Chebrolu Hanumaiah Institute of Pharmaceutical Sciences
Chandramoulipuram, Chowdavaram, Guntur – 522019, Andhra Pradesh.
(Sponsored by Nagarjuna Education Society)
Approved by AICTE & PCI, Affiliated to Acharya Nagarjuna University.
Recognised by Govt. of Andhra Pradesh, An ISO 9001:2015 Certified Institute.

Course: Doctor of Pharmacy

Duration: 6 years

Program outcomes:

- To understand the elements of pharmaceutical care and provide comprehensive patient care services.
- To understand fundamental aspects of pharmacotherapy based on pathological abnormalities that occur in various diseases and disorders.
- To impart basic knowledge regarding the rational use of various drugs in treating the patient in a view to individualize drug therapy for a specific diagnosis.
- 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 effect/s)
- To ensure effective communication of health related information to all healthcare professionals by providing patient counselling, identification and management of adverse drug reactions, conducting medication history interviews and reporting of medication errors.
- Impart knowledge on drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research.
- To ensure that effective, integrated and critically analyzed medicine and poison information is provided to healthcare professionals, which helps in the efficient patient management.

DOCTOR OF PHARMACY

FIRST YEAR

1.1 HUMAN ANATOMY & PHYSIOLOGY:

Course outcomes:

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 a 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.

Lecture wise program: (Theory)

1. Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)
2. Structure of cell – its components and their functions.
3. Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
4. a) Osseous system-structure, composition and functions of the Skeleton.
   b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)
5. Haemopoetic System
   a) Composition and functions of blood
   b) Haemopoesis and disorders of blood components (definition of disorder)
   c) Blood groups
   d) Clotting factors and mechanism
   e) Platelets and disorders of coagulation
6. Lymph
   a) Lymph and lymphatic system, composition, formation and circulation
   b) Spleen: structure and functions, Disorders
   c) Disorders of lymphatic system (definition only)
7. Cardio vascular system
   a) Anatomy and functions of heart
   b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
   c) Electrocardiogram(ECG)
   d) Cardiac cycle and heart sounds
   e) Blood pressure – its maintenance and regulation
   f) Definition of the following disorders. Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8. Respiratory system
    a) Anatomy of respiratory organs and functions
    b) Mechanism/physiology of respiration and regulation of respiration
    c) Transport of respiratory gases
    d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.
9. Digestive system
    a) Anatomy and physiology of GIT
    b) Anatomy and functions of accessory glands of GIT
    c) Digestion and absorption
    d) Disorders of GIT (definitions only)
10. Nervous system
    a) Definition and classification of nervous system
    b) Anatomy, physiology and functional areas of cerebrum
    c) Anatomy and physiology of cerebellum
    d) Anatomy and physiology of mid brain
    e) Thalamus, hypothalamus and Basal Ganglia
    f) Spinal cord: Structure & reflexes –mono-poly-planter
    g) Cranial nerves – names and functions
    h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.
11. Urinary system
    a) Anatomy and physiology of urinary system
    b) Formation of urine
    c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
    d) Clearance tests and micturition
12. Endocrine system
    a) Pituitary gland
    b) Adrenal gland
    c) Thyroid and Parathyroid glands
    d) Pancreas and gonads
13. Reproductive system
    a) Male and female reproductive system
    b) Their hormones – Physiology of menstruation
    c) Spermatogenesis & Oogenesis
    d) Sex determination (genetic basis)
    e) Pregnancy and maintenance and parturition
    f) Contraceptive devices
14. Sense organs
    a) Eye
    b) Ear
    c) Skin
    d) Tongue &Nose
15. Skeletal muscles
    a) Histology
    b) Physiology of Muscle contraction

c) Physiological properties of skeletal muscle and their disorders (definitions)

16. Sports physiology
    a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
    b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
    c) Drugs and athletics

Lecture wise program: (Practical)

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 haematological 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
   (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 gastroenemius sciatic nerve preparation.
14. To record simple summation curve using gastroenemius sciatic nerve preparation.
15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.
16. To record simple effect of load & afterload using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

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

- Describe the structure (gross and histology) and functions of various organs of the human body;
- Describe the various homeostatic mechanisms and their imbalances of various systems;
- Identify the various tissues and organs of the different systems of the human body;
- Perform the haematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
- Appreciate coordinated working pattern of different organs of each system; and
- Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Textbooks

- Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college, New York.
- Wilson,K.J.W. Ross and Wilson's foundations of anatomy and physiology .Publisher: Churchill Livingstone, Edinburg.

Reference books

- Guytonarthur, C. Physiology of human body. Publisher: Holt saunders.
- Chatterjee, C.C. Human physiology. Volume 1&11. Publisher: medical allied agency, Calcutta.
- Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
- Gray's anatomy. Publisher: Churchill Livingstone, London.

1.2 PHARMACEUTICS

Course outcomes:

This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

Lecture wise program: (Theory)

1. a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
2. Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
3. Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
4. Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
5. 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.
6. Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.
7. Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
8. Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
9. Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
10. Pharmaceutical calculations.
11. Surgical aids: Surgical dressings, absorbable gelatine sponge, sutures, ligatures and medicated bandages.
12. Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

Lecture wise program: (Practical)

1. **Syrups**
    a. Simple Syrup I.P
    b. Syrup of Ephedrine Hcl NF
    c. Syrup Vasaka IP
    d. Syrup of ferrous Phosphate IP
    e. Orange Syrup
2. **Elixir**
    a. Piperizine citrate elixir BP
    b. Cascara elixir BPC
    c. Paracetamol elixir BPC
3. **Linctus**
    a. Simple Linctus BPC
    b. Pediatric simple Linctus BPC
4. **Solutions**
    a. Solution of cresol with soap IP
    b. Strong solution of ferric chloride BPC
    c. Aqueous Iodine Solution IP
    d. Strong solution of Iodine IP
    e. Strong solution of ammonium acetate IP
5. **Liniments**
    a. Liniment of turpentine IP*
    b. Liniment of camphor IP
6. **Suspensions***
    a. Calamine lotion
    b. Magnesium Hydroxide mixture BP
7. **Emulsions***
    a. Cod liver oil emulsion
    b. Liquid paraffin emulsion
8. **Powders**
    a. Eutectic powder
    b. Explosive powder
    c. Dusting powder
    d. Insufflations
9. **Suppositories**
    a. Boric acid suppositories
    b. Chloral suppositories
10. **Incompatibilities**
    a. Mixtures with Physical
    b. Chemical & Therapeutic incompatibilities

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

- Know the formulation aspects of different dosage forms;
- Do different pharmaceutical calculations involved in formulation;
- Formulate different types of dosage forms; and
- Appreciate the importance of good formulation for effectiveness.

Text books

- Cooper and Gunns Dispensing for pharmacy students.
- A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

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

1.3 MEDICINAL BIOCHEMISTRY

Course outcomes:

This course 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.

Lecture wise program: (Theory)

1. **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
2. **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.
3. 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.
4. 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 (Atheroslerosis, fatty liver, Hyper cholesterolmiea).
5. Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
6. 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.
7. 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.
8. Introduction to clinical chemistry: Cell; composition; malfunction; Role of the clinical chemistry laboratory.
9. The kidney function tests: Role of kidney; Laboratory tests for normal function includes- a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.) b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid) c) Urine concentration test d) Urinary tract calculi. (stones)
10. Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation. a) Test for hepatic dysfunction- Bile pigments metabolism. b) Test for hepatic function test- Serum bilirubin, urine

bilirubin, and urine urobilinogen. c) Dye tests of excretory function. d) Tests based upon abnormalities of serum proteins. Selected enzyme tests.

11. Lipid profile tests: Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
12. 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)
13. Electrolytes: Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

Lecture wise program: (Practical)

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 Glucose oxidase.**
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

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

- Understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- Know the metabolic process of biomolecules in health and illness (metabolic disorders);
- Understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- Know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- Do the qualitative analysis and determination of biomolecules in the body fluids.

Text books

- Harpers review of biochemistry-Martin
- Text book of biochemistry –D. Satyanarayana
- Textbook of clinical chemistry-Alex Kaplan & Laverve L. Szabo

Reference books

- Principles of biochemistry —Lehninger
- Textbook of biochemistry—Rama rao
- Practical Biochemistry-David T. Plummer.
- Practical Biochemistry-Pattabhiraman.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY

Course outcomes:

This course is designed to impart a very good knowledge about various chemical aspects of different classes of organic compounds.

Lecture wise program: (Theory)

1. Structures and Physical properties:
   a. 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,
   b. Acids and bases, Lowry bronsted and Lewis theories c. Isomerism
2. 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.
3. Free radicals chain reactions of alkane: Mechanism, relative reactivity and stability.
4. Alicyclic compounds: Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
5. 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.
6. Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2mechanism, 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.
7. Electrophillic 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, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin 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.
8. 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.
9. 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, nucleophyllic 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.

10. Elecrophilic 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 halogination of alkyl benzene, resonance stabilization of benzyl radical.
11. 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 caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.
12. 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.
13. 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.
14. Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
15. Oxidation reduction reaction.
16. Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin,methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

<u>Lecture wise program:</u> (Practical)

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):
    1. Acetanilde / 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-napthol (Diazotisation and coupling)
    6. Benzoic acid / salicylic acid (Hydrolysis of ester)
    7. M-dinitro benzene (Nitration)
    8. 9, 10 – Antharaquinone (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-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. 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, nitro compounds.

III. Introduction to the use of stereo models:

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

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

- The 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 / nucleophyllic [alkyl / acyl / aryl] / electrophyllic substitution, free radical / nucleophyllic / electrophyllic 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
- The methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

Text books

- T.R.Morrison and R.Boyd-Organic chemistry,
- Bentley and Driver - Textbook of Pharmaceutical chemistry
- I.L.Finer – Organic chemistry, the fundamentals of chemistry

Reference books

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

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY

Course outcomes:

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.

Lecture wise program: (Theory)

1. **Errors:** Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical.
2. **Volumetric Analysis:** Principle of volumetric analysis, different methods of analysis, different methods of expressing concentrations of solutions, Primary and secondary standards.
3. **Acid – Base titrations:** Acid – Base concepts, relative strengths of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson – Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.
4. **Redox titrations:** Concepts of oxidation and reduction reactions. Redox reactions, theory of redox titrations, redox indicators, iodometry, iodimetry, titrations involving cerric sulphate, potassium iodate, potassium bromate, titanous chloride, potassium permanganate.
5. **Non Aqueous titrations:** Theoretical basis, types of solvents, preparations and standardization of titrant solutions, titration of weak acid, weak base and indicators. Standardization of perchloric acid, lithium and sodium methoxide tetra butyl ammonium hydroxide.
6. **Precipitation titrations:** Introduction, types of precipitation titrations, end point detection.
7. **Complexometric titrations:** Introduction, principle, types of titrations, end point detection.
8. **Theory of indicators**
9. **Gravimetry:** Basic concepts, precipitation techniques, co precipitations, post precipitations, various steps involved in gravimetric analysis, pharmaceutical applications.
10. **Limit tests:** Definitions, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals.
11. **Medicinal gases:** Preparation and uses of the following Oxygen, Carbon dioxide, Helium, Nitrogen and Nitrous oxide.
    - **Method of preparation, assay, storage conditions and uses of inorganic compounds listed in I.P belonging to the following category**
12. **Acidifiers:** Dilute HCL, Sodium Phosphate, Ammonium Chloride.
13. **Antacids:** Classification, qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, Sodium Bicarbonate, Potassium Citrate, Aluminium Hydroxide gel, Dried Aluminium Hydroxide gel, Magnesium Hydroxide

Light and Heavy Magnesium Trisilicate, Light and Heavy Magnesium Carbonate, Calcium Carbonate, Magaldrate and Bismuth Carbonate.

14. **Cathartics:** Magnesium Hydroxide, Magnesium Sulphate, Magnesium Carbonate, Sodium Phosphate.
15. **Electrolyte Replenishers:** Electrolytes used for replacement therapy, sodium Chloride, Potassium Acetate, Sodium Bicarbonate, Potassium Bicarbonate, Sodium Citrate, Sodium Lactate, Ammonium Chloride, Electrolyte combination therapy Compound Sodium Chloride solution, Sodium Chloride injection and Oral Rehydration Salt.
16. **Essential Trace elements:** Definition, Physiological role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.
17. **Antimicrobials:** Hydrogen peroxide, Potassium permanganate, Chlorinated Lime, Iodine, Boric acid, Silver nitrate, Selenium sulphide.
18. **Pharmaceutical Aids:** Sodium bisulphate, Sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methylcellulose, purified water, water for injection and sterile water for injection.
19. **Dental Products:** Anti- caries agents: Role of fluorides as anti-caries agents, sodium fluoride. Dentifrices: Calcium Carbonate, Dibasic Calcium Phosphate, Zinc Chloride.
20. **Miscellaneous Compounds:**
    a. Sclerosing agents: Hypertonic saline, Sodium tetradecyl sulphate
    b. Expectorants: Potassium citrate and potassium iodide
    c. Sedative: Potassium bromide
    d. Antidotes: Sodium nitrite, sodium thiosulphate and Charcoal
    e. Respiratory stimulant: Ammonium carbonate
21. **Radio Pharmaceuticals:** Introduction, Measurement of radioactivity, clinical applications and dosage, hazards and precautions

<u>Lecture wise program:</u> (Practical)

1. **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
2. **Assays (10 exercises)**
    a. Ammonium chloride- Acid-base titration
    b. Ferrous sulphate - Cerimetry
    c. Copper sulphate - Iodometry
    d. Calcium gluconate - Complexometry
    e. Hydrogen peroxide – Permanganometry

f. Sodium benzoate – Nonaqueous titration
g. Sodium chloride- Modified volhard's method
h. Assay of KI – KIO_3 titration
i. Gravimetric estimation of barium as barium sulphate
j. Sodium antimony gluconate or antimony potassium tartarate

3. **Estimation of mixture (Any two exercises)**
   a. Sodium hydroxide and sodium carbonate
   b. Boric acid and Borax
   c. Oxalic acid and sodium oxalate
4. **Test for identity (Any three exercises)**
   a. Sodium bicorbonate
   b. Barium sulphate
   c. Ferrous sulphate
   a. Potassium chloride
5. **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
6. **Preparations (Any two exercises)**
   a. Boric acids
   b. Potash alum
   c. Calcium lactate
   d. Magnesium suphate

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

- Understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals.
- Know the analysis of the inorganic pharmaceuticals their applications and
- Appreciate the importance of inorganic pharmaceuticals ain preventing and curing the disease.

Textbooks:

a) A text book Inorganic medicinal Chemistry by Surendra N. Pandya
b) Beckett and J.B. Stanlake's Practical Pharmaceutical Chemistry Vol-I & Vol –II
c) Inorganic Pharmaceutical Chemistry III- Edition P. Gundu Rao

Reference books:

a) Inorganic Pharmaceutical Chemistry by Anand & Chetwal
b) Pharmaceutical Inorganic chemistry by Dr. B. G. Nagavi.
c) Analytical Chemistry principles by John H. Kennedy
d) I.P 1985 and 1996, Govt. of India, Ministry of Health

1.6 REMEDIAL MATHEMATICS/BIOLOGY

Course outcomes: (Mathematics)

This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, Laplacetransform.

Lecture wise program: (Theory)

1. **Algebra :** Determinants, Matrices
2. **Trigonometry :** Sides and angles of a triangle, solution of triangles
3. **Analytical Geometry:** Points, Straight line, circle, parabola
4. **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic unction. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
5. **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
6. **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of secondorder.
7. **Laplace transform:** Definition, Laplacetransform of elementary functions, Properties of linearity and shifting.

Learning Outcomes:(Mathematics)

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

- Appreciate the important applications of mathematics in pharmacy.
- Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications.

Text books

- Differential calculus By Shantinarayan
- TextbookofMathematicsforsecondyearpre-universitybyProf.B.M.Sreenivas

Reference books

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

Course outcomes: (Biology)

This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources,

classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

Lecture wise program: (Theory)

PART – A

- Introduction
- General organization of plants and its inclusions
- Plan tissues
- Plant kingdom and its classification
- Morphology of plants
- Root, Stem, Leaf and Its modifications
- Inflorescence and Pollination of flowers 08 Morphology of fruits and seeds
- Plant physiology
- Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
- Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

- Study of Animal cell
- Study animal tissues
- Detailed study of frog
- Study of Pisces, Raptiles, Aves
- General organization of mammals
- Study of poisonous animals

Lecture wise program: (Practical)

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

Learning Outcomes:(Biology)

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

- Know all the important mechanisms behind the natural physiological processes happening in plants and animals.
- Appreciate and understand various facets of biological applications in the pharmacy.
- Identify various aspects drug sources in animal and plant kingdom.

Text books

- Textbook of Biology by S. B. Gokhale
- A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference books

- A Text book of Biology by B. V. Sreenivasa Naidu
- A Text book of Biology by Naidu and Murthy
- Botany for Degree students By A. C. Dutta.
- Outlines of Zoology by M. E kambaranathaayyer and T. N. Anantha krishnan.
- A manual for pharmaceutical biology practical by S. B. Gokhale and C.K. Kokate.

SECOND YEAR

2.1 **PATHOPHYSIOLOGY**

Course outcomes:

This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

Lecture wise program: (Theory)

1. **Basic principles of cell injury and Adaptation**
   - Causes, Pathogenesis and morphology of cell injury
   - Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen storage diseases
2. **Inflammation**
   - Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
   - Repairs of wounds in the skin, factors influencing healing of wounds
3. **Diseases of immunity**
   - Introduction to T and B cells
   - MHC proteins or transplantation antigens
   - Immune tolerance
     - 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)
   - Amylodosis
4. **Cancer:** differences between benign and malignant tumours, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumours, general biology of tumours, spread of malignant tumours, aetiology and pathogenesis of cancer.
5. Types of shock, mechanisms, stages and management
6. Biological effects of radiation
   - Environmental and nutritional diseases
   - Air pollution and smoking- SO2, NO, NO2, and CO Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
7. Pathophysiology of common diseases

a. Parkinsonism
b. Schizophrenia
c. Depression and mania
d. Hypertension,
e. Stroke (ischaemic and hemorrhage)
f. Angina, CCF, Atherosclerosis, Myocardial infarction
g. Diabetes Mellitus
h. Peptic ulcer and inflammatory bowel diseases
i. Cirrhosis and Alcoholic liver diseases
j. Acute and chronic renal failure
k. Asthma and chronic obstructive airway diseases

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

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

- Describe the aetiology and pathogenesis of the selected disease states;
- Name the signs and symptoms of the diseases;
- Mention the complications of the diseases.

Text books:

- Pathologic basis of disease by- Cotran, Kumar, Robbins
- Text book of Pathology- HarshMohan
- Text book of Pathology-Y.M. Bhinde

Reference books:

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

2.2 **PHARMACEUTICAL MICROBIOLOGY**

Course outcomes:

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It 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. 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.

Lecture wise program: (Theory)

1. Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
2. Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
3. 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.
4. 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.
5. 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.
6. Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.
7. Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . 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.
8. Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot, PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.
9. Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardisation of vaccines and sera.
10. Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

Lecture wise program: (Practical)

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

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

- Know the anatomy, identification, growth factors and sterilization of microorganisms;
- Know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- Estimate RNA and DNA and there by identifying the source;
- Cultivate and identify the microorganisms in the laboratory;
- Identify diseases by performing the diagnostic tests; and
- Appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books

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

Reference books

- Prescot L.M., Jarley G.P Klein D.A –Microbiology‖ 2nd- edition Mc Graw Hill Company Inc
- Rawlins E.A.‖Bentley's Text Book of Pharmaceutics‖ B ailliere Tindals 24-28 London 1988

- Forbisher ― Fundamentals of Microbiology‖ Philidelphia W.B. Saunders.
- Prescott L.M. Jarley G.P., Klein.D.A. ― Microbiology.‖2nd edition WMC Brown Publishers, Oxford. 1993
- War Roitt, Jonathan Brostoff, David male, ― Immunology‖3rd edition 1996, Mosby-year book Europe Ltd, London.
- Pharmacopoeia of India, Govt of India, 1996.

2.3 **PHARMACOGNOSY & PHYTOPHARMACEUTICALS**

Course outcomes:

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, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

Lecture wise program: (Theory)

1. Introduction.
2. Definition, history and scope of Pharmacognosy.
3. Classification of crude drugs.
4. Cultivation, collection, processing and storage of crude drugs.
5. Detailed method of cultivation of crude drugs.
6. Study of cell wall constituents and cell inclusions.
7. Microscopical and powder Microscopical study of crude drugs.
8. Study of natural pesticides.
9. Detailed study of various cell constituents.
10. Carbohydrates and related products.
11. Detailed study carbohydrates containing drugs.(11drugs)
12. Definition, sources, method extraction, chemistry and method of analysis of lipids.
13. Detailed study of oils.
14. Definition, classification, chemistry and method of analysis of protein.
15. Study of plants fibers used in surgical dressings and related products.
16. Different methods of adulteration of crude drugs.

Lecture wise program: (Practical)

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.

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

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

Text books

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

Reference books

- Pharmacognosy by Brady &Tyler.E.
- Pharmacognosy by T.E.Wallis.
- Pharmacognosy by C.S. Shah & Qadery.
- Pharmacognosy by M.A. Iyengar.

2.4 **PHARMACOLOGY**

Course outcomes:

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, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, 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.

Lecture wise program: (Theory)

1. General Pharmacology
    a) Introduction, definitions and scope of pharmacology
    b) Routes of administration of drugs
    c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
    d) Pharmacodynamics
    e) Factors modifying drug effects
    f) Drug toxicity - Acute, sub- acute and chronic toxicity.
    g) Pre-clinical evaluations
    h) 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.

2. Pharmacology of drugs acting on ANS
    a) Adrenergic and anti adrenergic drugs
    b) Cholinergic and anti cholinergic drugs
    c) Neuromuscular blockers
    d) Mydriactics and miotics
    e) Drugs used in myasthenia gravis
    f) Drugs used in Parkinsonism
3. Pharmacology of drugs acting on cardiovascular system
    a) Antihypertensives
    b) Anti- anginal drugs
    c) Anti-arrhythmic drugs
    d) Drugs used for therapy of Congestive Heart Failure
    e) Drugs used for hyperlipidaemias
4. Pharmacology of drugs acting on Central Nervous System
    a) General anesthetics

b) Sedatives and hypnotics
c) Anti convulsants
d) Analgesic and anti-inflammatory agents
e) Psychotropic drugs
f) Alcohol and methyl alcohol
g) CNS stimulants and cognition enhancers
h) Pharmacology of local anaesthetics

5. Pharmacology of Drugs acting on Respiratory tract
   a) Bronchodilators
   b) Mucolytics
   c) Expectorants
   d) Antitussives
   e) Nasal Decongestants
6. Pharmacology of Hormones and Hormone antagonists
   a) Thyroid and Anti thyroid drugs
   b) Insulin, Insulin analogues and oral hypoglycaemic agents
   c) Sex hormones and oral contraceptives
   d) Oxytocin and other stimulants and relaxants
7. Pharmacology of autocoids and their antagonists
   a) Histamines and Antihistaminics
   b) 5-Hydroxytryptamine and its antagonists
   c) Lipid derived autocoids and platelet activating factor

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

- Understand the pharmacological aspects of drugs falling under the above mentioned chapters;
- Handle and carry out the animal experiments;
- Appreciate the importance of pharmacology subject as a basis of therapeutics; and
- Correlate and apply the knowledge therapeutically.

Text books

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

Reference books

- 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.
- Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

2.5 **COMMUNITY PHARMACY**

Course outcomes:

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, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

Lecture wise program: (Theory)

1. Definition, Scope of community pharmacy. Roles and responsibilities of community pharmacist.
2. 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
3. Prescriptions – parts of prescription, legality & identification of medication related problems like drug interactions.
4. Inventory control in community pharmacy Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
5. Pharmaceutical care
6. Definition and Principles of Pharmaceutical care.
7. Patient counseling
8. Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels
9. Patient medication adherence
10. Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
11. Health screening services
12. Definition, importance, methods for screening Blood pressure/ blood sugar/ lung function and Cholesterol testing.
13. OTC Medication- Definition, OTC medication list & Counselling
14. Health Education
15. WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
16. Commonly occurring Communicable Diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS. Balance diet, and treatment & prevention of deficiency disorders Family planning – role of

pharmacist

17. Responding to symptoms of minor ailments
18. Relevant pathophysiology, common drug therapy to, Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.
19. Essential Drugs concept and Rational Drug Therapy Role of community pharmacist
20. Code of ethics for community pharmacists

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

- Know pharmaceutical care services;
- Know the business and professional practice management skills in community pharmacies;
- Do patient counselling & provide health screening services to public in community pharmacy;
- Respond to minor ailments and provide appropriate medication;
- Show empathy and sympathy to patients; and
- Appreciate the concept of rational drug therapy.

Text Books:

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

Reference books:

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

2.6 **PHARMACOTHERAPEUTICS**

Course outcomes:

Pharmacotherapeutics is introduced for the first time in second of PharmD program. The whole disorders and diseases seen in human population were divided and introduced in second, third and fourth year of PharmD. 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.

Lecture wise program: (Theory)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

1. Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
2. Respiratory system: Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
3. Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
4. General prescribing guidelines for
    a. Paediatric patients
    b. Geriatric patients
    c. Pregnancy and breastfeeding
5. Ophthalmology: Glaucoma, Conjunctivitis- viral &bacterial
6. Introductiontorationaldruguse:Definition,RoleofpharmacistEssentialdrugconcept Rational drug formulations

Lecture wise program: (Practical)

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.

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

- Describe the pathophysiology of selected disease states and the rationale for drug therapy;
- Understand the therapeutic approach to management of these diseases;

- Discuss the controversies in drug therapy and preparation of individualised therapeutic plans based on diagnosis; and
- 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);
- Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;

Text Books

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

Reference Books

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

THIRD YEAR

3.1 **PHARMACOLOGY**

Course outcomes:

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 autocoids 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.

Lecture wise program: (Theory)

1. Pharmacology of Drugs acting on Blood and blood forming agents
    a) Anticoagulants
    b) Thrombolytics and antiplatelet agents
    c) Haemopoietics and plasma expanders
2. Pharmacology of drugs acting on Renal System
    a) Diuretics
    b) Anti diuretics
3. Chemotherapy
    a) Introduction
    b) Sulfonamides and co-trimoxazole
    c) Penicillins and Cephalosporins
    d) Tetracyclins and Chloramphenicol
    e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
    f) Quinolines and Fluroquinolines
    g) Antifungal antibiotics
    h) Antiviral agents
    i) Chemotherapy of tuberculosis and leprosy
    j) Chemotherapy of Malaria
    k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
    l) Pharmacology of Anthelmintic drugs
    m) Chemotherapy of cancer (Neoplasms)

4 Immuno pharmacology: Pharmacology of immune suppressants and stimulants

5 Principles of Animal toxicology: Acute, sub acute and chronic toxicity

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.

6.Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

- The Gene: Genome structure and function:
  a) Gene structure: Organization and elucidation of genetic code.
  b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
  c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.
- 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.

Lecture wise program: (Practical)

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 rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

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

- Understand the pharmacological aspects of drugs falling under the above mentioned chapters,
- Carry out the animal experiments confidently,
- Appreciate the importance of pharmacology subject as a basis of therapeutics, and
- Correlate and apply the knowledge therapeutically.

Text books (Theory)

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

Reference books (Theory)

- 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.
- Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- 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.

Text books (Practical)

- Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

3.2 **PHARMACEUTICAL ANALYSIS**

Course outcomes:

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 drugtesting.

Lecture wise program: (Theory)

1. **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.
2. **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.

   a. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
   b. **TLC**: Introduction, principle, techniques, R_f value and applications.
   c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
   d. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
   e. **HPLC**: Introduction, theory, instrumentation, and applications.
   f. **HPTLC**: Introduction, theory, instrumentation, and applications.
   g. **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.

3. **Electrometric Methods:**

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

a. **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.

b. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.

c. **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.

d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

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

a. **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.

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

- **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.

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

b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceuticalapplications.

c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of

electrodes, instrumentation andapplications.

d. **Atomic Emission Spectroscopy:**Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
e. **NMR & ESR (introduction only):** Introduction, theoretical aspects andapplications.
f. **Mass Spectroscopy:** (Introduction only) –Fragmentation, types of ions produced mass spectrum and applications.
g. **Polarimetry: (Introduction only)** –Introduction to optical rotator dispersion, circular dichroism, polarimeter.
h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.
i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

Lecture wise program: (Practical)

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 a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha 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.

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

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

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.

3.3**PHARMACOTHERAPEUTICS-II**

Course outcomes:

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 theirmanagement.

Lecture wise program: (Theory)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

- **Infectiousdisease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection-Malaria, HIV& Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
- **Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- **Renalsystem**AcuteRenalFailure,ChronicRenalFailure,RenalDialysis,Druginduced renal disorders
- **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

Lecture wise program: (Practical)

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.

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

- Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
- The therapeutic approach to management of these diseases;
- The importance of preparation of individualised therapeutic plans based on diagnosis;

- 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);
- Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
- Discuss the controversies in drug therapy;
- Discuss the preparation of individualised therapeutic plans based on diagnosis;
- 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.

Textbooks:

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

3.4**PHARMACEUTICAL JURISPRUDENCE**

Course outcomes:

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 are 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.

Lecture wise program: (Theory)

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted byPCI.
3. **Drugs and Cosmetics Act, 1940,and its rules 1945.**
4. 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.
5. **Pharmacy Act –1948.** Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
6. **Medicinal and Toilet Preparation Act–1955.** Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
7. **NarcoticDrugsandPsychotropicsubstancesAct-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.
8. Study of Salient Features of Drugs and magic remedies Act and its rules.
9. Study of essential Commodities Act Relevant to drugs price control Order.
10. Drug Price control Order & National Drug Policy(Current).
11. PreventionOfCrueltytoanimalsAct-1960.
12. Patents & designAct-1970.
13. Brief study of prescription and Non- prescription Products

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

- To practice the Professional ethics;
- Understand the various concepts of the pharmaceutical legislation in India;

- Know the various parameters in the Drug and Cosmetic Act and rules;
- Know the Drug policy, DPCO, Patent and design act;
- Understand the labeling requirements and packaging guidelines for drugs and cosmetics;
- Understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books:

- Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.
- Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- Reports of the Pharmaceutical enquiry Committee
- I.D.M.A., Mumbai. DPCO 1995
- Various reports of Amendments.
- Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3.5**MEDICINAL CHEMISTRY**

Course outcomes:

The course deals with aspects like Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of anti sense molecules. Along with these the students are also exposed to other aspects like mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

Lecture wise program: (Theory)

1. 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.

   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.

2. Anti-infective agents
   a) Local anti-infective agents
   b) Preservatives
   c) Antifungal agents
   d) Urinary tract anti-infectives
   e) Antitubercular agents
   f) Antiviral agents and Anti AIDS agents
   g) Antiprotozoal agents
   h) Anthelmentics
   i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
   a) Antihypertensive agents
   b) Antianginal agents and vasodilators
   c) Antiarrhythmic agents
   d) Antihyperlipidemic agents
   e) Coagulants and Anticoagulants
8. Endocrine

a) Hypoglycemic agents.
b) Thyroid and Antithyroid agents

9. Diureties
10. Diagnostic agents
11. Steroidal Hormones and Adrenocorticoids

Lecture wise program: (Practical)

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.

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

- Able to conduct assays of important drugs.
- Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
- Perform monograph analysis of important drugs.
- Determine the partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Text Books:

- Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
- A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya,
- S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6**PHARMACEUTICAL FORMULATIONS**

Course outcomes:

This Subject deals with the formulation and evaluation of various pharmaceutical dosage forms. The student will be exposed various methods of formulations available for different kinds of pharmaceutical dosage forms along with basic principles behind their formulation.

Lecture wise program: (Theory)

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatine capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatine capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals:** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parentral, transdermal, buccal, rectal, nasal, implants, ocular.

Lecture wise program: (Practical)

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) Salicyclic 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)

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

- Understand the principle involved in formulation of various pharmaceutical dosage forms;
- Prepare various pharmaceutical formulation;
- Perform evaluation of pharmaceutical dosage forms; and
- Understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books:

- Pharmaceutical dosage forms, Vol, I, II and III by lachman
- Rowlings Text book of Pharmaceutics
- Tutorial Pharmacy – Cooper& Gun

Reference books:

- Remingtons Pharmaceutical Sciences
- USP/BP/IP

FOURTH YEAR

4.1 **PHARMACOTHERAPEUTICS:**

Course outcomes:

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.

Lecture wise program: (Theory)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

a. **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
b. **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
c. **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
d. **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
e. Pain management including Pain pathways, neuralgias, headaches.
f. Evidence Based Medicine

Lecture wise program: (Practical)

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.

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

- Describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
- The therapeutic approach to management of these diseases;
- The importance of preparation of individualised therapeutic plans based on diagnosis;
- 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);
- Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
- Discuss the controversies in drug therapy;

- Discuss the preparation of individualised therapeutic plans based on diagnosis;
- 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.

Text books (Theory)

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

Reference books (Theory)

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

4.2**HOSPITAL PHARMACY**

Course outcomes:

In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

Lecture wise program: (Theory)

1. **Hospital - its Organisation and functions**
2. **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
3. **The Budget – Preparation and implementation**
4. **Hospital drug policy**
   a) Pharmacy and Therapeutic committee (PTC)
   b) Hospital formulary
   c) Hospital committees
   - Infection committee
   - Research and ethical committee
   d) developing therapeutic guidelines
   e) Hospital pharmacy communication - Newsletter
5. **Hospital pharmacy services**
   a) Procurement & warehousing of drugs and Pharmaceuticals
   b) Inventory control
      Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time, safety stock
   c) Drug distribution in the hospital
      i) Individual prescription method
      ii) Floor stock method
      iii) Unit dose drug distribution method
   d) Distribution of Narcotic and other controlled substances
   e) Central sterile supply services – Role of pharmacist
6. **Manufacture of Pharmaceutical preparations**
   a) Sterile formulations – large and small volume parenterals
   b) Manufacture of Ointments, Liquids, and creams
   c) Manufacturing of Tablets, granules, capsules, and powders
   d) Total parenteral nutrition
7. **Continuing professional development programs**
   Education and training

8. **Radio Pharmaceuticals – Handling and packaging**
9. **Professional Relations and practices of hospital pharmacist**

Lecture wise program: (Practical)

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

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

- Know various drug distribution methods and manufacturing practices of various formulations in hospital set up.
- Know the professional practice management skills in hospital pharmacies.
- Provide unbiased drug information to the doctors.
- Appreciate the practice based research methods, the stores management and inventory control.

Text books: (latest editions)

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

References:

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

4.3 **CLINICAL PHARMACY**

Course outcomes:

This course completely deals with the practice of pharmacy at the hospital settings by providing sound knowledge to students on various proceedings that happen in and around the hospital. It also highlights the importance of clinical pharmacist various aspects of drug use by inculcating concepts of drug and poison information services, pharmacovigilance, medication history interview, ward round participation, laboratory and clinical data assessment, patient counselling etc.

Lecture wise program: (Theory)

1. **Definitions, development and scope of clinical pharmacy**
2. **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 poison information
    e) Medication history
    f) Patient counseling
    g) Drug utilisation evaluation(DUE)and review(DUR)
    h) Quality assurance of clinical pharmacy services
3. **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.
4. **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
5. **Drug & Poison Information**
    a) Introduction to drug information resources available
    b) Systematic approach in answering DI queries
    c) Critical evaluation of drug information and literature
    d) Preparation of written and verbal reports
    e) Establishing a Drug Information Centre
    f) Poisons information- organization & information resources
6. **Pharmacovigilance**

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

7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical Care Concepts.
9. Critical Evaluation of Biomedical literature.
10. Medication Errors.

Lecture wise program: (Practical)

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

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

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

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

Text books

- Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

- Australian drug information -Procedure manual. The Society of Hospital Pharmacists

of Australia.
- Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

4.4 **BIOSTATISTICS & RESEARCH METHODOLOGY**

Course outcomes:

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

Lecture wise program: (Theory)

1. **Research Methodology**
   - Types of clinical study designs:
   - Case studies, observational studies, interventional studies,
   - Designing the methodology
   - 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
   - Report writing and presentation of data
2. **Biostatistics**
   a) Introduction
   b) Types of data distribution
   c) Measures describing the central tendency distributions- average, median, mode
   d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

Data graphics

Construction and labeling of graphs, histogram, pie charts, scatter plots, semilogarthimic plots

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, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)
d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.
e) Introduction to statistical software: SPSS, Epi Info, SAS.

Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. **Computer applications in pharmacy**

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.

Computer In Community Pharmacy Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval Use of Computerized Retrieval

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

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

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. New York.

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

4.5 **BIOPHARMACEUTICS & PHARMACOKINETICS**

Course outcomes:

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.

Lecture wise program: (Theory)

1. **Biopharmaceutics**

   Introduction to Biopharmaceutics

   a) Absorption of drugs from gastrointestinal tract.
   b) Drug Distribution.
   c) Drug Elimination.

2. **Pharmacokinetics**

   Introduction to Pharmacokinetics.

   a) Mathematical model
   b) Drug levels in blood.
   c) Pharmacokinetic model
   d) Compartment models
   e) Pharmacokinetic study.

3. **One compartment open model.**

   a) Intravenous Injection(Bolus)
   b) Intravenous infusion.

4. **Multicompartment models.**

   a) Two compartment open model.
   b) IV bolus, IV infusion and oral administration

5. **Multiple – Dosage Regimens.**

   a) Repititive Intravenous injections–One Compartment Open Model
   b) Repititive Extravascular dosing –One Compartment Open model.
   c) Multiple Dose Regimen –Two Compartment Open Model

6. **Nonlinear Pharmacokinetics.**

   a) Introduction
   b) Factors causing Non-linearity.
   c) Michaelis-menton method of estimating parameters.

7. **Noncompartmental Pharmacokinetics.**

a) Statistical Moment Theory.
b) MRT for various compartment models.
c) Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.

a) Introduction.
b) Bioavailability study protocol.
c) Methods of Assessment of Bioavailability

Lecture wise program: (Practical)

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 Ka, Ke, $t_1/2$, Cmax, 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.

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

- Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- Understand the concepts of bioavailability and bioequivalence of drug products and their significance.

- Understand various pharmacokinetic parameters, their significance & applications.

References Books:

- Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
- Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
- Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- Biopharmaceutics; By Swarbrick
- Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4^{th} edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
- Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 **CLINICAL TOXICOLOGY**

Course outcomes:

This subject is designed to provide all necessary aspects of poison management and general principals involved behind them. It also deals with various poisonous substances and their remedial measures during any accidental exposure towards such substances. Synthetic chemicals, plant and animal toxins, drugs, heavy metals, radiation etc are all included in the subject and it offers a broader perspective of learning to the student.

Lecture wise program: (Theory)

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents–
    a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
    b) Opiates overdose.
    c) Antidepressants
    d) Barbiturates and benzodiazepines.
    e) Alcohol: ethanol, methanol.
    f) Paracetamol and salicylates.
    g) Non-steroidal anti-inflammatory drugs.
    h) Hydrocarbons: Petroleum products and PEG.
    i) Caustics: inorganic acids and alkali.
    j) Radiation poisoning
8. Clinicalsymptomsandmanagementofchronicpoisoningwiththefollowingagents– Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. En - venomations– Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants : amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens : LSD

e) Cannabis group

f) Tobacco

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

- Understand the preliminary steps involved in the management of accidental poisoning cases and their approach.
- Identify the nature of poisonous substance exposed to and evaluate the symptoms associated with poisoning and readily offer specific antidotes for them.
- Know the general management of poisoning occurring due to venous animals and specific plant products.

Reference Books:

- Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSISAND TREATMENT OF POISONING. Second edition. Williams and Willkins publication.
- V V Pillay. HANDBOOK OF FORENSIC MEDICINE ANDTOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad.

FIFTH YEAR

5.1 **CLINICAL RESEARCH:**

Course outcomes:

This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Lecture wise program: (Theory)

1. **Drug development process:**

   Introduction

   Various Approaches to drug discovery

   a) Pharmacological
   b) Toxicological
   c) IND Application
   d) Drug characterization
   e) Dosage form

2. **Clinical development of drug:**

   1. Introduction to Clinical trials
   2. Various phases of clinical trial.
   3. Methods of post marketing surveillance
   4. Abbreviated New Drug Application submission.
   5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
   6. Challenges in the implementation of guidelines
   7. Ethical guidelines in Clinical Research
   8. Composition, responsibilities, procedures of IRB / IEC
   9. Overview of regulatory environment in USA, Europe and India.
   10. Role and responsibilities of clinical trial personnel as per ICH GCP
       a) Sponsor
       b) Investigators
       c) Clinical research associate
       d) Auditors
       e) Contract research coordinators
       f) Regulatory authority
   11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
   12. Informed consent Process
   13. Data management and its components
   14. Safety monitoring in clinical trials.

Learning Outcomes: Upon completion of the couse, the student shall be able to

- Know the new drug development process.
- Understand the regulatory and ethical requirements.
- Appreciate and conduct the clinical trials activities
- Know safety monitoring and reporting in clinical trials
- Manage the trial coordination process

References Books:

- Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- 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.
- Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 **PHARMACOEDPIDEMIOLOGY & PHARMACOECONOMICS:**

Course outcomes:

This subject deals with various applications of epidemiological methods in the field of pharmacy along with various sources that provide pharmacoepidemiologic data for the conduction of studies like vaccine safety, drug induced birth disorders etc. Pharmaco-economics on the other hand deals with effective application of therapeutic regimens by reducing the overall cost occurring due to the treatment.

Lecture wise program: (Theory)

1. **Pharmacoepidemiology :**

   Definition and scope:

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

   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

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

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

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

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

2. **Phrmacoeconomics:**
   Definition, history, needs of pharmacoeconomic evaluations

   Role in formulary management decisions

   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

3. **Applications of Pharmacoeconomics**

Softwares and case studies.

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

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associated with pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and its applications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

5.3 **CLINICAL PHARMACOKINETICS & PHARMACOTHERAPEUTIC DRUG MONITORING:**

Course outcomes:

This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Lecture wise program: (Theory)

1. **Introduction to Clinical pharmacokinetics.**

2. **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.

3. **Pharmacokinetics of Drug Interaction:**
   a) Pharmacokinetic drug interactions
   b) Inhibition and Induction of Drug metabolism
   c) Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring:**
   a) Introduction
   b) Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   c) Indications for TDM. Protocol for TDM.
   d) Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e) TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. **Dosage adjustment in Renal and hepatic Disease.**
   a) Renal impairment
   b) Pharmacokinetic considerations
   c) General approach for dosage adjustment in Renal disease.
   d) Measurement of Glomerular Filtration rate and creatinine clearance.
   e) Dosage adjustment for uremic patients.
   f) Extracorporeal removal of drugs.
   g) Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
   a) Introduction to Bayesian Theory.

b) Adaptive method or Dosing with feedback.
c) Analysis of Population pharmacokinetic Data.

7. Pharmacogenetics

a) Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
b) Genetic Polymorphism in Drug Transport and Drug Targets.
c) Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

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

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs