volumetric analysis.

UNIT I

- Errors

UNIT II

- Volumetric analysis

UNIT III

- Acid-base titrations
- Redox titrations

UNIT IV

- Non aqueous titrations

- Precipitation titrations
- Complexometric titrations

UNIT V

- Theory of indicators

UNIT VI

- Gravimetry

UNIT VII

- Limit tests

UNIT VIII

Medicinal gases

UNIT IX

- Acidifiers
- Antacids
- Cathartics
- Electrolyte replenishers
- Essential Trace elements
- Antimicrobials
- Pharmaceutical aids
- Dental Products
- Miscellaneous compounds

UNIT X

- Radio Pharmaceuticals

Suggested Readings:

1. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
2. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol -I & Vol-II
3. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

Reference Books (Latest Editions):

1. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
2. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
3. Analytical Chemistry Principles by John H. Kennedy
4. I.P.1985 and 1996, Govt. of India, Ministry of Health

PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs./Week****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.

Limit test (6 exercises)

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

Assays (10 exercises)

- g. Ammonium chloride- Acid-base titration
- h. Ferrous sulphate- Cerimetry
- i. Copper sulphate- Iodometry
- j. Calcilugluconate- Complexometry
- k. Hydrogen peroxide – Permanganometry
- l. Sodium benzoate – Nonaqueous titration
- m. Sodium chloride – Modified volhard's method

- n. Assay of KI – KIO₃ titration
- o. Gravimetric estimation of barium as barium sulphate
- p. Sodium antimony gluconate or antimony potassium tartarate

Estimation of mixture (Any two exercises)

- q. Sodium hydroxide and sodium carbonate
- r. Boric acid and Borax
- s. Oxalic acid and sodium oxalate

Test for identity (Any three exercises)

- t. Sodium bicarbonate
- u. Barium sulphate
- v. Ferrous sulphate
- w. Potassium chloride

Test for purity (Any two exercises)

- a. Swelling power in Bentonite
- b. Acid neutralising capacity in aluminium hydroxide gel
- c. Ammonium salts in potash alum
- d. Adsorption power heavy Kaolin
- e. Presence of Iodates in KI

Preparations (Any two exercises)

- f. Boric acids
- g. Potash alum
- h. Calcium lactate
- i. Magnesium sulphate

Suggested Readings:

1. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
2. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

Reference Books (Latest Editions):

1. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
2. Analytical Chemistry Principles by John H. Kennedy
3. I.P.1985 and 1996, Govt. of India, Ministry of Health

19PD106RMT

FIRST YEAR

REMEDIAL MATHEMATICS (THEORY)**4H****4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory : 4 Hrs. /Week**Course Objectives:**

- This is an introductory course in mathematics.
- This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.
- Able to Perform calculations using matrices and determinants.
- Able to Solve problems using differential and integral calculus.
- To Calculate the equation for straight line and coordinates.
- Students can able to apply 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 fraction, logarithms, function and limits.
2. Perform calculations using matrices and determinants.
3. Solve problems using differential and integral calculus.
4. Calculate 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

UNIT I**Algebra:** Determinants, Matrices**UNIT II****Trigonometry:** Sides and angles of a triangle, solution of triangles**UNIT III****Analytical Geometry:** Points, Straight line, circle, parabola**UNIT IV****Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function.

UNIT V

Differential calculus: Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables

UNIT VI

Integral Calculus: Definite integrals, integration by substitution and by parts, Properties of definite integrals.

UNIT VII

Differential equations: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear.

UNIT VIII

Differential equations: Differential equation with constant coefficient, simultaneous linear equation of second order.

UNIT IX

Laplace transform: Definition, Laplace transform of elementary functions

UNIT X

Laplace transform: Properties of linearity and shifting.

Suggested Readings:

1. Differential calculus By Shantinakaran
2. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference Books (Latest Editions):

1. Integral calculus By Shanthinarayan
2. Engineering mathematics By B.S.Grewal
3. Trigonometry Part-I By S.L.Loney

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Course Objectives:

- To learn and understand the components of living world, structure and functional system 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 (CO's): 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

- Introduction
- General organization of plants and its inclusions

UNIT II

- Plant tissues
- Plant kingdom and its classification
- Morphology of plants

UNIT III

- Root, Stem, Leaf and its modifications
- Inflorescence and Pollination of flowers
- Morphology of fruits and seeds

UNIT IV

- Plant physiology
- Taxonomy of Leguminosae, Umbelliferae, Solanaceae, Liliaceae, Zinziberaceae, Rubiaceae

UNIT V

- Study of Fungi, Yeast, Penicillin and Bacteria

UNIT VI

- Study of Animal cell
- Study animal tissues

UNIT VII

- Detailed study of frog

UNIT VIII

- Study of Pisces, Raptiles, Aves

UNIT IX

- General organization of mammals

UNIT X

- Study of poisonous animal

Suggested Readings:

1. Text book of Biology by S.B.Gokhale
2. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference Books (Latest Editions):

1. A Text book of Biology by B.V.Sreenivasa aidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthkrishnan.
5. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Practical : 3 Hrs./Week

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.

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Suggested Readings:

1. Text book of Biology by S.B.Gokhale
2. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference Books (Latest Editions):

1. A Text book of Biology by B.V.Sreenivasa aidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthkrishnan.
5. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory : 3 Hrs. /Week

Course Objectives:

- 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):

Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.
4. Describe the mechanism of the diseases.
5. Understand the etiology and pathogenesis of diseases.
6. Discuss about the Sexually transmitted diseases.

UNIT I

Basic principles of cell injury and Adaptation

- Causes, Pathogenesis and morphology of cell injury
- Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

UNIT II

Inflammation

- Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
- Repairs of wounds in the skin, factors influencing healing of wounds

UNIT III

Diseases of Immunity

- Introduction to T and B cells
- MHC proteins or transplantation antigens

Immune tolerance

- **Hypersensitivity**
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
- **Autoimmunity**
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
- Acquired immune deficiency syndrome (AIDS)
- Amyloidosis

UNIT IV

Cancer: Differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread,

- Disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- Types of shock, mechanisms, stages and management
- Biological effects of radiation

UNIT V

Environmental and nutritional diseases

- Air pollution and smoking- SO₂,NO, NO₂, and CO
- Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

UNIT VI

Pathophysiology of common diseases

- Parkinsonism
- Schizophrenia
- Depression and mania

UNIT VII

Pathophysiology of common diseases

- Hypertension,
- Stroke (ischaemic and hemorrhage)
- Angina, CCF, Atherosclerosis, Myocardial infarction

UNIT VIII

Pathophysiology of common diseases

- Diabetes Mellitus

- Peptic ulcer and inflammatory bowel diseases

UNIT IX

Pathophysiology of common diseases

- Cirrhosis and Alcoholic liver diseases
- Acute and chronic renal failure
- Asthma and chronic obstructive airway diseases

UNIT X

Infectious diseases :

Sexually transmitted diseases (HIV, Syphilis, Gonorrhoea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Suggested Readings:

1. Pathologic basis of disease by- Cotran, Kumar, Robbins
2. Text book of Pathology- Harsh Mohan
3. Text book of Pathology- Y.M. Bhide

Reference Books (Latest Editions):

1. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker;
Churchill Livingstone publication

PHARMACEUTICAL MICROBIOLOGY (THEORY)**4H****4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week**Course Objectives:**

- Microbiology has always been an essential component of pharmacy curriculum.
- This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry.
- Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.
- This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance.
- It's also discusses with sterilization of pharmaceutical products, equipment, media etc.
- The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

Course Outcomes (CO's):**Upon completion of the subject student shall be able to –**

1. Know the anatomy, identification, growth factors and sterilization of microorganisms;
2. Know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
3. Do estimation of RNA and DNA and there by identifying the source;
4. Do cultivation and identification of the microorganisms in the laboratory;
5. Do identification of diseases by performing the diagnostic tests; and
6. Appreciate the behavior of motility and behavioral characteristics of microorganisms.

UNIT I

Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

UNIT II

Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

UNIT III

- Nutritional requirements, growth and cultivation of bacteria and virus.
- Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria - Total and Viable counting techniques.

UNIT IV

- Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations.
- Brief information on Validation.

UNIT V

Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteriostatic, virucidal activities, evaluation of preservatives in pharmaceutical preparations.

UNIT VI

Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) .

UNIT VII

Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

UNIT VIII

Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.

UNIT IX

Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of

- Penicillin, Streptomycin and vitamin B₂ and B₁₂.
- Standardisation of vaccines and sera.

UNIT X

Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhoea and HIV.

Reference Books (Latest Editions):

1. Vanitha Kale and Kishor Bhusari — Applied Microbiology | Himalaya Publishing house Mumbai.
2. Mary Louis Turgeon — Immunology and Serology in Laboratory Medicines| 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
3. Harsh Mohan, — Text book of Pathology| 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

1. Prescott L.M., Jarley G.P Klein D.A — Microbiology| 2nd- edition Mc Graw Hill Company Inc
2. Rawlins E.A. | Bentley's Text Book of Pharmaceutics| B ailliere Tindals 24-28 London 1988
3. Forbisher — Fundamentals of Microbiology| Philadelphia W.B. Saunders.
4. Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology. | 2nd edition WMC Brown Publishers, Oxford. 1993
5. War Roitt, Jonathan Brostoff, David male, — Immunology| 3rd edition 1996, Mosby-year book Europe Ltd, London.
6. Pharmacopoeia of India, Govt of India, 1996.

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SECOND YEAR

PHARMACEUTICAL MICROBIOLOGY (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**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 of 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 of antibiotics.
6. Execute different sterility tests and bacteriological analysis of water

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation.*
- 3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro*-organisms
- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1. Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Reference Books (Latest Editions):

1. Vanitha Kale and Kishor Bhusari — Applied Microbiology | Himalaya Publishing house Mumbai.
2. Harsh Mohan, — Text book of Pathology | 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

1. Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology. | 2nd edition WMC Brown Publishers, Oxford. 1993
2. War Roitt, Jonathan Brostoff, David male, — Immunology | 3rd edition 1996, Mosby-year book Europe Ltd, London.
3. Pharmacopoeia of India, Govt of India, 1996.

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YEAR

SECOND

PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)**4H 4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory: 4 Hrs. /Week****Course Objectives:**

- This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, and distribution
- To know its method of cultivation,
- To know active constituents, medicinal uses
- To understand its preservation methods, identification tests, substitutes and adulterants.
- To understand the traditional system of medicine.
- To explain the Plant Products Primary metabolites Proteins, Enzymes, Lipids, Marine drugs.

Course Outcomes (CO's):

1. Understand the basic principles of cultivation, collection and storage of crude drugs;
2. Know the source, active constituents and uses of crude drugs; and
3. Appreciate the applications of primary and secondary metabolites of the plant.
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.

UNIT I

- Introduction.
- Definition, history and scope of Pharmacognosy.

UNIT II

- Classification of crude drugs.
- Cultivation, collection, processing and storage of crude drugs.
- Detailed method of cultivation of crude drugs.

UNIT III

- Study of cell wall constituents and cell inclusions.
- Microscopical and powder Microscopical study of crude drugs.

UNIT IV

Study of natural pesticides.

UNIT V

Detailed study of various cell constituents.

UNIT VI

- Carbohydrates and related products.
- Detailed study carbohydrates containing drugs.(11 drugs)

UNIT VII

- Definition sources, method extraction, chemistry and method of analysis of lipids.
- Detailed study of oils.

UNIT VIII

Definition, classification, chemistry and method of analysis of protein.

UNIT IX

Study of plants fibers used in surgical dressings and related products.

UNIT X

Different methods of adulteration of crude drugs.

Suggested Readings:

1. Pharmacognosy by G.E. Trease & W.C.Evans.
2. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference Books (Latest Editions):

1. Pharmacognosy by Brady & Tyler.E.
2. Pharmacognosy by T.E.Wallis.
3. Pharmacognosy by C.S. Shah & Qadery.
4. Pharmacognosy by M.A. Iyengar.

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SECOND YEAR

PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)**3H 2C**

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**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.
- Perform 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. Perform 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.

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.**List of experiments:**

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia, Cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.

- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil, sesame oil, shark liver oil, bees wax)
- 27 Chemical tests for Gelatin.

Suggested Readings:

1. Pharmacognosy by G.E. Trease & W.C.Evans.
2. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference Books (Latest Editions):

1. Pharmacognosy by Brady & Tyler.E.
2. Pharmacognosy by T.E.Wallis.
3. Pharmacognosy by C.S. Shah & Qadery.
4. Pharmacognosy by M.A. Iyengar.

PHARMACOLOGY – I (THEORY)**4H 4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory: 4 Hrs. /Week****Course Objectives:**

- This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects
- To know adverse effects, uses, dose
- To understand the route of administration, precautions, contraindications and interaction with other drugs.
- In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system
- To know the blood and blood forming agents and renal system will be taught.
- In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

Course Outcome (CO's):

Upon completion of the subject student shall be able to (Know, do, appreciate) –

1. Understand the pharmacological aspects of drugs falling under the above mentioned chapters;
2. Handle and carry out the animal experiments;
3. Appreciate the importance of pharmacology subject as a basis of therapeutics; and
4. Correlate and apply the knowledge therapeutically.
5. Demonstrate the Pharmacology of drugs acting on various cardio vascular disease.
6. Illustrate the Pharmacology of Autocoids, Non-steroidal anti-inflammatory agents, Anti-gout drugs and Antirheumatic drugs.

UNIT I**General Pharmacology**

- Introduction, definitions and scope of pharmacology
- Routes of administration of drugs
- Pharmacokinetics (absorption, distribution, metabolism and excretion)

UNIT II

- Pharmacodynamics
- Factors modifying drug effects
- Drug toxicity - Acute, sub- acute and chronic toxicity.
- Pre-clinical evaluations
- Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

UNIT III

Pharmacology of drugs acting on ANS

- Adrenergic and antiadrenergic drugs
- Cholinergic and anticholinergic drugs
- Neuromuscular blockers
- Mydriatics and miotics

UNIT IV

- Drugs used in myasthenia gravis
- Drugs used in Parkinsonism

UNIT V

Pharmacology of drugs acting on cardiovascular system

- Antihypertensives
- Anti-anginal drugs
- Anti-arrhythmic drugs
- Drugs used for therapy of Congestive Heart Failure
- Drugs used for hyperlipidaemias

UNIT VI

Pharmacology of drugs acting on Central Nervous System

- General anesthetics
- Sedatives and hypnotics
- Anticonvulsants
- Analgesic and anti-inflammatory agents

UNIT VII

- Psychotropic drugs
- Alcohol and methyl alcohol
- CNS stimulants and cognition enhancers
- Pharmacology of local anaesthetics

UNIT VIII

Pharmacology of Drugs acting on Respiratory tract

- Bronchodilators
- Mucolytics
- Expectorants
- Antitussives
- Nasal Decongestants

UNIT IX

Pharmacology of Hormones and Hormone antagonists

- Thyroid and Antithyroid drugs
- Insulin, Insulin analogues and oral hypoglycemic agents
- Sex hormones and oral contraceptives
- Oxytocin and other stimulants and relaxants

UNIT X

Pharmacology of autocooids and their antagonists

- Histamines and Antihistaminics
- 5-Hydroxytryptamine and its antagonists
- Lipid derived autocooids and platelet activating factor

Suggested Readings(Theory):

(Author, Title, Edition, Publication Place, Publisher, Year of Publication)

1. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
3. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference Books (Theory-Latest Editions) :

(Author, Title, Edition, Publication Place, Publisher, Publication Year)

1. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
2. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co

3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
4. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Instruction hours/ week: L:2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory: 3 Hrs. /Week

Course Objectives:

- In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services.
- In order to meet this demand, students will be learning various skills such as dispensing of drugs
- To know responding to minor ailments by providing suitable safe medication
- To understand patient counseling
- To know health screening services for improved patient care in the community set up.
- To study the concept of Rational drug therapy

Course Outcome (CO's):

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

1. Know pharmaceutical care services;
2. Know the business and professional practice management skills in community pharmacies;
3. Do patient counseling & provide health screening services to public in community pharmacy;
4. Respond to minor ailments and provide appropriate medication;
5. Show empathy and sympathy to patients; and
6. Appreciate the concept of Rational drug therapy.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N Requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

UNIT I

Definition, scope, of community pharmacy

Roles and responsibilities of Community pharmacist

UNIT II

Community Pharmacy Management

- a) Selection of site, Space layout, and design
- b) Staff, Materials- coding, stocking
- c) Legal requirements

- d) Maintenance of various registers
- e) Use of Computers: Business and health care soft wares

UNIT III

Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions.

Inventory control in community pharmacy Definition, various methods of Inventory Control

ABC, VED, EOQ, Lead time, safety stock

UNIT IV

Pharmaceutical care

Definition and Principles of Pharmaceutical care.

Patient counselling

Definition, outcomes, various stages, barriers, Strategies to overcome barriers

Patient information leaflets- content, design, & layouts, advisory labels

UNIT V

Patient medication adherence

Definition, Factors affecting medication adherence, role of Pharmacist in improving the adherence.

Health screening services

Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing

UNIT VI

OTC Medication- Definition, OTC medication list & Counselling

Health Education

WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.

UNIT VII

Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhoea and AIDS

UNIT VIII

Balance diet, and treatment & prevention of deficiency disorders

Family planning – role of pharmacist

UNIT IX

Responding to symptoms of minor ailments Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.

UNIT X

Essential Drugs concept and Rational Drug Therapy Role of community pharmacist

Code of ethics for community pharmacists

Suggested Readings:

1. Health Education and Community Pharmacy by N.S.Parmar.
2. WHO consultative group report.
3. Drug store & Business management by Mohammed Ali & Jyoti.

Reference Books (Latest Editions):

1. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
2. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

PHARMACOTHERAPEUTICS - I (THEORY)**4H****4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 4 Hrs. /Week****Course Objectives:**

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines.
- Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases.
- This will enable the student to understand the pathophysiology of common diseases and their management.
- To know the importance of preparation of individualized therapeutic plans based on diagnosis;
- To understand patient-specific parameters relevant in initiating drug therapy
- To know the pathophysiology of selected disease states and explain the rationale for drug therapy

Course Outcome (CO's):

At completion of this subject it is expected that students will be able to understand –

1. The pathophysiology of selected disease states and the rationale for drug therapy;
2. The therapeutic approach to management of these diseases;
3. The controversies in drug therapy;
4. The importance of preparation of individualized therapeutic plans based on diagnosis;
5. Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
6. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
7. Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
8. Discuss the controversies in drug therapy;
9. Discuss the preparation of individualised therapeutic plans based on diagnosis; and

10. Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Detailed syllabus and lecture wise schedule:

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

UNIT I

Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris

UNIT II

Myocardial infarction, Hyperlipidaemias

UNIT III

Electrophysiology of heart and Arrhythmias

UNIT IV

Respiratory system : Introduction to Pulmonary function test, Asthma,

UNIT V

Chronic obstructive airways disease, Drug induced pulmonary diseases

UNIT VI

Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives

UNIT VII

Hormone replacement therapy, Osteoporosis

UNIT VIII

General prescribing guidelines for

- a. Paediatric patients
- b. Geriatric patients
- c. Pregnancy and breast feeding

UNIT IX

Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial

UNIT X

Introduction to rational drug use

Definition, Role of pharmacist Essential drug concept Rational drug formulations

Suggested Readings:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books (Latest Editions):

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
4. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
5. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
6. Relevant review articles from recent medical and pharmaceutical literature

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Practical : 3 Hrs./Week

Course Objectives:

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines.
- Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases.
- This will enable the student to understand the pathophysiology of common diseases and their management.
- To know the importance of preparation of individualized therapeutic plans based on diagnosis;
- To understand patient-specific parameters relevant in initiating drug therapy
- To know the pathophysiology of selected disease states and explain the rationale for drug therapy

Course Outcome (CO's):

At completion of this subject it is expected that students will be able to understand –

1. The pathophysiology of selected disease states and the rationale for drug therapy;
2. The therapeutic approach to management of these diseases;
3. The controversies in drug therapy;
4. The importance of preparation of individualized therapeutic plans based on diagnosis;
5. Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
6. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy

Practicals :

- Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

- A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Suggested Readings:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books (Latest Editions):

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
2. Relevant review articles from recent medical and pharmaceutical literature

19PD301T

PHARMACOLOGY – II (THEORY)THIRD YEAR
4H 4C

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 4 Hrs. /Week****Course Objectives:**

- This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs.
- In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated.
- In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught.
- In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- To understand drugs acting on Blood and blood forming agents
- To study structures and functions of the components of the cell

Course Outcomes (CO's):

1. Understand the pharmacological aspects of drugs falling under the above mentioned chapters,
2. Carry out the animal experiments confidently,
3. Appreciate the importance of pharmacology subject as a basis of therapeutics, and
4. Correlate and apply the knowledge therapeutically.
5. Drugs acting on Blood and blood forming agents
6. structures and functions of the components of the cell

UNIT I**Pharmacology of Drugs acting on Blood and blood forming agents**

- Anticoagulants
- Thrombolytics and antiplatelet agents
- Haemopoietics and plasma expanders

UNIT II**Pharmacology of drugs acting on Renal System**

- Diuretics
- Antidiuretics

UNIT III

Chemotherapy

- Introduction
- Sulfonamides and co-trimoxazole
- Penicillins and Cephalosporins
- Tetracyclines and Chloramphenicol
- Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
- Quinolines and Fluroquinolines

UNIT IV

Chemotherapy

- Antifungal antibiotics
- Antiviral agents
- Chemotherapy of tuberculosis and leprosy
- Chemotherapy of Malaria
- Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
- Pharmacology of Anthelmintic drugs

UNIT V

Chemotherapy : Chemotherapy of cancer (Neoplasms)

UNIT VI

Immunopharmacology

Pharmacology of immune suppressants and stimulants

UNIT VII

Principles of Animal toxicology Acute, sub acute and chronic toxicity

UNIT VIII

The dynamic cell: The structures and functions of the components of the cell

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.

- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors).

UNIT IX

The Gene: Genome structure and function:

Gene structure: Organization and elucidation of genetic code.

Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families).

Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

UNIT X

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Suggested Readings(Theory):

1. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
3. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference Books (Latest Editions):

1. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.

2. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
3. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
4. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week

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.

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea -pig ileum preparation.

9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea -pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotarod.
 - f) Cardiotoxic activity of drugs using isolated frog heart and mammalian heart preparations.

Suggested Readings(Theory):

1. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
2. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
3. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference Books (Latest Editions):

1. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

19PD302T

THIRD YEAR

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

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 4 Hrs. /Week****Course Objectives:**

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

UNIT I**Quality Assurance:**

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

UNIT II**Chromatography:**

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- h. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- i. **TLC:** Introduction, principle, techniques, R_f value and applications.
- j. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- k. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- l. **HPLC:** Introduction, theory, instrumentation, and applications.
- m. **HPTLC:** Introduction, theory, instrumentation, and applications.
- n. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

UNIT III

Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.

- **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

UNIT IV

Spectroscopy:

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on.

Absorption Spectroscopy:

Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

UNIT V

Instrumentation – Photometer, UV Visible spectrometer – sources of UV – Visible radiations, collimating systems, monochromators, sample cells and following detectors – photocell Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

UNIT VI

Infrared Spectroscopy: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectro-meter – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

UNIT VII

Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

Atomic Absorption Spectrometry: Introduction, Theory, types of electrodes, instrumentation and applications.

UNIT VIII

Atomic Emission Spectroscopy: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

NMR & ESR (introduction only): Introduction, theoretical aspects and applications.

UNIT IX

Mass Spectroscopy: (Introduction only) – Fragmentation, types of ions produced mass spectrum and applications.

Polarimetry: (Introduction only) – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

UNIT X

X-RAY Diffraction: (Introduction only) – Theory, reciprocal lattice concept, diffraction patterns and applications.

Thermal Analysis: Introduction, instrumentation, applications, and DSC and DTA.

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.

Reference Books (Latest Editions):

1. John H. Kennedy, Analytical chemistry principles.
2. Indian Pharmacopoeia.

19PD308P

THIRD YEAR

PHARMACEUTICAL ANALYSIS (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs./Week****Course Objectives:**

- To estimate the samples using analytical instruments.
- To perform assay of drug samples using analytical instruments
- 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 instruments
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.

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.
11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.

14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

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.

Reference Books (Latest Editions):

1. John H. Kennedy, Analytical chemistry principles.
2. Indian Pharmacopoeia.

19PD303T

PHARMACOTHERAPEUTICS – II (THEORY)

THIRD YEAR

4H 4C

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 4 Hrs. /Week****Course Objectives:**

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines.
- Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- To know the importance of preparation of individualised therapeutic plans based on diagnosis
- To appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- To develop patient case based assessment skills

Course Outcomes (CO's):

1. Know the pathophysiology of selected disease states and the rationale for drug therapy
2. Know the therapeutic approach to management of these diseases;
3. Know the controversies in drug therapy;
4. Know the importance of preparation of individualised therapeutic plans based on diagnosis; and
5. Appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
6. Students will be developing patient case based assessment skills

Detailed syllabus and lecture wise schedule : Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –**UNIT I****Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections**UNIT II**

Infectious disease: Gastroenteritis, Endocarditis, Septicemia

UNIT III

Infectious disease: Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections

UNIT IV

Infectious disease: Fungal infections, Viral infections, Gonorrhoea and Syphilis

UNIT V

Musculoskeletal disorders

Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.

UNIT VI

Renal system

Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

UNIT VII

Oncology: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents

UNIT VIII

Chemotherapy of breast cancer, leukemia.

UNIT IX

Infectious disease: Management of chemotherapy nausea and emesis

UNIT X

Dermatology: Psoriasis, Scabies, Eczema, Impetigo

Suggested Readings:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference Books (Latest Editions):

1. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
2. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
3. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

19PD309P

THIRD YEAR

PHARMACOTHERAPEUTICS – II (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**Course Objectives:**

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines.
- Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- To know the importance of preparation of individualised therapeutic plans based on diagnosis
- To appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- To develop patient case based assessment skills

Course Outcomes (CO's):

1. Know the pathophysiology of selected disease states and the rationale for drug therapy
2. Know the therapeutic approach to management of these diseases;
3. Know the controversies in drug therapy;
4. Know the importance of preparation of individualised therapeutic plans based on diagnosis; and
5. Appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
6. Students will be developing patient case based assessment skills

Practicals :

- Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

- The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.
- A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Suggested Readings:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference Books (Latest Editions):

1. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

19PD304T

THIRD YEAR

PHARMACEUTICAL JURISPRUDENCE (THEORY) 2H 2C

Instruction hours/ week: L: 2 T:0 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 2 Hrs. /Week****Course Objectives:**

- This course exposes the student to several important legislations related to the profession of pharmacy in India.
- The Drugs and Cosmetics Act, along with its amendments is the core of this course.
- Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc.
- Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
- 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):

Upon completion of the subject student shall be able to (Know, do, and appreciate) –

1. Practice the Professional ethics;
2. Understand the various concepts of the pharmaceutical legislation in India;
3. Know the various parameters in the Drug and Cosmetic Act and rules;
4. Know the Drug policy, DPCO, Patent and design act;
5. Understand the labeling requirements and packaging guidelines for drugs and cosmetics;
6. Be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act.

Detailed syllabus and lecture wise schedule:**UNIT I**

- **Pharmaceutical Legislations** – A brief review.
- Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.

UNIT II**Drugs and Cosmetics Act, 1940, and its rules 1945.**

Objectives, Legal definition, Study of Schedule's with reference to Schedule B,C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.

Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.

Constitution and Functions of DTAB,DCC,CDL.

Qualification and duties –Govt. analyst and Drugs Inspector.

UNIT III

Pharmacy Act –1948.

Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.

UNIT IV

Medicinal and Toilet Preparation Act –1955.

Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.

UNIT V

Narcotic Drugs and Psychotropic substances Act-1985 and Rules. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.

UNIT VI

Study of Salient Features of Drugs and magic remedies Act and its rules.

UNIT VII

Study of essential Commodities Act Relevant to drugs price control Order.

UNIT VIII

Drug Price control Order & National Drug Policy (Current).

UNIT IX

Prevention of Cruelty to animals Act-1960.

Patents & design Act-1970.

UNIT X

Brief study of prescription and Non-prescription Products.

Assignments:

Format of the assignment

- Minimum & Maximum number of pages
- It shall be a computer draft copy
- Reference(s) shall be included at the end.

- Name and signature of the student
- Assignment can be a combined presentation at the end of the academic year.
- Time allocated for presentation may be 8+2 Min

Case studies relating to

- Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
- Various prescription and non-prescription products.
- Medical and surgical accessories.
- Diagnostic aids and appliances available in the market.

Suggested Readings:

1. Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

Reference Books (Latest Editions):

1. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
2. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
3. Reports of the Pharmaceutical enquiry Committee
4. I.D.M.A., Mumbai. DPCO 1995
5. Various reports of Amendments.
6. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
7. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory : 3 Hrs. /Week**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.

UNIT I

Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

UNIT II

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

UNIT III**Anti-infective agents**

- Local anti-infective agents
- Preservatives
- Antifungal agents
- Urinary tract anti-infectives

UNIT IV**Anti-infective agents**

- Antitubercular agents
- Antiviral agents and Anti AIDS agents
- Antiprotozoal agents
- Anthelmintics
- Antiscabies and Antipedicular agents

UNIT V

- Sulphonamides and sulphones
- Antimalarials

UNIT VI

- Antibiotics
- Antineoplastic agents

UNIT VII**Cardiovascular agents**

- Antihypertensive agents
- Antianginal agents and vasodilators

UNIT VIII**Cardiovascular agents**

- Antiarrhythmic agents
- Antihyperlipidemic agents
- Coagulants and Anticoagulants
- Endocrine

UNIT IX

- Hypoglycemic agents
- Thyroid and Antithyroid agents

UNIT X

- Diuretics
- Diagnostic agents
- Steroidal Hormones and Adrenocorticoids

Suggested Readings:

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
3. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
4. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
5. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.

Reference Books (Latest Editions):

1. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
2. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
3. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
4. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

19PD310P

THIRD YEAR

MEDICINAL CHEMISTRY (PRACTICAL) 3H 2C

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**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.

CONTENT

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Suggested Readings:

1. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
2. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.

Reference Books (Latest Editions):

1. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.

2. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
3. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
4. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

19PD306T

THIRD YEAR

PHARMACEUTICAL FORMULATIONS (THEORY)**3H 3C**

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 3 Hrs. /Week****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. Acquire 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.

Detailed syllabus and lecture wise schedule:**UNIT I**

Pharmaceutical dosage form- concept and classification

UNIT II**Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets.**UNIT III**

Tablet coating, Type of coating, quality control tests for coated tablet.

UNIT IV**Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules.**UNIT V**

Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.

UNIT VI

Liquid orals: Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations

UNIT VII

Parenterals Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization

UNIT VIII

Ophthalmic preparations (Semi – Solids): Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling

UNIT IX

Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging

UNIT X

Definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

Suggested Readings:

1. Pharmaceutical dosage forms, Vol, I,II and III by lachman
2. Rowlings Text book of Pharmaceutics
3. Tutorial Pharmacy – Cooper & Gunn

Reference Books (Latest Editions):

1. Remington's Pharmaceutical Sciences
2. USP/BP/IP

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Practical : 3 Hrs./Week

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.

List of Experiments :

1. **Manufacture of Tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
 - a. Tablets
 - b. Capsules

- c. Injections
- 5. Formulation of two liquid oral preparations and evaluation by assay**
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
- 6. Formulation of semisolids and evaluation by assay**
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
- 7. Cosmetic preparations**
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
- 8. Tablet coating (demonstration)**

Suggested Readings:

- 1. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- 2. Rowlings Text book of Pharmaceutics
- 3. Tutorial Pharmacy – Cooper & Gunn

Reference Books (Latest Editions):

- 1. Remington's Pharmaceutical Sciences
- 2. USP/BP/IP

19PD401T

PHARMACOTHERAPEUTICS – III (THEORY)

FOURTH YEAR

4H 4C

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Theory : 3 Hrs. /Week**Course Objectives:**

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines.
- Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases.
- This will enable the student to understand the pathophysiology of common diseases and their management.
- To summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
- To discuss the controversies in drug therapy;
- To discuss the preparation of individualised therapeutic plans based on diagnosis

Course Outcome (CO's):

At completion of this subject it is expected that students will be able to understand –

1. The Pathophysiology of selected disease states and the rationale for drug therapy;
2. The therapeutic approach to management of these diseases;
3. The controversies in drug therapy;
4. The importance of preparation of individualised therapeutic plans based on diagnosis;
5. Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
6. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:**UNIT I****Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease**UNIT II**

Inflammatory bowel disease

UNIT III

Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice

UNIT IV

Drug induced liver disorders.

UNIT V

Haematological system: Anaemias, Venous thromboembolism

UNIT VI

Drug induced blood disorders.

UNIT VII

Nervous system: Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,

UNIT VIII

Psychiatry disorders: Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders

UNIT IX

Pain management including Pain pathways, neuralgias, headaches.

UNIT X

Evidence Based Medicine

Suggested Readings:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books (Latest Editions):

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
3. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
4. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda -Kimble MA
5. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**Course Objectives:**

- This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines.
- Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases.
- This will enable the student to understand the pathophysiology of common diseases and their management.
- To summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
- To discuss the controversies in drug therapy;
- To discuss the preparation of individualised therapeutic plans based on diagnosis

Course Outcome (CO's):

At completion of this subject it is expected that students will be able to understand –

1. The Pathophysiology of selected disease states and the rationale for drug therapy;
2. The therapeutic approach to management of these diseases;
3. The controversies in drug therapy;
4. The importance of preparation of individualised therapeutic plans based on diagnosis;
5. Needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
6. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Suggested Readings:

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference Books (Latest Editions):

1. Pathologic basis of disease - Robins SL, W.B.Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory : 4 Hrs. /Week

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,
- to know drug dispensing, manufacturing of parenteral preparations,
- to understand drug information, patient counselling,
- to learn therapeutic drug monitoring for improved patient care.
- To know The Stores Management And Inventory Control.

Course Outcome (CO's):

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

1. Know various drug distribution methods;
2. Know the professional practice management skills in hospital pharmacies;
3. Provide unbiased drug information to the doctors;
4. Know the manufacturing practices of various formulations in hospital set up;
5. Appreciate the practice based research methods; and
6. Appreciate The Stores Management And Inventory Control.

UNIT I

Hospital - its Organisation and functions

UNIT II

Hospital pharmacy-Organisation and management

- a) Organizational structure-Staff, Infrastructure & work load statistics
- b) Management of materials and finance
- c) Roles & responsibilities of hospital pharmacist

UNIT III

The Budget – Preparation and implementation

Hospital drug policy

- a) Pharmacy and Therapeutic committee (PTC)

b) Hospital formulary

UNIT IV

Hospital committees

- Infection committee
- Research and ethical committee

c) developing therapeutic guidelines

d) Hospital pharmacy communication - Newsletter

UNIT V

Hospital pharmacy services

- Procurement & warehousing of drugs and Pharmaceuticals
- Inventory control
- Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

UNIT VI

Drug distribution in the hospital

- Individual prescription method
- Floor stock method
- Unit dose drug distribution method

UNIT VII

Distribution of Narcotic and other controlled substances

Central sterile supply services – Role of pharmacist

UNIT VIII

Manufacture of Pharmaceutical preparations

Sterile formulations – large and small volume parenterals

Manufacture of Ointments, Liquids, and creams

UNIT IX

Manufacturing of Tablets, granules, capsules, and powders

Total parenteral nutrition

Continuing professional development programs

Education and training

Radio Pharmaceuticals – Handling and packaging

UNIT X

Professional Relations and practices of hospital pharmacist

Suggested Readings:

1. Hospital pharmacy by William E. Hassan
2. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

Reference Books (Latest Editions):

1. WHO consultative group report.
2. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
3. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**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,
- to know drug dispensing, manufacturing of parenteral preparations,
- to understand drug information, patient counselling,
- to learn therapeutic drug monitoring for improved patient care.
- To know The Stores Management And Inventory Control.

Course Outcome (CO's):

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

1. Know various drug distribution methods;
2. Know the professional practice management skills in hospital pharmacies;
3. Provide unbiased drug information to the doctors;
4. Know the manufacturing practices of various formulations in hospital set up;
5. Appreciate the practice based research methods; and
6. Appreciate The Stores Management And Inventory Control.

COURSE CONTENT

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.

6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Suggested Readings:

1. Hospital pharmacy by William E. Hassan

Reference Books (Latest Editions):

1. WHO consultative group report.
2. R.P.S. Vol.2. Part –B; Pharmacy Practice section.

19PD403T

FOURTH YEAR

CLINICAL PHARMACY (THEORY)**4H 4C**

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 4 Hrs. /Week****Course objective:**

- To Monitor drug therapy of patient through medication chart review and clinical review;
- To Obtain medication history interview and counsel the patients;
- To Identify and resolve drug related problems;
- To detect, assess and monitor adverse drug reaction;
- To Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- To Retrieve, analyse, interpret and formulate drug or medicine information.

Course Outcomes (CO's):

1. Monitor drug therapy of patient through medication chart review and clinical review;
2. Obtain medication history interview and counsel the patients;
3. Identify and resolve drug related problems;
4. Detect, assess and monitor adverse drug reaction;
5. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states;
6. Retrieve, analyse, interpret and formulate drug or medicine information.

Detailed syllabus and lecture wise schedule:**UNIT I****Definitions, development and scope of clinical pharmacy****Introduction to daily activities of a clinical pharmacist**

- a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
- b. Ward round participation
- c. Adverse drug reaction management
- d. Drug information and poisons information

UNIT II

Medication history

Patient counseling

UNIT III

Drug utilisation evaluation (DUE) and review (DUR)

UNIT IV

Quality assurance of clinical pharmacy services

UNIT V

Patient data analysis

The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.

Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results

- a. Haematological, Liver function, Renal function, thyroid function tests
- b. Tests associated with cardiac disorders
- c. Fluid and electrolyte balance
- d. Microbiological culture sensitivity tests
- e. Pulmonary Function Tests

UNIT VI

Drug & Poison information

- Introduction to drug information resources available
- Systematic approach in answering DI queries
- Critical evaluation of drug information and literature
- Preparation of written and verbal reports
- Establishing a Drug Information Centre
- Poisons information- organization & information resources

UNIT VII

Pharmacovigilance

- Scope, definition and aims of pharmacovigilance
 - Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - Reporting, evaluation, monitoring, preventing & management of ADRs
 - Role of pharmacist in management of ADR.

UNIT VIII

Communication skills, including patient counselling techniques, medication history interview, presentation of cases.

UNIT IX

- Pharmaceutical care concepts
- Critical evaluation of biomedical literature

UNIT X

Medication errors

Suggested Readings:

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
2. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
3. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
4. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt. Ltd. ISSN8125026

Reference Books (Latest Editions):

- 1 Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- 2 Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- 3 Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

19PD409P

FOURTH YEAR

CLINICAL PHARMACY (PRACTICAL)**3H 2C**

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100

External Semester Exam: 3 Hours

Practical : 3 Hrs./Week**Course objective:**

- To Monitor drug therapy of patient through medication chart review and clinical review;
- To Obtain medication history interview and counsel the patients;
- To Identify and resolve drug related problems;
- To detect, assess and monitor adverse drug reaction;
- To Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- To Retrieve, analyse, interpret and formulate drug or medicine information.

Course Outcomes (CO's):

1. Monitor drug therapy of patient through medication chart review and clinical review;
2. Obtain medication history interview and counsel the patients;
3. Identify and resolve drug related problems;
4. Detect, assess and monitor adverse drug reaction;
5. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states;
6. Retrieve, analyse, interpret and formulate drug or medicine information.

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- 1 Answering drug information questions (4 Nos)
- 2 Patient medication counseling (4 Nos)
- 3 Case studies related to laboratory investigations (4 Nos)
- 4 Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Suggested Readings:

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
2. A text book of Clinical Pharmacy Practice; Essential concepts and skills,
Dr.G.Parthasarathi etal, Orient Orient Langram Pvt. Ltd. ISSN8125026

Reference Books (Latest Editions):

- 1 Australian drug information -Procedure manual. The Society of Hospital Pharmacists
of Australia.
- 2 Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.

BIostatISTICS AND RESEARCH METHODOLOGY (THEORY) 3H 3C

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory : 3 Hrs. /Week

Course Objectives:

- To understand some basic concepts of research and its methodologies
- To identify appropriate research topics
- To select and define appropriate research problem and parameters
- To prepare a project proposal
- To organize and conduct research in a more appropriate manner
- To write a research report and thesis

Course Outcomes (CO's):

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

1. Understand some basic concepts of research and its methodologies
2. Identify appropriate research topics
3. Select and define appropriate research problem and parameters
4. Prepare a project proposal
5. Organize and conduct research in a more appropriate manner
6. Write a research report and thesis

UNIT I

Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments,
determination of sample size to obtain a confidence interval of specified
width, power of a study
- d) Report writing and presentation of data

UNIT II

Biostatistics

- Introduction
- Types of data distribution
- Measures describing the central tendency distributions- average, median, mode

- Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

UNIT III

Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

UNIT IV

Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation coefficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

UNIT V

Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

UNIT VI

Computer applications in pharmacy

UNIT VII

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

UNIT VIII

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

UNIT IX

Accounting and General ledger system

UNIT X**Drug Information Retrieval & Storage :**

Introduction – Advantages of Computerized Literature Retrieval Use of
Computerized Retrieval

Suggested Readings:

1. Pharmaceutical statistics- practical and clinical applications, Sanford
Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

Reference Books (Latest Editions):

1. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E
Stanovich , 3rd edition, McGraw Hill Publications 2006

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory: 4 Hrs. /Week

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 raised 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.

UNIT I

Biopharmaceutics

Introduction to Biopharmaceutics

- Absorption of drugs from gastrointestinal tract.
- Drug Distribution.
- Drug Elimination.

UNIT II

Pharmacokinetics

Introduction to Pharmacokinetics.

- Mathematical model
- Drug levels in blood.
- Pharmacokinetic model
- Compartment models
- Pharmacokinetic study.

UNIT III**One compartment open model.**

- Intravenous Injection (Bolus)
- Intravenous infusion.

UNIT IV**Multicompartment models.**

- Two compartment open model.
- IV bolus, IV infusion and oral administration

UNIT V**Multiple – Dosage Regimens.**

Repetitive Intravenous injections – One Compartment Open Model
Repetitive Extravascular dosing – One Compartment Open model c.
Multiple Dose Regimen – Two Compartment Open Model

UNIT VI**Nonlinear Pharmacokinetics.**

- Introduction
- Factors causing Non-linearity.
- Michaelis-menton method of estimating parameters.

UNIT VII**Non-compartmental Pharmacokinetics.**

- Statistical Moment Theory.
- MRT for various compartment models.

UNIT VIII

Physiological Pharmacokinetic model.

UNIT IX**Bioavailability and Bioequivalence.**

- Introduction.
- Bioavailability study protocol.

UNIT X

Methods of Assessment of Bioavailability

Suggested Readings:

- 1 Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- 2 Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- 3 Pharmacokinetics: By Milo Gibaldi Donald, R. Mercei Dekker Inc.
- 4 Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- 5 Biopharmaceutics and Pharmacokinetics; By Robert F Notari

Reference Books (Latest Editions):

1. Biopharmaceutics; By Swarbrick
2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.

19PD410P

FOURTH YEAR

BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)**3H 2C**

Instruction hours/ week: L: 0 T:0 P:3

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Practical : 3 Hrs./Week****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 raised 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.
-
1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
 2. Comparison of dissolution studies of two different marketed products of same drug.
 3. Influence of polymorphism on solubility and dissolution.
 4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
 5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
 6. Bioavailability studies of some commonly used drugs on animal/human model.
 7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.

8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

Suggested Readings:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari

Reference Books (Latest Editions):

1. Biopharmaceutics; By Swarbrick
2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours

Theory : 2 Hrs. /Week

Course Objectives:

- To understand the general working knowledge of the principles and practice of clinical toxicology
- To know the health implications of toxic exposures and commonly involved chemicals for toxicity
- To understand principles of general toxicology and clinical management practice.
- To demonstrate and apply history, assessment and therapy considerations associated with the management of a toxic exposure.
- To understand treatment guidelines for specific toxic substances.
- To get knowledge about preventive approaches to reduce unintentional poisoning.

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

1. Understand the general working knowledge of the principles and practice of clinical toxicology
2. The health implications of toxic exposures and commonly involved chemicals for toxicity
3. Understand principles of general toxicology and clinical management practice.
4. Demonstrate and apply history, assessment and therapy considerations associated with the management of a toxic exposure.
5. Understand treatment guidelines for specific toxic substances.
6. Knowledge about preventive approaches to reduce unintentional poisoning.

UNIT I

- General principles involved in the management poisoning
- Antidotes and the clinical applications.
- Supportive care in clinical Toxicology.

UNIT II

- Gut Decontamination.
- Elimination Enhancement.
- Toxicokinetics.

UNIT III

Clinical symptoms and management of acute poisoning with the following agents –

- Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
- Opiates overdose.
- Antidepressants
- Barbiturates and benzodiazepines.

UNIT IV

Clinical symptoms and management of acute poisoning with the following agents –

Alcohol: ethanol, methanol.

- Paracetamol and salicylates.
- Non-steroidal anti-inflammatory drugs.

UNIT V

Clinical symptoms and management of acute poisoning with the following agents –

Hydrocarbons: Petroleum products and PEG.

Caustics: inorganic acids and alkali.

Radiation poisoning

UNIT VI

Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper

UNIT VII

Clinical symptoms and management of acute poisoning with the following agents –

Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.

UNIT VIII

Plants poisoning. Mushrooms, Mycotoxins.

Food poisonings

Envenomations – Arthropod bites and stings.

UNIT IX

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- CNS stimulants :amphetamine
- Opioids
- CNS depressants

UNIT X

Hallucinogens: LSD

- Cannabis group
- Tobacco

Suggested Readings:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
2. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London

Reference Books (Latest Editions):

1. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003
Paras Publication, Hyderabad

19PD501T

CLINICAL RESEARCH (THEORY)

FIFTH YEAR

4H 4C

Instruction hours/ week: L: 3 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory : 4 Hrs. /Week****Course Objectives:**

- To understand the regulatory and ethical process
- To know the new drug development process
- To understand and conduct the clinical trials activities
- To know safety monitoring and reporting in clinical trials
- To manage trial coordination process.
- To get knowledge about preventive approaches to reduce unintentional poisoning.

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

1. Understand the regulatory and ethical process
2. Know the new drug development process
3. Understand and conduct the clinical trials activities
4. Know safety monitoring and reporting in clinical trials
5. Manage trial coordination process.
6. Knowledge about preventive approaches to reduce unintentional poisoning.

UNIT I**Drug development process: Introduction**

Various Approaches to drug discovery

Pharmacological

Toxicological

UNIT II

IND Application

Drug characterization

Dosage form

UNIT III**Clinical development of drug:**

- Introduction to Clinical trials
- Various phases of clinical trial.
- Methods of post marketing surveillance

UNIT IV

Abbreviated New Drug Application submission.

- Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
- Challenges in the implementation of guidelines
- Ethical guidelines in Clinical Research

UNIT V

- Composition, responsibilities, procedures of IRB / IEC
- Overview of regulatory environment in USA, Europe and India.

UNIT VI

Role and responsibilities of clinical trial personnel as per ICH GCP

- Sponsor
- Investigators
- Clinical research associate
- Auditors
- Contract research coordinators
- Regulatory authority

UNIT VII

Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)

UNIT VIII

Informed consent Process

UNIT IX

Data management and its components

UNIT X

Safety monitoring in clinical trials.

Suggested Readings:

- 1 Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- 2 International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- 3 Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

- 4 Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

Reference Books (Latest Editions):

1. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
2. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

PHARMACOEPIDEMOLOGY AND PHARMACOECONOMICS (THEORY)
4H 4C

Instruction hours/ week: L: 3 T: 1 P: 0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory: 3 Hrs. /Week****Course Objectives:**

- To identify the application pharmacoepidemiology and pharmacoeconomics in clinical settings
- To Discuss the various pharmacoepidemiology outcome measures.
- To understand the concept of risk in pharmacoepidemiology and different methods of measuring risk
- To know various pharmacoepidemiological methods
- To know the methods to measure outcomes in pharmacoenomic studies.
- To get knowledge about current pharmacoenomic evaluation methods

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

1. Identify the application pharmacoepidemiology and pharmacoeconomics in clinical settings
2. Discuss the various pharmacoepidemiology outcome measures.
3. Understand the concept of risk in pharmacoepidemiology and different methods of measuring risk
4. Know various pharmacoepidemiological methods
5. Know the methods to measure outcomes in pharmacoenomic studies.
6. Knowledge about current pharmacoenomic evaluation methods

UNIT I**Pharmacoepidemiology:****Definition and scope:**

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

UNIT II

Measurement of outcomes in pharmacoepidemiology Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

UNIT III**Concept of risk in pharmacoepidemiology**

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

UNIT IV

Pharmacoepidemiological methods

- Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

UNIT V

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

UNIT VI

Sources of data for pharmacoepidemiological studies Ad Hoc data sources and automated data systems

UNIT VII

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

UNIT VIII

Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

UNIT IX

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

UNIT X

Applications of Pharmacoeconomics Software and case studies

Suggested Readings:

1. Rascati K L. Essentials of Pharmacoeconomics, 2nded. Philadelphia: Woulters Kluwer Lippincott Williams & Wilkins, 2013.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. 1997, 2003. John Wiley & Sons, second edition.

3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Published by the Oxford University Press 2006.

Reference Books (Latest Editions):

1. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press (Third Edition) – 2005.
2. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics, 2013.

19PD503T

FIFTH YEAR

**CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC
DRUG MONITORING (THEORY)****3H 3C**

Instruction hours/ week: L: 2 T:1 P:0

Marks: Internal: 30 External: 70 Total: 100
External Semester Exam: 3 Hours**Theory: 3 Hrs. /Week****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.

UNIT I**Introduction to Clinical pharmacokinetics.****UNIT II****Design of dosage regimens:**

Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

UNIT III

Pharmacokinetics of Drug Interaction:

- a. Pharmacokinetic drug interactions
- b. Inhibition and Induction of Drug metabolism
- c. Inhibition of Biliary Excretion.

UNIT IV

Therapeutic Drug monitoring:

- d. Introduction
- e. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
- f. Indications for TDM. Protocol for TDM.

UNIT IV

Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.

TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

UNIT V

Dosage adjustment in Renal and hepatic Disease.

- Renal impairment
- Pharmacokinetic considerations

UNIT VI

General approach for dosage adjustment in Renal disease.

- Measurement of Glomerular Filtration rate and creatinine clearance.
- Dosage adjustment for uremic patients.

UNIT VII

- Extracorporeal removal of drugs.
- Effect of Hepatic disease on pharmacokinetics.

UNIT VIII

Population Pharmacokinetics.

- Introduction to Bayesian Theory.
- Adaptive method or Dosing with feed back.

- Analysis of Population pharmacokinetic Data.

UNIT IX

Pharmacogenetics

- Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
- Genetic Polymorphism in Drug Transport and Drug Targets.

UNIT X

Pharmacogenetics and Pharmacokinetics / Pharmacodynamic considerations

Suggested Readings:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. 6th edition. New York: Mc Graw Hill; 2012.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. 2nd edition. USA: Springer; 2011.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. 4th edition. US: Lippincott Williams & Wilkins; 2005.

Reference Books (Latest Editions):

1. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. 1st edition. USA: CRC Press; 1996.
2. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press; 2006.