Pharm. D (Doctor of Pharmacy)

I Year:

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Total Credit
17CPHDA1	Human Anatomy and Physiology	3	3	1	8
17CPHDB1	Pharmaceutics	2	3	1	4
17CPHDC1	Medicinal Biochemistry	3	3	1	6
17CPHDD1	Pharmaceutical Organic Chemistry	3	3	1	4
17CPHDE1	Pharmaceutical Inorganic Chemistry	2	3	1	4
17EPHD1B	Remedial Biology	3	3	1	4
17EPHD1A	Remedial Mathematics	3	-	1	2
	TOTAL	16	18	6	30/28

II Year:

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17CPHDA2	Pathophysiology	3	-	1	3
17CPHDB2	Pharmaceutical Microbiology	3	3	1	6
17CPHDC2	Pharmacognosy & Phytopharmaceuticals	3	3	1	6
17CPHDD2	Pharmacology-I	3	-	1	4
17CPHDE2	Community Pharmacy	2	-	1	4
17CPHDF2	Pharmaco-therapeutics-I	3	3	1	7
	TOTAL	17	09	06	30

III Year:

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17CPHDA3	Pharmacology-II	3	3	1	6
17CPHDB3	Pharmaceutical Analysis	3	3	1	6
17CPHDC3	Pharmaco-therapeutics-II	3	3	1	7
17CPHDD3	Pharmaceutical Jurisprudence	2	-	-	2
17CPHDE3	Medicinal Chemistry	3	3	1	4
17CPHDF3	Pharmaceutical Formulations	2	3	1	5
	TOTAL	16	17	05	30

IV Year:

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17CPHDA4	Pharmaco-therapeutics-III	3	3	1	6
17CPHDB4	Hospital Pharmacy	2	3	1	6
17CPHDC4	Clinical Pharmacy	3	3	1	6
17CPHDD4	Biostatistics & Research Methodology	2	-	1	3
17CPHDE4	Biopharmaceutics & Pharmacokinetics	3	3	1	6
17CPHDF4	Clinical Toxicology	2	-	1	3
	TOTAL	17	12	05	30

V Year:

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17CPHDA5	Clinical Research	3	-	1	4
17CPHDB5	Pharmacoepidemiology& Pharmacoeconomics	3	-	1	4
17CPHDC5	Clinical Pharmacokinetics & Therapeutic Drug Monitoring	2	-	1	4
17IPHDR5	Clerkship*	-	-	1	8
17RPHDR5	Project	-	20	-	10
	TOTAL	08	20	04	30

*Attending ward rounds on daily basis.

******30 marks – viva-voce (oral) 70 marks – Thesis work

VI Year:

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17IPHDI6	Internship/Residency training	-	20	-	-
17RPHDR6	Project	-	-	-	30
	TOTAL				30

Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

1) Six months in General Medicine department, and
2) Two months each in three other specialty departments

PHARM.D
CORE SYLLABUS

First Year

17CPHDA1-HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

Course Objectives: This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since 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.

1. **Course materials:**
2. **Lecture wise program : Topics**

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. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5 <u>Haemopoetic System</u>
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 <u>Lymph</u>
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7 <u>Cardiovascular system</u>
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 card: 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Develop a vocabulary of appropriate terminologies and identify the various cell organelles & tissues of human body.
CO2 Apply the knowledge of organization of bones and joints of human body along with their disorders.
CO3 Examine the importance of blood components and lymph along with their disorders.
CO4 Analyze the gross anatomy and physiology of different Systems of Human Body and their disorders
CO5 Illustrate the interlinked mechanisms in the maintenance of normal and physical exercise conditions.

REFERENCES:

Text books

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

Reference books

a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
b. Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
d. *Gray's anatomy.* Publisher:Churchill Livingstone, London.

17CPHDA1-HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

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

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.
   (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.
   (e) Digestive system.
   (f) Urinary system.
   (g) Nervous system.
   (h) Special senses.
   (i) Reproductive system.
10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using 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 & after load using gastroenemius sciatic nerve preparation.
17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Justify the various types of tissues of human body and appliances used in haematological experiments.

CO2 Estimate the hematological parameters such as bleeding time, clotting time, blood groupings, RBC Count, WBC Count and Blood pressure.

CO3 Discuss the structure and functions of different organ systems with help of charts, models and specimens.

CO4 Develop the knowledge of appliances used in experimental physiology, pregnancy diagnosis test, family planning devices.

CO5 Evaluate various parameters using gastroenemius sciatic nerve preparation by simulated experiment and videos.

REFERENCES:

Text books

1. Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

1. Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune Anderson Experimental Physiology, Latest edition, Publisher: NA

17CPHDB1 - PHARMACEUTICS (THEORY)

Theory: 2 Hrs. /Week

Course Objectives: 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.

Topics

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 gelatin sponge, sutures, ligatures and medicated bandages.
12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the different dosage forms, prescription, posology, historical development of pharmacy profession, and pharmacopoeia.

CO2 Describe weight, measures and calculation of various pharmaceutical dosage forms.

CO3 Discuss different powders, granules and monophasic dosage forms along with their formulation development.

CO4 Demonstrate various biphasic liquid dosage forms and suppositories along with their formulation development.

CO5 Develop various galenical formulations, surgical aids and their importance in pharmacy and discuss various incompatibilities and methods to overcome

REFERENCES:

Text books

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

Reference books

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

17CPHDB1 - PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

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

***** colourless bottles required for dispensing **♣** Paper envelope (white), butter paper and white paper required for dispensing.

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Discuss formulation development, principle, procedure, labelling and dispensing of various monophasic liquid dosage forms.

CO2 Explain formulation development, principle, procedure, labelling and dispensing of various biphasic liquid dosage forms.

CO3 Enumerate the formulation development, preparation, labelling and dispensing of various powders and suppositories.

CO4 Enumerate the formulation development, preparation, labelling and dispensing of suppositories.

CO5 Describe different incompatibilities in pharmaceutical formulations and method to overcome such problems.

17CPHDC1 - MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

Course Objectives: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells.Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

Topics

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, hypercholesterolmiea).
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; Roll 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.
) 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 distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

COURSE OUTCOME

At the end of this course students will be able to,

CO1	Explain the different terminologies used in the metabolism of substrates and also its significance. Illustrate the metabolism of nutrient molecules in physiological and pathological conditions.
CO2	Describe the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.
CO3	Deduce in detail the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
CO4	Illustrate the different diagnostic tests performed for the Organ function tests
CO5	Differentiate the major and minor nutrients required by the human body for its functioning and also illustrate on its deficiencies

REFERENCES:

Text books (Theory)

a. Harpers review of biochemistry - Martin
b. Text book of biochemistry – D.Satyanarayana
c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

Reference books (Theory)

a. Principles of biochemistry -- Lehninger
b. Text book of biochemistry -- Ramarao
c. Practical Biochemistry-David T.Plummer.
d. Practical Biochemistry-Pattabhiraman.

17CPHDC1 - MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin-Wu tube method.**
11. Estimation of SGOT in serum.**
12. Estimation of SGPT in serum.**
13. Estimation of Urea in Serum.**
14. Estimation of Proteins in Serum.**
15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase.**
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18. 1Study of factors affecting Enzyme activity. (pH & Temp.)**
19. 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the color reactions involved in the identification of carbohydrates , protein and fats.

CO2 Interpret the normal and abnormal constituents of Urine

CO3 Estimate the amount of major and minor constituent of the blood fluids by serum analysis for example- glucose, urea, creatinine, calcium etc

CO4 Elaborate on the Experiment of action salivary amylase of starch and enzymatic hydrolysis of starch

CO5 Elaborate on the Experiment of action salivary amylase of starch on the effect temperature

17CPHDD1 - PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

Course objectives:

This course is designed to impart a very good knowledge about

a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
b. Some important physical properties of organic compounds;
c. 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;
d. Some named organic reactions with mechanisms; and
e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

Topics

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 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 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 E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

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 additon, 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, comparision 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 substituion 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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the various terminologies used in Organic chemistry along with their reactions and reactivity in organic compounds.

CO2 Identify & classify the different organic compounds and understand concepts of Isomerism

CO3 Describe the Structure, IUPAC nomenclature of different functional groups and general method of preparations, reactions and orientation of various organic compounds.

CO4 Illustrate on mechanisms and orientation of chemical reactions in organic compounds, experimental techniques, procedures and safe laboratory practices

CO5 Classify and Explain the properties, Analysis and significance of organic and biochemical compounds

REFERENCES:

Text books

a. T.R.Morrison and R. Boyd - Organic chemistry,
b. Bentley and Driver-Text book of Pharmaceutical chemistry
c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

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

17CPHDD1 - PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

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)
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, nitrocompounds.

III. Introduction to the use of stereo models:

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the synthetic procedures of some important medicinal compounds

CO2 Explain the Construction of molecular models

CO3 Discuss in detail the Systematic qualitative analysis of unknown organic compounds .

CO4 Justify the procedures performed during the analysis by preparing some important derivatives

CO5 Justify the procedures for the confirmation of the given organic compound

17CPHDE1 - PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory: 2 Hrs. /Week

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

Topics

1 Errors
2 Volumetric analysis
3 Acid-base titrations
4 Redox titrations
5 Non aqueous titrations
6 Precipitation titrations
7 Complexometric titrations
8 Theory of indicators
9 Gravimetry
10 Limit tests
11 Medicinal gases
12 Acidifiers
13 Antacids
14 Cathartics
15 Electrolyte replenishers
16 Essential Trace elements
17 Antimicrobials
18 Pharmaceutical aids
19 Dental Products
20 Miscellaneous compounds
21 Radio Pharmaceuticals

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain in detail the constituents synonyms and discuss the general assay procedure , applications of various inorganic compounds

CO2 Explain the sources and methods for detection of impurities in inorganic drugs and pharmaceuticals and its general analysis procedure

CO3 Describe in detail the principles and procedures involved the inorganic drugs and pharmaceuticals using various assay techniques

CO4 Describe in detail the Systematic Analysis the inorganic drugs and pharmaceuticals using various assay techniques

CO5 Focus the various applications of the various inorganic drugs and Pharmaceuticals, Appraise the importance of inorganic pharmaceuticals in preventing and curing of disease

REFERENCES:

Text books

a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya

b. A. H. 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

17CPHDE1 - PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

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 sulpahte- Iodometry
   d. Calcilugluconate- 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**
   (Anytwo 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
   d. 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 potashalum
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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Predict the impurity by performing the limit tests
CO2 Estimate the given Inorganic compound by performing the Qualitative Analysis
CO3 Discuss the synthetic track Inorganic compounds using a simple technique
CO4 Evaluate the purity of the Inorganic compound by performing different techniques
CO5 Estimate the given Inorganic compound by performing the Qualitative Analysis

17EPHD1A - REMEDIAL MATHEMATICS (THEORY)

Theory: 3 Hrs. /Week

Course objectives: This is an introductory course in mathematics. These subjects' deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

Topics

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 function. 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 second order.
7. **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

COURSE OUTCOME
At the end of this course students will be able to,

CO1	Relate the use of determinants and matrices in Pharmaceutical applications by knowing the algebra like simultaneous equations, Cramer's rule & En1, En2 and En3
CO2	Extend the application of logarithms in pharmaceutical computations with trigonometry
CO3	Illustrate the Certain co-ordinates, distance between two points, straight line; slope and intercept form, double-intercept form, slope-point and two point form, equation of first degree.
CO4	Outline the Calculus: Parametric differentiation, differentiation of implicit functions, logarithmic differentiation, successive differentiation and its Integral
CO5	Explain the basic Statistics - Ideal measure, mean, mode and median

REFERENCES:

Text books

a. Differential calculus By Shantinarayan
b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

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

17EPHD1B - REMEDIAL BIOLOGY (THEORY)

Course objectives: 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..

Topic

PART – A

01 Introduction
02 General organization of plants and its inclusions
03 Plant tissues
04 Plant kingdom and its classification
05 Morphology of plants
06 Root, Stem, Leaf and Its modifications
07 Inflorescence and Pollination of flowers
08 Morphology of fruits and seeds
09 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

01 Study of Animal cell
02 Study animal tissues
03 Detailed study of frog
04 Study of Pisces, Raptiles, Aves
05 Genearal organization of mammals
06 Study of poisonous animals

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Understand the basic concepts and components of Living world . Generalise and study the salient features of plant kingdom and various tissues and organs systems of plants.

CO2 Apply the acquired knowledge for general organization of plants and its morphology . Explain the importanceof modifications of different organs of the plants

CO3 Analyze the physiological functions of plant and its taxonomical characters . Catagorise the different types microorganisms and its utilisation.

CO4 Analyze the gross morphology of frog and its organ systems. Catagorise different types tissue system of animals.

CO5 Illustrate the general organisation of animal kingdom.

REFERENCES:

Text books

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

Reference books

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

17EPHD1B - REMEDIAL BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

Introduction of biology experiments
Study of cell wall constituents and cell inclusions
Study of Stem modifications
Study of Root modifications
Study of Leaf modifications
Identification of Fruits and seeds
Preparation of Permanent slides
T.S. of Senna, Cassia, Ephedra, Podophyllum.
Simple plant physiological experiments
Identification of animals
Detailed study of Frog
Computer based tutorials

COURSE OUTCOME
At the end of this course students will be able to,

CO1	Examine the plant cell wall constituents and its Inclusions
CO2	Identify the different types of modifications of plant organs.
CO3	Establish and apply techniqiues for preparation of permanent slide and anatomy of some medicinal plants
CO4	Develop simple physiological experiments of plants and its illustration . Identification of animals.

Second year

17CPHDA2 - PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

Course Objective

Upon completion of the subject student shall be able to

a. describe the etiology and pathogenesis of the selected disease states;
b. name the signs and symptoms of the diseases; and
c. mention the complications of the diseases.

1 **Basic principles of cell injury and Adaptation**

a) Causes, Pathogenesis and morphology of cell injury
b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

2 **Inflammation**

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

3 **Diseases of Immunity**

a) Introduction to Tand B cells
b) MHC proteins or transplantation antigens
c) Immune tolerance

- Hypersensitivity

Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs

- Autoimmunity

Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.

- Acquired immune deficiency syndrome (AIDS)

- Amylodosis

4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5 Types of shock, mechanisms, stages and management

6 Biological effects of radiation

7 Environmental and nutritional diseases

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

8 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.

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Describe the etiology and pathogenesis of the selected disease states

CO2 Name the signs and symptoms of the diseases

CO3 Mention the complications of the diseases.

CO4 Explain the basis for some laboratory tests and other diagnostic procedures

CO5 Explain how the various organ systems are interrelated, and use this understanding to promote a holistic approach towards the evaluation and treatment of patients

REFERENCES

Text books (Theory)

a. Pathologic basis of disease by- Cotran, Kumar, Robbins
b. Text book of Pathology- Harsh Mohan
c. Text book of Pathology- Y.M. Bhinde

Reference books (Theory)

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

17CPHDB2 - PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week

Course Objectives:

Upon completion of the subject student shall be able to –

a. know the anatomy, identification, growth factors and sterilization of microorganisms;
b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
c. do estimation of RNA and DNA and there by identifying the source;
d. do cultivation and identification of the microorganisms in thelaboratory;
e. do identification of diseases by performing the diagnostic tests; and
f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Title of the topic

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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1	Demonstrate the growth and cultivation of bacteria and virus. Study of different important media. 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 technique
CO2	Explain different methods of sterilization . Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of disinfectants
CO3	Illustrate the 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.
CO4	Explain the principle and concepts in the diagnostic tests Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite. Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B2 and B12.
CO5	Illustrate the clinical manifestations of Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV .

REFERENCES:

Text books (Theory)

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

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A –Microbiology‖ 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A.‖Bentley's Text Book of Pharmaceutics‖ B ailliere Tindals 24-28 London 1988
c. Forbisher ― Fundamentals of Microbiology‖ Philidelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein.D.A. ― Microbiology.‖2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, ― Immunology‖3rd edition 1996, Mosby- year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

17CPHDB2 - PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

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

* Indicate minor experiment & ** indicate major experiment

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Explain the Sterilisation process and aseptic transfer of micro-organisms and different staining techniques for the identification of bacteria
CO2 Study of motility characters of the microorganisms by hanging drop techniques
CO3 Explain the procedures and the different methods for the isolation of pure cultures
CO4 Evaluate the disinfecticton and to identify potential using Minimum inhibitory concentration and by zone of inhibition
CO5 Illustrate biochemical test of microorganisms for the production of industrial enzymes

17CPHDC2 - PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory: 3 Hrs. /Week

Course Objectives: This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

Topics

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.(11 drugs)
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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Describes the basic concepts underlying the subject pharmacognosy, defines the terminologies covered under pharmacognostic items, illustrates the principles of various systems of medicine with an account about their origin and development, generalizes the classification of crude drugs with suitable examples that are of pharmacognostic importance, elaborates the development of pharmacognsoy through various periods and stages, emphasizes the scope of pharmacognosy in treatment of various diseases and disorders and discusses briefly about cultivation, collection, storage and processing of crude drugs.

CO2 Ilustrates and discusses in detail about the various methods of cultivation of crude drugs with relevant examples, factors influencing cultivation, advantages and disadvantanges of cultivation. Identify and explain the cell wall components and thoir inclusions, generalize the facts and ideas about the interpretation and identification of cell contents in crude drugs, examine and evaluate the powder characters and microscopical features of few pharmacognostically significant drugs.

CO3 Discusses about the natural pesticides, definition, types, methods , their control measures and pharmacognostic study of few natural pesticides. Analyse the cell contents in few pharmacognostically significant crude drugs, illustrated with suitable examples in few crude drugs. Define, classify and enumerate carbohydrates and carbohydrate containing crude drugs with detailed study on a few important crude

drugs.

CO4 Define, classify and analyse lipids & oils. Study the chemical nature of lipds and oils. Describe the various methods of extraction of lipds and oil containing drugs. Enumerate and identify the different parameters for quality check of lipid and oil containing drugs with suitable examples.

CO5 List out the sources of proteins and explain the different types, chemistry, methods of extaction and analysis of protein and protein containing drugs. Elaborate the plant fibres used in surgical dressings and detailed study about related produtcts. Eumerate the role of medicinal plants in the identification of adulteration and contamination of herbal medicines and determine the adulteration in crude drugs..

REFERENCES:

Text books

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

Reference books

a. Pharmacognosy by Brady &Tyler.E.
b. Pharmacognosy by T.E.Wallis.
c. Pharmacognosy by C.S. Shah & Qadery.
d. Pharmacognosy by M.A. Iyengar.

17CPHDC2 - PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical: 3 Hrs./Week

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

List of experiments:

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Illustrate the parts of a microscope, prepare and report the permanent slide of monocot and dicot stem and root, practice staining and mounting of section, infer and interpret on a few sections and preparations. Enumerate and list the cell contents and cell inclusions in a plant part. Anslyse, predict & infer few cell contents in crude drugs.

CO2 Experiment macroscopical & microscopical characters of few pharmacognostically important crude drugs with neat labelled diagrams. Examine the powder microscopy of few crude drugs with well demonstrated diagrams.

CO3 Determine the chemical parameters of few oils that is of pharmacognostic significance and justify on the adulteration and contamination of the crude drugs.

CO4 To test and validate the presence of few phytoconstituents by preliminary qualitative chemical tests and report on the same..

CO5 Able to identify compound by performing chemical test

17CPHDD2 - PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

Course Objectives:

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

a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
b. handle and carry out the animal experiments;
c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
d. correlate and apply the knowledge therapeutically.

Title of the topic

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 antiadrenergic drugs
   b) Cholinergic and anticholinergic 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) Anticonvulsants
   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) NasalDecongestants

6. **Pharmacology of Hormones and Hormone antagonists**
   a) Thyroid and Antithyroid drugs
   b) Insulin, Insulin analogues and oral hypoglycemic 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

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Employ the knowledge of general pharmacology like Pharmacokinetic and Phamacodynmaic studies.
CO2 Analyze the Pharmacology of drugs acting on Autonomic Nervous System and Central Nervous System
CO3 Compare & study about the Pharmacology of drugs acting on Cardiovascular System
CO4 Apply the knowledge of Pharmacology of drugs acting on Respiratory System and Endocrine System
CO5 Classify and explain the various types of autocoids and their pharmacological actions.

REFERENCES:
Text books (Theory

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

Churchill Living stone.

Reference books (Theory

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

17CPHDE2 - COMMUNITY PHARMACY (THEORY)

Theory: 2 Hrs. /Week

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

a. know pharmaceutical care services;
b. know the business and professional practice management skills in community pharmacies;
c. do patient counselling & provide health screening services to public in community pharmacy;
d. respond to minor ailments and provide appropriate medication;
e. show empathy and sympathy to patients; and
f. appreciate the concept of Rational drug therapy.

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Topics

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
Definition and Principles of Pharmaceutical care.

6 Patient counselling
Definition, outcomes, various stages, barriers, Strategies to overcome barriers Patient information leaflets- content, design, & layouts, advisory labels

7 Patient medication adherence
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

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

9 OTC Medication- Definition, OTC medication list & Counselling

10 Health Education
WHO Definition of health, and health promotion, care for children, pregnant

& breast feeding women, and geriatric patients.
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

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

12 Essential Drugs concept and Rational Drug Therapy Role of community pharmacist

13 Code of ethics for community pharmacists

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Describe the patient- centered care to diverse patients using the best available evidence and in consideration of patients' circumstances to devise, modify, implement, document and monitor pharmacotherapy care plans, either independently or as part of healthcare team
CO2 Describe the methods to identify symptoms of minor ailments and provide appropriate medication
CO3 Identify symptoms of minor ailments and provide appropriate medication also exhibit professional ethics by promoting safe and appropriate medication use throughout society
CO4 Demonstrate knowledge of the business and professional practice management skills in community pharmacies.
CO5 Apply the knowledge to educate patients through counseling &provide health screening services to public , also participate in prevention programs of communicable diseases

REFERENCES:
Text Books:

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

Reference books:

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

17CPHDF2 - PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

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

a. the pathophysiology of selected disease states and the rationale for drug therapy;
b. the therapeutic approach to management of these diseases;
c. the controversies in drug therapy;
d. the importance of preparation of individualised therapeutic plans based on diagnosis;
e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
h. discuss the controversies in drug therapy;
i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
j. 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).

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

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
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3 **General prescribing guidelines for**
   a. Paediatric patients
   b. Geriatric patients
   c. Pregnancy and breast feeding

4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Describe the pathophysiology and management of cardiovascular,respiratory and endocrine diseases
CO2 Describe the Patient case based Assessment Skills
CO3 describe the quality use of medicines issues surrounding the therapeutic agents in the treatment of these diseases
CO4 Demonstrate the clinical skills in the therapeutic management of these conditions
CO5 Apply the knowledge on communication skills to provide patient – centred care to diverse patients using the evidence based medicine

REFERENCE:

Text Books

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

Reference Books

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

17CPHDF2 - PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical's: 3 Hrs/Week

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.

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Explain the pathophysiology of selected disease states
CO2 Justify the diagnosis arrived based on investigations ordered
CO3 Develop individualized therapeutic plans based on diagnosis
CO4 Identify the patient-specific parameters relevant in initiating drug therapy and monitoring therapy by implementing SOAP / FARM notes
CO5 Able to provide appropriateness of the drug therapy

Third Year

17CPHDA3 - PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

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

a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
b. carry out the animal experiments confidently,
c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
d. correlate and apply the knowledge therapeutically.

Title of the topic

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) Antidiuretics

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 **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants

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

6. **The dynamic cell: The structures and functions of the components of the cell**
    a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
    b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
    c) DNA replication: General, bacterial and eukaryotic DNA replication.
    d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
    e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Apply the knowledge of pharmacology of drugs acting on Hemopoietic system and Renal System
CO2 Employ the new udates and problems associated with the drugs acting as chemotherapeutic agents
CO3 Focus on the importance of animal toxicology and Immunopharmacology
CO4 Develop the knowledge on cell, macromolecules, Chromosomes, DNA Replication & cell cycle and cell signalling in future filed of personalized medicine
CO5 Analyze the gene structure, gene expression, transcription factors and recombinant DNA technology

REFERENCES:

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999.

Publisher: Jaypee, Delhi.

b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

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

17CPHDA3 - PHARMACOLOGY – II (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Develop the knowledge related tohandling of laboratory animals, Use of anesthetics and routes of administration in animals, Physiological salt solution & appliances used in experimental pharmacology.

CO2 Report the dose response curve of drugs using isolated tissue preparation

CO3 Compare the agonist and antagonistic action of drugs on isolated tissue preparation

CO4 Estimate the concentration of unknown sample of drugs using bioassay method on isolated tissue preparation

CO5 Evaluate the invivo pharmacological activity & cardiotonic acitivity using models/ isolated preparations**.**

REFERENCES:

Text books (Practical)

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

Reference books (Practical) :

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

17CPHDB3 - PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

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.

b. **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.

c. **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.

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

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

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

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

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

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

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

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

COURSE OUTCOME

At the end of this course students will be able to,

CO 1	Understand the importance of Regulatory authorities like GLP, ISO, TQM and Validation Guidelines involved in Pharmaceutical Analysis and various methods to ensure the Quality assurance of Drug and formulation.
CO 2	Discuss the Application of Chromatography technique like TLC, Paper Chromatography and Electrophoresis used in analysis of Pharmaceuticals.
CO 3	Examine the application of electrometric method utilized in analysis of drugs and Pharmaceuticals.
CO 4	Illustrate the Principle, Instrumentation and application of various spectroscopic techniques involved in Analysis of Drug and Pharmaceuticals
CO 5	Inculcate theoretical knowledge on various hyphenated instrumental techniques adopted for analysis of Pharmaceuticals

REFERENCES:

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.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

17CPHDB3 - PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of 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.

COURSE OUTCOME

At the end of this course students will be able to,

CO 1 Demonstrate the working procedure of various analytical instruments used in analysis of Pharmaceuticals

CO 2 Develop basic practical skills using instrumental techniques like chromatography and Spectroscopy technique.

CO 3 Experiment with various spectroscopy techniques is used to determine the Qualitative and Quantitative analysis of Drugs and Formulation.

CO 4 Understand and gain knowledge on trouble shooting in adopting various methodologies using instrumental techniques

CO 5 Discriminate the various Analytical techniques used in analysis of Drugs and Pharmaceuticals.

17CPHDC3 - PHARMACOTHERAPEUTICS – II (THEORY)

Theory: 3 Hrs. /Week

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

a. know the pathophysiology of selected disease states and the rationale for drug therapy
b. know the therapeutic approach to management of these diseases;
c. know the controversies in drug therapy;
d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

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

Title of the topic

1. **Infectious disease:** 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
2. **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
3. **Renal system**
   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
4. **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
5. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Describe the pathophysiology and management of cancer, bone and joint disorders, infectious diseases

CO2 Describe the Patient case based Assessment Skills

CO3 Describe the quality use of medicines issues surrounding the therapeutic agents in the treatment of these diseases

CO4 Demonstrate the clinical skills in the therapeutic management of these conditions

CO5 Apply the knowledge on communication skills to provide patient – centred care to diverse patients using the evidence based medicine

REFERENCES:

Text books (Theory)

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

Reference books (Theory)

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

17CPHDC3 - PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical: 3 hrs/week

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Identify the clinical signs and symptoms of selected disease states

CO2 Explain the pathophysiology of selected disease states

CO3 Justify the diagnosis arrived based on investigations ordered

CO4 Develop individualized therapeutic plans based on diagnosis

CO5 Identify the patient-specific parameters relevant in initiating drug therapy and monitoring therapy by implementing SOAP / FARM notes

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17CPHsDD3 - PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

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

a. practice the Professional ethics;
b. understand the various concepts of the pharmaceutical legislation in India;
c. know the various parameters in the Drug and Cosmetic Act and rules;
d. know the Drug policy, DPCO, Patent and design act;
e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

2. Detailed syllabus and lecture wise schedule: Title of the topic

1. **Pharmaceutical Legislations –** A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940,and its rules 1945.**
   Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
   Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.
   Constitution and Functions of DTAB,DCC,CDL.
   Qualification and duties –Govt. analyst and Drugs Inspector.
4. **Pharmacy Act –1948**.
   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955**.
   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

COURSE OUTCOME

At the end of this course students will be able to,

CO.1 Defend Professional ethics

CO.2 Understood the various concepts of the Pharmaceutical Legislation in India.

CO.3 Justify the various parameters in the Drug and Cosmetic Act and rules.

CO.4 Explain the various concepts of Drug policy, DPCO, Patent and Designing act.

CO.5 Express about the salient features of different laws which have been prescribed by the Pharmacy Council of India from time to time including International Laws.

REFERENCES:

Text books (Theory)

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

Reference books (Theory)

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

17CPHDE3 - MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

Course Objectives: Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationaship (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.

1. 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
2. Sulphonamides and sulphones
3. Antimalarials
4. Antibiotics
5. Antineoplastic agents
6. Cardiovascular agents
   a) Antihypertensive agents
   b) Antianginal agents and vasodilators
   c) Antiarrhythmic agents
   d) Antihyperlipidemic agents
   e) Coagulants and Anticoagulants
   f) Endocrine
7. Hypoglycemic agents
8. Thyroid and Antithyroid agents
9. Diureties
10. Diagnostic agents
11. Steroidal Hormones and Adrenocorticoids

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the terminologies used in various pharmacological actovities
CO2 Describe in detail the Classification of based of Pharmacological action and Chemical Structure.
CO3 Illustrate the Structural Activity Relationship of the given Chemical compound
CO4 Deduce the synthetic pathway of the drug
CO5 Write in detail the Chemistry of drugs with respect to their pharmacological activity and their applications

REFERENCES:

Reference Books:

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

17CPHDE3 - MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Outline the synthetic procedures of some important medicinal compounds

CO2 Explain the principle , procedure to estimate the actual amount of drug present in given powder/ Formulation

CO3 Identify the impurity profile of official listed drugs by performing Monograph Analysis

CO4 Define partition coefficient and illustrate the determination of partition coefficient using different solvent system

C05 Estimate the amount of substance present in the given sample be performing the simple quantitative analysis

17CPHDF3 - PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week

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

a. understand the principle involved in formulation of various pharmaceutical dosage forms;
b. prepare various pharmaceutical formulation;
c. perform evaluation of pharmaceutical dosage forms; and
d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Title of the topic

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 gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin 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, trans dermal, buccal, rectal, nasal, implants, ocular

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the solid dosage form and describe about tablets ,capsule and its types and method preparations
CO2 Expalin the Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations .
CO3 Analyze and catagorise the Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization.
CO4 Determine the 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
CO5 Illustrate the definition and concept of Controlled and novel Drug delivery systems with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

REFERENCES:

Text books (Theory)

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

Reference books (Theory)

a. Remington's Pharmaceutical Sciences
b. USP/BP/IP

17CPHDF3 - PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical: 3 Hrs./Week

List of Experiments :

1. **Manufacture of Tablets**
   - **a.** Ordinary compressed tablet-wet granulation
   - **b.** Tablets prepared by direct compression.
   - **c.** Soluble tablet.
   - **d.** Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
   - **a.** Ascorbic acid injection
   - **b.** Calcium gluconate injection
   - **c.** Sodium chloride infusion.
   - **d.** Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
   - **a.** Tablets
   - **b.** Capsules
   - **c.** Injections
5. **Formulation of two liquid oral preparations and evaluation by assay**
   - **a.** Solution: Paracetamol Syrup
   - **b.** Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
   - **a.** 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**

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Formulate different type tablets including Ordinary compressed tablet, Tablets prepared by direct compression,Soluble tablet, Chewable tablet. Formulation and filling of hard gelatin capsules

CO2 Explain the different types of parentral and formulate the parentrals including Ascorbic acid injection ,Calcium gluconate injection ,Sodium chloride infusion, Dextrose and Sodium chloride injection/ infusion.

CO3 Evaluate the prepared tablets , capsule and parentrals

CO4 Develop and Formulate the liquid preparation like syrups, suspension

CO5 Formulate and evaluate the sermisolid preparation and cosmetics

Fourth Year

17CPHDA4 - PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

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

a. the pathophysiology of selected disease states and the rationale for drug therapy;
b. the therapeutic approach to management of these diseases;
c. the controversies in drug therapy;
d. the importance of preparation of individualised therapeutic plans based on diagnosis;
e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
h. to discuss the controversies in drug therapy;
i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
j. 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).

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

Title of the topic

1 **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.
2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5 Pain management including Pain pathways, neuralgias, headaches.
6 Evidence Based Medicine

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Understand the pathophysiology of selected disease states and the rationale for drug therapy of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO2 Analyze the therapeutic approach to management of of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO3 Importance of preparation of individualised therapeutic plans based on diagnosis of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO4 Discuss the pathophysiology of selected disease states and the rationale for drug therapy o f Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO5 Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

REFERENCES

Text Books

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

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice -

Green and Harris, Chapman and Hall publication

c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

17CPHDA4 - PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs/Week

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Analyze the principle and practice involved in selection of drug therapy including clinical discussion.

CO2 Understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy

CO3 Importance of of case presentation and discussion of cases collected from hospital

CO4 Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

CO5 Prepare individualized therapeutic plans based on diagnosis

17CPHDB4 - HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

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

a. know various drug distribution methods;
b. know the professional practice management skills in hospital pharmacies;
c. provide unbiased drug information to the doctors;
d. know the manufacturing practices of various formulations in hospital set up;
e. appreciate the practice based research methods; and
f. appreciate the stores management and inventory control.

2. Topics

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

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Able to know the professional activates of hospital pharmacy
CO2 Provide drug information query appropriately
CO3 Enable effective inventory procedures in the pharmacy
CO4 Know the manufacturing procedure for bulk drugs required in the hospital
CO5 Promote continuing medical education in hospitals

REFERENCES:

Text books: (latest editions)

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

References:

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

17CPHDB4 - HOSPITAL PHARMACY (PRACTICAL)

Practical: 6 Hrs./Week

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Able to perform ABC Analysis to maintain inventory in hospital pharmacy
CO2 Provide drug information query appropriately to health care professionals and patients
CO3 Enable effective procurement of drugs in the pharmacy
CO4 Know the manufacturing procedure for large volume parenteral required in the hospital
CO5 Know to assess the prescription of individual patients

17CPHDC4 - CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

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

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

2. Detailed syllabus and lecture wise schedule: Title of the topic

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 poisons 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the elements of pharmaceutical care and provide comprehensive patient care services

CO2 Interpret the laboratory results to aid the clinical diagnosis of various disorders

CO3 Produce integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

CO4 Prepare individualized therapeutic plans based on diagnosis

CO5 Analyze the practice involved in Clinical Pharmacy Services including clinical discussion.

REFERENCES:

Text books (Theory)

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

References

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

17CPHDC4 - CLINICAL PHARMACY (PRACTICAL)

Practical: 3 Hrs./Week

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)

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Monitor drug therapy of patient through medication chart review and clinical review
CO2 Obtain medication history interview and counsel the patients
CO3 Identify and resolve drug related problems
CO4 Detect, assess and monitor adverse drug reaction;
CO5 Retrieve, analyze, interpret and formulate drug or medicine information

17CPHDD4 - BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. **Detailed syllabus and lecture wise schedule**

1 Research Methodology

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 Biostatistics

2.1 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.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatterplots, semilogarthimic plots

2.3 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.

2.4 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

COURSE OUTCOME
At the end of this course students will be able to,

CO1 Explain basic statistical concepts such as statistical collection, tabular and graphical representation of data
CO2 Demonstrate the concept of mean, median and mode, geometric mean, harmonic mean
CO3 Construct appropriate displays of data
CO4 Illustrate the common measures of dispersion from grouped and ungrouped data
CO5 Develop problem-solving techniques needed to accurately calculate probabilities and test values.

REFERENCES:
Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, JohnE Stanovich , 3rd edition, McGraw Hill Publications 2006

17CPHDE4 - BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory: 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain physiology of GIT, drug absorption, distribution and elimination process and factors affecting the ADME.

CO2 Describe various compartment models and their importance for the determination of pharmacokinetic parameters.

CO3 Discuss multi compartments, multiple dosage regimens and their importance.

CO4 Demonstrate non-linear pharmacokinetics, and non-compartment models and their importance to determine pharmacokinetic parameters.

CO5 Apply the knowledge to study the bioavailability and bioequivalence and discuss how to develop study protocol.

REFERENCES:

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

17CPHDE4 - BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical: 3 Hrs./Week

2. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
3. Comparison of dissolution studies of two different marketed products of same drug.
4. Influence of polymorphism on solubility and dissolution.
5. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
6. 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.
7. Bioavailability studies of some commonly used drugs on animal/human model.
8. Calculation of Ka, Ke, $t_1/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
9. Calculation of bioavailability from urinary excretion data for two drugs.
10. Calculation of AUC and bioequivalence from the given data for two drugs.
11. In vitro absorption studies.
12. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
13. Absorption studies in animal inverted intestine using various drugs.
14. Effect on contact time on the plasma protein binding of drugs.
15. Studying metabolic pathways for different drugs based on elimination kinetics data.
16. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
17. Determination of renal clearance.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Discuss the improvement of dissolution characteristics and determination of dissolution behaviors with the model drug.

CO2 Explain the protein binding study of poorly and highly protein bound drug and extent of binding with one model drug.

CO3 Determine pharmacokinetic parameters of drug using biological fluids by considering one, two and non-compartment models

CO4 Describe bioavailability studies of different marketed drug utilizing experimental design.

CO5 Describe bioequivalence studies of different marketed drug utilizing experimental design.

17CPHDF4 - CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

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. Clinical symptoms and management of chronic poisoning with the following agents – 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. Envenomations – 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 To understand the principles and practice of clinical toxicology in order to prevent drug overdose/poisoning

CO2 To promote better care for the poisoned patient particularly through providing appropriate poisons information

CO3 Demonstrate an understanding of the health implications of toxic exposures and commonly involved chemicals for toxicity

CO4 Apply an understanding of the history, assessment, and therapy considerations associated with the management of a toxic exposure

CO5 Enable the pharmacist to function as contributing health care team member when faced with a toxic exposure experience, including emergencies

REFERENCES:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London

b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

17CPHDA5 - CLINICAL RESEARCH (THEORY)

Theory: 3 Hrs. /Week

1. **Drug development process:**

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. 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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the new drug development process.

CO2 Describe the regulatory and ethical requirements.

CO3 Judge and justify the clinical trials activities

CO4 Illustrate the safety monitoring and reporting in clinical trials

CO5 Elaborate the trial coordination process

REFERENCES :

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

17CPHDB5 - PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

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.

Pharmacoeconomics:

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

Applications of Pharmacoeconomics

Software and case studies

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the various epidemiological methods and their applications
CO2 Explain the fundamental principles of Pharmacoeconomics
CO3 Identify and determine relevant cost and consequences associated with pharmacy products and services.
CO4 Perform the key Pharmacoeconomics analysis methods

CO5 Analyze the Pharmacoeconomic decision analysis methods and its applications.

REFERENCES:

1.Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2.Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3.Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4.Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5.George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6.Graker, Dennis. Pharmacoeconomics and outcomes.
7.Walley, Pharmacoeconomics.
8.Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
Relevant review articles from recent medical and pharmaceutical literature

17CPHDC5 - CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory: 2 Hrs. /Week

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:**
   d. Introduction
   e. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   f. Indications for TDM. Protocol for TDM.
   g. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   h. 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.**
   i. Renal impairment
   j. Pharmacokinetic considerations
   k. General approach for dosage adjustment in Renal disease.
   l. Measurement of Glomerular Filtration rate and creatinine clearance.
   m. Dosage adjustment for uremic patients.
   n. Extracorporeal removal of drugs.
   o. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
   p. Introduction to Bayesian Theory.
   q. Adaptive method or Dosing with feed back.
   r. Analysis of Population pharmacokinetic Data.

7. **Pharmacogenetics**
   s. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
   t. Genetic Polymorphism in Drug Transport and Drug Targets.
   u. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Design the drug dosage regimen for individual patients
CO2 Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes

CO3 Recommend dosage adjustment for patients with renal/ hepatic impairment
CO4 Manage pharmacokinetic drug interaction
CO5 Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

REFERENCES

1.Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2.Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3.Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4.Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5.Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6.Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7.Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.