SYLLABUS

DOCTOR OF PHARMACY (PHARM. D) COURSE

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DOCTOR OF PHARMACY - (POST BACCALAUREATE) COURSE
PHARM. D - PB

Pharm. D. - First Year

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**13/16^{+}**	**15/18***	**5/6^{+}* = 33/37^{+}/40***

$^{+}$ For Mathematics (PCB students)
* For Biology (PCM students)

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. **Scope and 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.

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

   1. describe the structure (gross and histology) and functions of various organs of the human body;
   2. describe the various homeostatic mechanisms and their imbalances of various systems;
   3. identify the various tissues and organs of the different systems of the human body;
   4. perform the hematological tests and also record blood pressure, heart rate, pulse and respiratory volumes;
   5. appreciate coordinated working pattern of different organs of each system; and

6. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

2. Course materials:

Text books

a) Gerard J. Tortora and Bryan Derrickson. Principles of anatomy and physiology, Publisher Harpercollins College New York.

b) Anne Waught & Allison Grant. Ross and Wilson's foundations of Anatomy and Physiology in Health and Ilness. 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. *Gray's anatomy*. Publisher: Churchill Livingstone, London.

d) K. Sembulingam & Prema Sembulingam, Medical Physiology, 4th Edition. Publisher: Jaypee Brothers

1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical: 3 Hrs/Week

General Requirements: Laboratory napkin, muslin cloth, record, observation book (100pages), stationary items, and blood lancet.

Course materials:

Text books

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

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

List of Experiments:

1. Study of compound microscope.
2. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
3. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
4. Study of appliances used in haematological experiments.
5. Determination of total WBC count of blood.
6. Determination of total RBC count of blood.

7. Determination of differential leukocyte count of blood.
8. Determination of
   (a) Erythrocyte Sedimentation Rate. (ESR)
   (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. Study of pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. Study of record of simple muscle curve using gastrocnemius sciatic nerve preparation.
14. Study of simple summation curve using gastrocnemius sciatic nerve preparation.
15. Study of simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. Study of simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. Study of fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and 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.

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

   1. know the formulation aspects of different dosage forms;
   2. do different pharmaceutical calculation involved in formulation;
   3. formulate different types of dosage forms; and
   4. appreciate the importance of good formulation for effectiveness.

2. **Course materials:**

   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.

3. **Lecture wise programme:**

	Topics	Hrs
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.	**06**
2	History of profession of Pharmacy in India in relation to pharmacy education, industry and organization in brief.	**03**
3	Development of Indian Pharmacopoeia. Salient features of latest edition of IP (IP 2008) and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian National formulary.	**03**
4	Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions.	**06**
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.	**05**
6	Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like Vehicles, Organoleptic additives and Stabilizers, with examples. Study of Monophasic liquids (formulation aspects and examples) like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.	**06**

7	Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification and formulation of Suspensions and Emulsions. Test for the type of emulsion and stability problems in emulsions.	**06**
8	Suppositories: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.	**03**
9	Galenicals: Definition, of different extraction processes like infusion, Decoction, Maceration and Percolation. Study of Maceration and Percolation processes	**06**
10	Surgical aids: Surgical dressings, sutures, ligatures and preparation of surgical catgut.	**04**
11	Incompatibilities: Introduction, classification, Examples and methods to overcome Physical and therapeutic incompatibilities.	**02**

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of Ephedrine Hydrochloride NF
   c. Orange Syrup
2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Paracetamol elixir BPC
3. **Linctus**
   a. Simple linctus BPC
   b. Pediatric simple linctus BPC
4. **Solutions**
   a. Solution of cresol with soap IP
   b. 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. Dusting powder
   d. Insufflations

9. **Suppositories**♣
    a. Boric acid suppositories
    b. Chloral suppositories

10. **Incompatibilities**
    a. Preparations having with Physical Incompatibilities (3 Nos)

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

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. **Scope and Objectives:** Biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells in normal and abnormal state. 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.
   The objective of the present course is providing biochemical facts and the principles to the students of pharmacy.

   Upon completion of the course student shall be able to –
   1. understand the catalytic activity of enzymes and importance of enzymes in diagnosis of diseases and therapeutic agents;
   2. know the metabolic pathways of biomolecules in health and illness (metabolic disorders);
   3. understand the genetic organization of mammalian genome, protein synthesis, replication, mutation and repair mechanism.
   4. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
   5. do the qualitative analysis and determination of biomolecules in the body fluids and their clinical significance.

2. **Course materials:**

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.

3. Lecture wise programme:

	Topics	Hrs
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.	**05**
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.	**10**
3	**Carbohydrate metabolism**: Glycolysis, citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, glycogenesis gluconeogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose tolerance test and its significance; hormonal regulation of carbohydrate metabolism.	**11**
4	**Lipid metabolism:** β-Oxidation of saturated fatty acid; Ketogenesis and ketolysis; biosynthesis of fatty acids and lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).	**09**
5	**Biological oxidation:** Enzymes and Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture, regulation and inhibition); Oxidative phosphorylation and uncouplers of ETC.	**04**
6	**Protein and amino acid metabolism:** protein turn over; nitrogen balance; general reactions of catabolism of amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphorias, jaundice. Metabolic disorder of Amino acids.	**08**
7	**Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; DNA damage and repair mechanism; DNA replication (semi conservative).	**12**

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

a) Urine analysis (macroscopic and physical examination, quantitative and semi quantitative tests.)

b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood/ urine creatinine, urea and uric acid)

c) Urine concentration test **03**

d) Urinary tract calculi. (stones)

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

a) Test for hepatic dysfunction-Bile pigments metabolism.

b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.

c) Dye tests of excretory function.

d) Tests based upon abnormalities of serum proteins. **04**

e) Selected enzyme activity determination tests.

10 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides. **02**

11 **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). **03**

12 **Electrolytes:** Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids. **03**

1.3 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 chlorides by Volhard's method.
4 Quantitative estimation of urine creatinine by Jaffe's method.
5 Quantitative estimation of urine calcium by precipitation method.
6 Quantitative estimation of serum cholesterol.
7 Preparation of Folin Wu filtrate from blood.
8 Quantitative estimation of blood creatinine.
9 Quantitative estimation of blood sugar Folin-Wu tube method.
10 Estimation of SGOT in serum.
11 Estimation of SGPT in serum.
12 Estimation of Urea in Serum.
13 Estimation of Proteins in Serum.
14 Determination of serum bilirubin
15 Determination of Glucose by means of Glucoseoxidase.

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

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30(20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives**: This course is designed to impart a very good knowledge about
   a. IUPAC/Common systems of nomenclature of simple organic compounds belonging to different classes of organic compounds
   b. Some important physical properties of organic compounds
   c. Free radical/ nucleophylic [alkyl/ acyl/ aryl] /electrophylic- substitution, free radical/ nucleophylic / electrophylic- addition, elimination, oxidation and reduction reactions with mechanism, orientation, order of reactivity, stability of compounds
   d. Some named organic reactions with mechanisms
   e. Uses of organic compounds in pharmacy.

   At the end of the course the student should be able to
   1. name , write the structure of organic compound
   2. name the type of isomerism
   3. compare physical properties
   4. tell the name, class of reaction
   5. tell the method of conversion of compounds
   6. account for reactivity, orientation of reactions
   7. prepare organic compounds
   8. identify, confirm the identification of organic compound

2. **Course materials:**

   Text books
   a. Organic chemistry- T.R.Morrison and R. Boyd
   b. Text book of Pharmaceutical chemistry - Bentley and Driver
   c. Organic chemistry, the fundamentals of chemistry - I.L.Finar
   d. Organic chemistry - P.L.Soni
   e. Text book of organic chemistry - B.S.Bahl and Arun Bahl

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

3. Lecture wise programme :

Note: **To emphasise also on definition, examples, uses in pharmacy, mechanisms of reactions .**

	Topic	Hrs
I.	**Classification and Nomenclature** Different types of classification of organic compounds i. Common- IUPAC systems of nomenclature of following classes of open chain compounds. Hydrocarbons, halohydrocarbons, alcohols, aldehydes, ketones, carboxylic acids, carboxylic acid halides, carboxylic acid amides, carboxylic acid esters, acid anhydrides, amines, ethers ii. Nomenclature of alicyclic compounds and aromatic compounds (non heterocyclic)	**10**
II	**Isomerism** a. Structural isomerism, chain isomerism, positional isomerism, functional isomerism, metamerism, tautomerism b. Stereo isomerism, optical isomerism, geometrical isomerism, specification of configuration, conformational isomerism	**04**
III.	**Structure and Properties** a Polar molecules, nonpolar molecules, protic molecules, aprotic molecules b Inter molecular forces *c* Melting point, boiling point of organic compounds, solubility of organic compounds	**05**
IV	**Alkanes** Free radical substitution reactions of alkanes- reactivity, inhibition. Reaction between methane, ethane, propane and halogens	**03**
V.	**Alkenes** a. i. Dehydrohalogenation reactions of alkyl halides- kinetics, rearrangement of carbo cations, reactivity, orientation ii. Dehydration of alcohols reactions- kinetics, rearrangement of carbo cations, reactivity, orientation iii. E_1 versus E_2 reactions b. Electrophilic addition reactions of alkenes- orientation, rearrangement of carbo cations, reactivity c. Free radical addition reactions of alkenes- orientation, reactivity	**08**
VI.	**Alkyl halides** Preparation of alkyl halides from alcohols by Nucleophylic substitution reactions, Nucleophylic substitution reactions of alkyl halides- kinetics, reactivity, rearrangement of carbocations, solvent effect, stereochemistry. SN^1 versus SN^2 reactions	**03**
VII.	**Alicyclic compounds**	**03**

a. Baeyer's strain theory, Sachse Mohr theory
b. General methods of preparation

VIII. **Dienes** **03**

Classification, stability, ease of formation of conjugated dienes, electrophylic and free radical addition reactions of conjugated dienes

IX. **Aromatic compounds** **08**

a) Evidences in the derivation of structure of Benzene, aromatic characters

b) i. Electrophylic substitution reactions of Benzene- nitration, sulfonation, halogenations, reactivity of halogens, Friedel craft's alkylation, reactivity of alkyl halides and limitation of Friedel crafts alkylation reactions, Friedel crafts acylation reactions.
ii. Classification of substituents
iii. Orientation of mono substituted Benzene compounds towards electrophylic substitution reactions.

c). Nucleophilic aromatic substitution reactions- reactivity, comparison with aliphatic nucleophylic substitution reactions

X. **Carbonyl compounds** **06**

a). Nucleophylic addition reactions, reactions between carbonyl compounds and hydrogen cyanide, Sodium bisulphite, hydroxyl amine, hydrazine, phenyl hydrazine, 2,4- dinitro phenyl hydrazine, alcohol

b). Aldol, crossed aldol, Cannizaro, crossed Cannizaro, Benzoin, Perkin reactions

XI. **Carboxylic acids and derivatives** **05**

a). Acidity of carboxylic acids and effect of substituents on it.
b). Nucleophylic acyl substitution reactions, esterification.
c). Comparison of alkyl nucleophylic substitution with nucleophylic acyl substitution reactions

XII. **Amines** **03**

a. Basicity of amines
b. Hoffmanns degradation of amides, diazotization reactions, coupling reactions, replacement reactions of aromatic diazonium salts

XIII. **Phenols** **03**

a. Acidity of phenols
b. Kolbe's synthesis, Riemer tiemann reactions, pthalein reaction, Schotten Bauman reaction, Libermann's nitrosation reaction

XIV. **Heterocyclic compounds** **04**

Classification, nomenclature of mono and bicyclic compounds, medicinal uses of some important heterocyclic compounds

XV. **Carbohydrates** **03**

Classification, qualitative tests

XVI. **Amino acids and proteins** **04**

a) Classification of amino acids, qualitative tests for amino acids
b) Classification, structure, colour reactions of proteins. Qualitative tests for proteins

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hours/week

	Title of the experiment	No of classes
1	Recrystallisation of organic compounds	**1**
2	Preparation of simple non hetero cyclic organic compounds and recrystallisation of compounds prepared. (Minimum of 08 compounds) Aspirin/Benzanilide/Phenyl benzoate/Acetanilide by acylation 2,4,6-Tribromo aniline/Para bromo acetanilide by halogenation 5-Nitro salicylic acid/Meta di nitro benzene by nitration Dibenzal acetone from benzaldehyde by Claisen Schmidt Benzoic acid from benzyl chloride by oxidation Benzoic acid/Salicylic acid by hydrolysis 1- Phenyl azo -2- napthol from aniline by diazotization and coupling Benzophenone oxime from benzophenone	**8**
3	Systematic qualitative analysis of unknown organic compounds for preliminary and Lassaigns tests.	**2**
4	Systematic qualitative analysis of unknown organic compounds for functional groups (for preliminary / Lassaigns / solubility / functional group tests) Following classes of compounds may be analysed Phenols, amide/ urea, carbohydrate, amine, carboxylic acid, aldehyde, ketone, alcohol, carboxylic acid ester, hydrocarbon, halohydrocarbon, nitrocompound, anilide	**11**
5	Determination of melting and boiling points of organic compounds	**1**
6	Preparation of suitable solid derivatives from organic compounds	**1**
7	Introduction to the use of stereomodels – Methane,Ethane, Ethene, Acetylene, Cyclo hexane, Benzene (Students to prepare the ball and stick stereomodels using china clay, plastic sticks individually and to explain the formation of bonds& bond angles, bond lengths)	**1**

Course Materials :

a. Practical organic chemistry – Mann and Saunders
b. Introduction to organic laboratory techniques – Pavia, Lampman, Kriz
c. Text book of Practical Organic Chemistry - Vogel

Scheme of Practical Examination:

	Sessional	**Annual**
Synopsis	04	15
Major Experiment	12	25
Minor Experiment	-	15
Viva	04	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

Theory: 2 hrs/Week

1. **Scope and objectives**: This course mainly deals with fundamentals of analytical chemistry and also the study the Inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

   Upon completion of course student shall be able to:

   1. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceutical;
   2. know the analysis of the inorganic pharmaceuticals their applications
   3. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

2. **Course materials:**

   Text books

   a. A.H.Beckett & J.B. Stenlake's -Practical Pharmaceutical Chemistry Vol I & II, Stahl one Press of University of London, 4th edition.
   b. Text Book of Quantitative Inorganic analysis by Vogel
   c. Inorganic Pharmaceutical Chemistry III-Edition P. Gundu Rao

   Reference books

   a. A text book of Inorganic medicinal Chemistry by Surendra N. Pandey.
   b. Inorganic pharmaceutical Chemistry by M.L Schroff
   c. Bentely and Driver's Textbook of Pharmaceutical chemistry
   d. Pharmaceutical Analysis Vol – I, Dr. A.V. Kasture et al., Nirali Prakashan, 13th Edition.
   e. Inorganic Pharmaceutical Chemistry by Anand & Chetwal.
   f. Analytical chemistry principles by John H. Kennedy.
   g. I.P.1985 ,1996, 2008 Govt. of India, Ministry of Health

3. **Lecture wise programme :**

	Topics	Hrs
1.	Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures.	**02**
2.	Fundamentals of volumetric analysis, theories of indicators and methods of expressing concentrations. Primary and secondary standard. Preparation and standardization of various volumetic solutions like oxalic acid, sodium hydroxide, hydrochloric acids, sodium thiosulphate, sulpuric acid, potassium permanganate, iodine and cerric ammonium sulphate solutions.	**04**
3.	**Acid base titration**: Classification and estimation of strong, weak, and very weak acids and bases.	**02**
4.	**Principles of redox titrations**: Concepts of oxidation and reduction. Redox reactions, strength and equivalent weights of oxidizing and reducing agents, theory of redox titrations, cerrimetry, Iodimetry, Iodometry, bromometry, titrations with potassium iodate, potassium bromate, titanous chloride, 2,6-dichlorophenol indophenol.	**03**
5.	**Non aqueous titration**: Introduction to solvents, classification and estimation of Sodium benzoate and ephedrine HCl.	**02**

6. **Principles of precipitation titrations:** Different methods-Mohr's, Modified Mohr's, Volhard's, Modified Volhard's, Fajans with example. Estimation of sodium chloride by modified volhards method. **03**

7. **Complexometric titration and its classification**: Estimation of Magnesium sulphate, and Calcium Gluconate by complexometric method. Metal ion indicators. **03**

8. **Gravimetry**: Introduction to gravimetric method, steps involved in gravimetric method, precipitants and estimation of Barium sulphate by gravimetric method. **02**

9. **Limit test:** Source and effect of impurities in pharmacopoeial substances, importance of limit test, general principle and procedures for limit test, limit test for chloride, sulphate, iron, arsenic and lead and heavy metals. Special procedure for limit test for chloride and sulphate **06**

General methods of preparation, assays*, storage condition and Medicinal uses of inorganic compounds belonging to the following classes.

10. **Medicinal gases:** Oxygen, Nitrous oxide, Carbon dioxide **01**

11. **Acidifies**: Dil HCl, Ammonium Chloride* **01**

12. **Antacid**: Aluminum hydroxide gel*, sodium bicarbonate*, Magnesium triisilicate, Magnesium carbonate (Light and Heavy), Magnesium hydroxide mixture*, Preparation containing combination of antacids. **03**

13. **Cathartics**: Magnesium sulphate, Sodium orthophosphate **01**

14. **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Sodium chloride Injection, Sodium chloride compound injection, Potassium chloride, Potassium chloride injection, Calcium Gluconate* and Electrolyte combination therapy and ORS, Physiological acid base balance. **04**

15. **Essential trace elements:** Copper, Iron, Iodine and Zinc **01**

16. **Antimicrobials:** Potassium permanganate*, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations, Boric acid*. **03**

17. **Pharmaceutical aids:** Bentonite, sodium metabisulphite, Barium sulphate* **01**

18. **Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, Stannous fluoride, Zinc Eugenol cement. **02**

19. **Miscellaneous compounds:** **04**
    i) Expectorants: Potassium iodide*
    ii) Haematinics: Ferrous sulphate*, Ferrous gluconate, Ferrous fumarate,
    iii) Emetics: Copper sulphate*, Sodium potassium tartarate
    iv) Poison and Antidote: Sodium thoisulphate, Activated charcoal,

20. **Radiopharmaceuticals:** Radio activity, natural radio activity and artificial radio activity. Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes sodium iodide I-121, Ferric citrate Fe-59. Storage conditions, precautions & pharmaceutical application of radioactive substances. **02**

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical: 3 Hours/week

(Following experiments to be covered in 25 different practical classes)

1. Limit tests (7 exercises) *
    1. Limit test for chlorides
    2. Limit test for sulphate
    3. Limit test for Iron
    4. Limit test for heavy metals
    5. Limit test for Arsenic
    6. Modifications in limit tests for chloride and sulphates in potassium permanganate, sodium bicarbonate, sodium benzoate and sodium Salicylate.
2. Preparation and standardization of the following (3 exercises)*.
    1. 0.IN NaOH
    2. 0.IN $KMnO_4$
    3. 0.IN Cerric ammonium sulphate
    4. 0.IN $HClO_4$
    5. 0.05M Di sodium EDTA
    6. 0.IN Sodium thiosulphate
3. Assay of the following compounds **
    1. Ammonium chloride-acid base titration (Formal titration)
    2. Ferrous sulphate- (redox) Ceric ammonium sulphate titration
    3. Copper sulphate- (redox) Iodometry
    4. Calcium gluconate-complexometry
    5. Hydrogen peroxide- (redox -Permanganometry)
    6. Sodium benzoate-nonaqueous titration
    7. Sodium chloride-Modified Volhard's method
    8. Assay of KI-KIO_3 titration
    9. Assay of Zinc oxide (acid base back titration)
4. Test for identify for the following (2 exercises)*
    1. Sodium bicarbonate
    2. Ferrous sulphate
    3. Potassium iodide.
    4. Calcium chloride
5. Test for purity for the following (2 exercises)*
    1. Swelling power in Bentonite
    2. Ammonium salts in Potash alum.
    3. Presence of Iodates in KI
6. Preparation of inorganic pharmaceuticals (2 exercises)*
    1. Boric acid
    2. Potash alum
    3. Magnesium hydroxide.
    4. Magnesium sulphate

Scheme of Practical Examination	**Sessional**	**Annual**
Synopsis	05	15
Major Experiment(Experiment indicated by**)	10	25
Minor Experiment(Experiment indicated by*) 1&2	3	20
Viva-Voce	2	10
Max. Marks	20 #	70

 # Note: Total sessional marks is 30 (20 for practical sessional and 10 marks for regularity, promptness, viva-voce and record maintenance)

1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives**: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
   Upon completion of the course the student shall be able to : –
   1. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   2. solve the problems of different types by applying theory; and
   3. appreciate the important applications of mathematics in pharmacy.

2. **Course materials:**

   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.Loncy

3. **Lecture wise programme :**

	Topic	Hrs
1	**Algebra :** Matrices : Definition, Addition, Subtraction and Multiplication of matrices, Determinants: Determinants of order two and three, Properties of determinants (without Proof). Inverse of square Matrices, Adjoint of square matrix, Solution of linear equation by Matrix method, Cramer's rule, Characteristic equation, Statement of Cayley-Hamilton Theorem (Without Proof) – Pharmaceutical examples	**18**
2	**Trigonometry :** Relation between Sides and angles of a triangle, solution of triangles – Simple problems	**05**
3	**Analytical Geometry :**Points, Straight line, Types of straight lines – Y= mx + c, $(y-y_1) = m*(x-x_1)$, $(y-y_1) = ((y_2-y_1)/(x_2-x_1))*(x-x_1)$ Parallel and Perpendicular straight lines, Angle between two lines, Perpendicular distance from a point to the line, distance between parallel lines, Circle: General equation of circle, finding centre and radius of the circle, Parabola: Equation of the parabola $y^2= 4ax$, Simple problems	**15**
4	**Differential calculus:** Function, Limit, Differentiation, Differentiation of sum, Product, Quotient, Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, simple problems.	**16**
5	**Integral Calculus:** Partial fractions, Definition of integration, integration by substitution and integration by parts, Properties of definite integrals, Simple problems.	**07**
6	**Differential equations:** Definition, order, degree, variable separable, homogeneous differential equation, linear differential equation, exact differential equation, Simple problems	**10**
7	**Laplace transform:** Definition, Laplace transform of elementary functions, linearity and shifting property , simple problems	**04**

REMEDIAL BIOLOGY :

1. **Scope and 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.

2. **Course materials:**

   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.

3. **Lecture wise programme :**

	Topic	Hrs
	PART – A	
01	Introduction	**02**
02	General organization of plants and its inclusions	**04**
03	Plant tissues	**04**
04	Plant kingdom and its classification	**04**
05	Morphology of plants	**04**
06	Root, Stem, Leaf and Its modifications	**05**
07	Inflorescence and Pollination of flowers	**04**
08	Morphology of fruits and seeds	**04**
09	Plant physiology	**04**
10	Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae	**06**
11	Study of Fungi, Yeast, Penicillin and Bacteria	**04**
	PART-B	
01	Study of Animal cell	**04**
02	Study animal tissues	**04**
03	Detailed study of frog	**08**
04	Study of Pisces, Reptiles, Aves	**05**
05	General organization of mammals	**05**
06	Study of poisonous animals	**04**

1.6 REMEDIAL BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title

1. Introduction of biology experiments (section cutting techniques, Mounting and staini9ng, permanence slide preparation and Microscope)
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog by using computer models
12. Computer based tutorials

Scheme of Practical Examination:

	Sessional	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total Sessional marks is 30 (20 for practical Sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Pharm. D. - Second Year

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	**17**	**9**	**6 = 32**

2.1 PATHOPHYSIOLOGY (THEORY)

Theory: 3 Hrs. /Week

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

   Upon completion of the course student shall be able to –
   1. Describe the etiology and pathogenesis of the selected disease states;
   2. Name the signs and symptoms of the diseases; and
   3. Mention the complications of the diseases.

2. Course Materials:

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; Fourth edition; Walker & Whittlesea, Churchill Livingstone publication

3. Lecture wise Programme:

	Topic	Hrs
1	**Basic principles of cell injury and Adaptation**	**05**
	a) Causes, Pathogenesi s 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	**05**
3	**Diseases of Immunity** a) Introduction to T and B cells b) MHC proteins or transplantation antigens c) Immune tolerance	**02**
	- Hypersensitivity Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs	**03**
	- 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.	**03**
	- Acquired immune deficiency syndrome (AIDS)	**01**
	- Amylodosis	**01**
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.	**05**
5	**Shock** Types of shock, mechanisms, stages and management	**03**
6	**Biological effects of radiation**	**02**
7	**Environmental and nutritional diseases** i) Air pollution and smoking- SO_2,NO, NO_2, and CO ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.	**04**
8	**Pathophysiology of common diseases**	
	Parkinsonism	**01**
	Schizophrenia	**01**
	Depression and mania	**02**
	Hypertension	**02**
	Stroke (ischemic and hemorrhage)	**02**
	Angina, CCF, Atherosclerosis, Myocardial infarction	**08**
	Diabetes Mellitus	**02**
	Peptic ulcer and inflammatory bowel diseases	**04**
	Cirrhosis and Alcoholic liver diseases	**04**
	Acute and chronic renal failure	**02**
	Asthma and chronic obstructive airway diseases	**02**
9	**Infectious diseases :** Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria, Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.	**11**

4. Assignments:

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

Format of the assignment

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

2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory: 3 Hrs. /Week

1. Scope & Objectives: Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

Upon completion of the course student shall be able to

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

2. Course Materials:

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.

c) Harsh Mohan, "Text book of Pathology" 3rd edition, 1998, B-3 Ansari road Daryaganj 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" Bailliere Tindals 24-28 London 1988.
c) Forbisher "Fundamentals of Microbiology" Philadelphia 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.

3. Lecture wise Programme:

	Topic	Hrs
1	**Introduction to the science of microbiology**. Major divisions of microbial world and Relationship among them.	**03**
2	**Morphology & Physiology of Microorganisms** Different methods of classification of microbes and study of Bacteria, Fungi, Virus, Rickettsiae, Spirochetes.	**07**
3	**Growth & Nutrition** Nutritional requirements Growth and cultivation of bacteria and virus. Culture Media for aerobic and anaerobic bacteria & fungi. Maintenance of lab cultures.	**08**
4	**Isolation and Identification of Bacteria** Different methods-Staining reactions Biochemical reactions. Counting of bacteria -Total and Viable counting techniques.	**08**
5	**Sterilization** Detailed study of different methods of sterilization with merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations. Validation of various sterilization techniques.	**08**
6	**Disinfectants** Study of disinfectants, antiseptics, fungicidal and virucidal agents. Factors affecting their action and mechanism of action. Evaluation of bactericidal, bacteriostatic, virucidal and preservatives in pharmaceutical preparations.	**07**
7	**Immunology** 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.	**12**

8 **Diagnostic tests**
Schick's Test, Elisa test, Western Blot test, Southern Blot PCR
Widal, QBC, Mantaux Peripheral smear.
Study of malarial parasite. **07**

9 **Microbiological Assays**
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}.
Standardization of vaccines and sera. **05**

10 **Study of infectious diseases**
Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV. **10**

2.2 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 and sterilisation of media*
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.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

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

Format of the assignment:

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

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hours/Week

1. **Scope and 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 their history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
   Upon completion of the course student shall be able to:
   1. Understand the basic principles of cultivation, collection and storage of crude drugs
   2. Know the source, active constituents and uses of crude drugs and
   3. Appreciate the applications of primary and secondary metabolites of the plant.

2. **Course materials:**
   Text books
   a. Pharmacognosy by G.E. Trease & W.C. Evans.
   b. Pharmacognosy by C.K. Kokate, S.B. Gokhale & A.C. Purohit.

   Reference books
   a. Pharmacognosy by R. Brady & V.E. Tyler.
   b. Pharmacognosy by T.E. Wallis.
   c. Pharmacognosy by C.S. Shah & J.S. Quadry.
   d. Pharmacognosy by M.A. Iyengar.

3. **Lecture wise programme:**

	Topics	**Hrs**
1	Introduction.	**01**
2	Definition, history and scope of Pharmacognosy.	**02**
3	Classification of crude drugs viz. alphabetical, morphological, chemical, pharmacological, taxonomical methods. General methods of chemotaxonomy.	**05**
4	Cultivation, collection, processing and storage of crude drugs. Conservation of medicinal plants.	**05**
5	Detailed method of cultivation of crude drugs. a) Senna b) Cinchona c) Cardamom d) Opium e) Isapgol f) Ergot h) Ginger	**06**
6	Study of cell wall constituents and cell inclusions.	**04**

7	Study of morphology and microscopy of different plants parts. i. Leaf: Datura, Senna ii. Bark: Cinnamon (Cassia), Cinchaona iii. Wood: Quassia iv. Stem: Ephedra v. Root: Rauwolfia, Liquorice vi. Rhizome: Ginger, Podophyllum. vii. Flower buds: Clove. viii. Fruits: Coriander, Fennel ix . Seeds: Isapgol, Nux Vomica.	**10**
8	Study of natural pesticides. Pyrethrum, Neem, Tobacco	**03**
9	Detailed study of various plant constituents. a) Detailed study of Carbohydrates and related products. b) Biological source, method of production, chemical constituents, tests, uses and adulterants of i) Honey ii) Acacia iii) Agar iv) Sterculia v) Tragacanth vi) Cellulose and its products vii) Pectin viii) Guar gum ix) Sodium alginate.	**10**
10	a) Definition, sources, method extraction, chemistry and method of analysis of Lipids. b) Study of method of production, chemical constituents, tests, uses and adulterants of the following drugs. i) Castor oil ii) Shark liver oil iii) Chaulmoogra oil iv) Wool fat v) Bees wax vi) Spermaceti vii) Cocoa butter viii) Olive oil	**02** **05**
11	Therapeutic application of herbal drugs, poisonous plants, herbal-drug interaction, edible vaccines, marine Pharmacognosy.	**04**
12	Introduction, definition, classification, general properties, chemical tests and general method of isolation of Alkaloids, Glycosides, Essential Oils, Flavonoids, Resins and Tannins.	**12**
13	Study of plants fibers used in surgical dressings and related products.	**04**
14	Different methods of adulteration of crude drugs and general methods of detection of adulterants.	**02**

2.3 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. Macro, powder and microscopic study of Datura.
3. Macro, powder and microscopic study of Senna.
4. Macro, powder and microscopic study of Cassia Cinnamon.
5. Macro, powder and microscopic study of Cinchona
6. Macro, powder and microscopic study of Ephedra.
7. Macro, powder and microscopic study of Quassia.
8. Macro, powder and microscopic study of Clove
9. Macro, powder and microscopic study of Fennel.
10. Macro, powder and microscopic study of Coriander.
11. Macro, powder and microscopic study of Isapgol.
12. Macro, powder and microscopic study of Nux vomica.
13. Macro, powder and microscopic study of Rauwolfia.
14. Macro, powder and microscopic study of Liquorice.
15. Macro, powder and microscopic study of Ginger.
16. Macro, powder and microscopic study of Podophyllum.
17. Determination of Iodine value.
18. Determination of Saponification value and unsoponifiable matter.
19. Determination of Acid value.
20. Chemical tests for Acacia and Tragacanth
21. Chemical tests for Agar and Starch
22. Chemical tests for Gelatin
23. Chemical tests for Lipids (Castor oil, Sesame oil, Shark Liver oil, Bees wax).
24. Determination of moisture content of crude drug.
25. Isolation of Volatile oil.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	04	10
Identification	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03 hrs**	**04 hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

2.4 PHARMACOLOGY – I (THEORY)

Theory: 3 Hrs. /Week

1. **Scope & Objectives:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught.

   Upon completion of the course student shall be able to:

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

   Text books (Theory)

   a. Tripathi, K. D. Essentials of medical pharmacology. 6th edition, 2008. Publisher: Jaypee, Delhi.
   b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 20th edition, 2008. Publisher: Popular, Mumbai.
   c. Rang, H.P. & Dale, M.M. Pharmacology. 5h edition, 2003. 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. 11th edition, 2006. Publisher McGraw Hill, Pergamon Press.
   b. Craig, C.R. & Stitzel, R.E. Modern Pharmacology. 5th edition, 1997. Publisher: Little Brown Co.
   c. Katzung, B.G. Basic and clinical pharmacology. 9th edition, 2004. Publisher: Prentice Hall, Int.
   d. Shargel and Leon. Applied Biopharmaceutics and Pharmacokinetics. Latest edition 2002. Publisher: Prentice Hall, London.

3. **Lecture wise Programme:**

	Topics	Hrs
1.	**General Pharmacology**	**16**
	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 – Basic concepts, acute, sub-acute and chronic toxicity.	
	g) Pre-clinical evaluation	
	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** **09**
   a) Introduction to neurotransmission
   b) Adrenergic and antiadrenergic drugs
   c) Cholinergic and anticholinergic drugs
   d) Neuromuscular blockers
   e) Mydriatics and miotics
   f) Drugs used in myasthenia gravis
   g) Drugs used in Parkinsonism
3. **Pharmacology of drugs acting on cardiovascular system** **09**
   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** **20**
   a) Excitatory and inhibitory neurotransmitters of CNS
   b) General anesthetics
   c) Sedatives and hypnotics
   d) Anticonvulsants
   e) Analgesic and anti-inflammatory agents
   f) Psychotropic drugs
   g) Alcohol and methyl alcohol
   h) CNS stimulants and cognition enhancers
   i) Centrally acting skeletal muscle relaxants
   h) Drug dependence, abuse and tolerance. List of drugs causing such problems
5. **Pharmacology of Local anaesthetics** **02**
6. **Pharmacology of Drugs acting on Respiratory tract** **05**
   a) Bronchodilators
   b) Mucolytics
   c) Expectorants
   d) Antitussives
   e) Nasal Decongestants
7. **Pharmacology of Hormones and Hormone antagonists** **08**
   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
8. **Pharmacology of autocoids and their antagonists** **06**
   a) Histamines and Antihistaminics
   b) 5-Hydroxytryptamine and its antagonists
   c) Lipid derived autocoids and platelet activating factor

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope & Objecives:** This course is designed to ensure that students are skilled and knowledgeable to provide various pharmaceutical care services to patients and general practitioners in the community setup.

   Upon completion of the course, the student shall be able to –
   1. Handle the prescriptions and manage the community pharmacies
   2. Deliver the pharmaceutical care services in the community pharmacies.
   3. Respond to minor ailments and provide health education
   4. Promote rational drug therapy.

2. **Course Materials:**
   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.

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

3. **Lecture wise programme :**

	Topic	Hrs
1.	**Definition and scope of community pharmacy** **Roles and responsibilities of Community pharmacist**	**02**
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	**04**
3.	**Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.	**02**
4.	**Inventory control in community pharmacy** Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time and safety stock	**03**
5.	**Pharmaceutical care** Definition and Principles of Pharmaceutical care.	**02**
6.	**Patient counseling** Definition, outcomes, various stages, barriers, strategies to overcome barriers Patient information leaflets- content, design, layouts & advisory labels	**04**

7.	**Patient medication adherence** Definition, Factors affecting medication adherence and role of pharmacist in improving the adherence	**02**
8.	**Health screening services** Definition, importance, methods for screening blood pressure/ blood sugar/ lung function and Cholesterol testing	**03**
9.	**OTC Medication - Definition, OTC medication list & Counselling**	**03**
10.	**Health Education** WHO Definition of health and health promotion, care for children, pregnant & breast feeding women and geriatric patients.	**02**
11.	Commonly occurring communicable diseases, causative agents, Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS	**09**
12.	Balance diet, treatment & prevention of deficiency disorders	**02**
13.	Family planning – role of pharmacist	**01**
14.	Responding to symptoms of minor ailments Relevant pathophysiology and common drug therapy to Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms and worms infestations.	**08**
15.	**Essential Drugs concept and Rational Drug Therapy** **Role of community pharmacist**	**02**
16.	**Code of ethics for community pharmacists**	**01**

2.6 PHARMACOTHERAPEUTICS-I

Theory: 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

   At completion of this course it is expected that students will be able to understand:
   1. The pathophysiology of selected disease states and the rationale for drug therapy
   2. The therapeutic approach to management of these diseases
   3. The importance of preparation of individualized therapeutic plans based on diagnosis
   4. 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)
   5. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
   6. Summarise the therapeutic approach to management of these diseases including reference to the latest available evidence
   7. Discuss the controversies in drug therapy
   8. Discuss the preparation of individualised therapeutic plans based on diagnosis

9. 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)

2. Course materials

TEXT BOOKS

a. Clinical Pharmacy and Therapeutics – Walker and Whittlesea, Churchill Livingstone publication

b. Pharmacotherapy: A Pathophysiology approach - Joseph T. Dipiro et al. Appleton & Lange

REFERENCE BOOKS

a. Pathologic basis of disease : Robbins 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, Williams and Wilkins Publication

e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

f. Relevant review articles from recent medical and pharmaceutical literature.

3. Lecture wise Programme

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

	Title	Hrs
1.	**Cardiovascular system** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidemia , Electrophysiology of heart and Arrhythmias	13
2.	**Respiratory system** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases	06
3	**Endocrine system** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	08
4	**General prescribing guidelines for** Paediatric patients 4.2 Geriatric patients 4.3 Pregnancy and breast feeding	04
5	**Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial	03

6 Introduction to rational drug use 02

Definition, Role of pharmacist in promoting rational drug use and essential drug concept.

2.6 PHARMACOTHERAPEUTICS-I (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. A minimum of 15 cases should be presented and recorded covering most common diseases.

ASSIGNMENTS

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

Assignments

Format of the assignment

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

Scheme of Practical Examination

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

* Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance)

Pharm. D. - Third Year

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	**(2)**	**(3)**	**(4)**	**(5)**
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	**16**	**15**	**5 = 36**

PHARMACOLOGY – II (THEORY)

Theory: 3 Hrs. /Week

1. **Scope and Objectives:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system, hormones, pharmacology of autocoids and different aspects of genes will be concentrated. In addition, pharmacology of chemotherapeutic agents and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

   Upon completion of the subject student shall be able to:

   1. Understand the pharmacological aspects of drugs falling under the above mentioned chapters.
   2. Carry out the animal experiments confidently.
   3. Appreciate the importance of pharmacology subject as a basis of therapeutics.
   4. Correlate and apply the knowledge therapeutically.
   5. Understand different aspects of genes and their regulatory functions.

2. Course materials:

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 6th edition, 2008. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 20th edition (single volume), 2008. Publisher: Popular, Mumbai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 5th edition, 2003. Publisher: Churchill Living stone.
d. Alberts, B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD Molecular Biology of the Cell by, 5rd edition, 2008, Publisher: Garland Science.

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. 11th edition, 2006. Publisher: McGraw Hill, Pergamon press.
b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. 5th edition 1997. Publisher: Little Brown and company.
c. Katzung, B.G. Basic and clinical pharmacology. 9th edition 2004. Publisher: Prentice Hall, International.
d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. 1985. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.
e. Crommelin, DJA and Sindelar RD. Pharmaceutical Biotechnology. 3rd edition 2008. Publisher: Infarma Healthcare.
f. Watson, JD., Gilman, M., et al. Recombinant DNA. 2nd edition 1992. Publisher: Scientific America.
g. Walsh, G. Biopharmaceutical: Biochemistry and Biotechnology. 2nd edition 2007. Publisher: John Wily.
h. Derelanko MG. Handbook of toxicology. 2nd edition 2002; Publisher: CRC Press.

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, 1970, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, 1970, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. 3rd edition, 2005; Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. 1984. Publisher: Black well Scientific.

3. Lecture wise Programme:

	Topics	Hrs
1.	**Pharmacology of drugs acting on Blood and blood forming agents** a) Anticoagulants b) Thrombolytics and antiplatelet agents c) Haemopoietics and plasma expanders	**06**
2.	**Pharmacology of drugs acting on Renal System** a) Diuretics b) Antidiuretics	**03**
3	**Pharmacology of drugs acting on Gastrointestinal Tract** a) Antiulcer drugs, Antacids b) Laxatives and purgatives c) Emetics and antiemetics d) Appetizers, digestants and carminatives	**06**
4.	**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)	**22**
5	**Immunopharmacology** Pharmacology of immunosuppressants and stimulants	**03**

6. **Principles of Animal toxicology** **02**

a) Acute, subacute and chronic toxicity.
b) Principles involved in the various toxicity screening methods available for drugs in the laboratory animals.

7. **The dynamic cell: The structures and functions of the components of the cell** **11**

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.

8 **The Gene: Genome structure and function:** **18**

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.
d. RNA processing: rRNA, tRNA and mRNA processing.
e. Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
f. Altered gene functions: Mutations, deletions, amplifications, LOH, translocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.
g. The gene sequencing, mapping and cloning of human disease genes.
h. Introduction to gene therapy and targeting.
i. Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

9 **Bio-assay methods** **04**

Scope, principles involved in general methods, bioassay designing, applications and limitations.

3.1 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 Acetylcholine using isolated rat ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated rat 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. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
10. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
11. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
12. To study different 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 (tail flick and hotplate).
    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.
    e) Pentobarbitone induced sleeping time in mice.
    f) Locomotor activity of drugs using actophotometer.
    g) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
    g) Skeletal muscle relaxant activity of the drugs using rotarod.
    h) Drugs effect on the blood pressure, heart rate and respiratory rate of dog.
14. Simulated experiments
    a) Effect of drugs on frog's isolated heart.
    b) Effect of drugs on rabbit eye.
    c) Effect of drugs on ciliary motility of frog's esophagus.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph/ simulated experiment)	04	10
Viva	02	10
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

Note: Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory: 3 Hrs. /Week

1. **Scope and objectives**: This course is designed to impart a fundamental knowledge on the art and science of testing drugs by various instrumental methods of analysis. This focuses on various modern instruments that are used for testing the purity of drugs in various dosage forms. This course also gives idea about modern instruments that are used for drug testing like NMR, IR, Mass, HPLC, HPTLC forms. etc,. It prepares the students for most basics of the applied field of pharmacy.

   At the end of course, students are able

   1. To understand the construction and working of various analytical instruments.
   2. To know principle and mechanism of instrumentation.
   3. To understand the different modern techniques of drug analysis.
   4. To appreciate the advantages of instrumental methods of drug analysis.

2. Course materials:

Text books

a. Instrumental methods of analysis by Willard, Merrit, Dean and Settlle 6th edition
b. Practical Pharmaceutical Chemistry Vol-II- Beckett and Stenlake 3rd edition

Reference books

a. Text book of quantitative chemical analysis by A.I. Vogel
b. Text book of Pharmaceutical Analysis by K.A. Cannors
c. Pharmaceutical analysis by Skoog and West.
d. William Kemp- Spectroscopy methods.

3. Lecture wise Programme

1 Quality Assurance:

a. Introduction, sources of quality variation, control of quality variation. **03**

b. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.

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. **03**

b. **TLC**: Introduction, principle, techniques, R_f value and applications. **02**

c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications. **02**

d. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications. **03**

e. **HPLC**: Introduction, theory, instrumentation, and applications. **03**

f. **HPTLC**: Introduction, theory, instrumentation, and applications. **02**

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. **04**

h. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application. **02**

i. **Gel filtration** and **affinity chromatography**: Introduction, technique, applications. **03**

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. **05**

b. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications. **03**

c. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over Potentiometry. Pharma applications. **04**

4. **Spectroscopy:**

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

a. Absorption Spectroscopy: **08**

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

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations. **05**

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. **06**

Fluorimetric Analysis: Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry. **04**

b. Flame Photometry: Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications. **04**

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

d. **Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection. **02**

e. **NMR (introduction only):**Introduction,theoretical aspects and applications **02**

f. **Mass Spectroscopy**: (**Introduction only**) – Fragmentation, types of ions produced, mass spectrum and applications. **02**

3.2 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 Dyes by radial paper chromatography*.
3. Separation and identification of Sulpha drugs by TLC technique*.
4. Effect of pH and solvent on the UV spectrum of given compound*.
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 strong acid with a strong base**.
8. Estimation of drugs by Fluorimetric technique**.
9. Study of quenching effect in fluorimetry**.
10. Colorimetric estimation of Supha drugs using BMR reagent**.
11. Simultaneous estimation of two drugs present in given formulation**.
12. Assay of Dextrose by colorimetry**
13. Colorimetric estimation of Ferrous ions using 1,10-Phenonthroline**.
14. UV spectroscopic estimation of Paracetamol tablets*
15. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method**.
16. Determination of Na/K by Flame Photometry**.
17. Determination of pKa using pH meter*.
18. Infrared spectral graphs/ peak identiofication of samples with different functional groups (-COOH, -COOR, -NH_2, -NHR, -OH, -CHO, -C=O)
19. Demonstration of HPLC.

SCHEME OF PRACTICAL EXAMINATION:

	Sessional	**Annual**
Synapses	05	10
Major Experiment(Experiment indicated by**)	10	30
Minor Experiment(Experiment indicated by*)	3	20
Viva-Voce	2	10
Max. Marks	20#	70

#Note: Total sessional marks is 30 (20 for practical sessional and 10 marks for regularity, promptness, viva-voce and record maintenance)

3.3 PHARMACOTHERAPEUTICS-II

Theory : 3 Hrs. /Week

1. Scope and Objectives: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

Upon completion of the course student shall be able to

1. know the pathophysiology of selected disease states and the rationale for drug therapy
2. know the therapeutic approach to management of these diseases
3. know the controversies in drug therapy
4. know the importance of preparation of individualised therapeutic plans based on diagnosis
5. 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)

2. Course Materials:

Text books (Theory)

a. Clinical Pharmacy and Therapeutics - Walker and Whittlesea, 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

3. Lecture wise programme

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases

No.	Topics	Hrs
1.	**Infectious diseases:** 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, Gonorrhoea and Syphilis	**18**
2	**Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	**06**
3	**Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders	**05**
4	**Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy induced nausea and emesis	**06**
5	**Dermatology:** Psoriasis, Scabies, Eczema, Impetigo	**04**

3.3 PHARMACOTHERAPEUTICS-II (PRACTICALS)

Practical : 3 Hrs./Week

Hospital postings for a period of at least one month is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation.

ASSIGNMENTS

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

Format of the assignment

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

Scheme of Practical Examination

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

**** Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance)***

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory: 2 Hrs. /Week

1. **Scope and Objectives**: This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments is the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
   Upon completion of the subject student shall be able to (Know, do, and appreciate) –
   1. practice the Professional ethics;
   2. understand the various concepts of the pharmaceutical legislation in India;
   3. know the various parameters in the Drug and Cosmetic Act and rules;
   4. know the Drug policy, DPCO, Patent and design act;
   5. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
   6. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
   7. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.
2. **Course materials**

   Text books (Theory)

   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.

3. **Detailed syllabus and lecture wise schedule:**

	Topic	Hrs
1.	**Pharmaceutical Legislations –** A brief review. - Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee	**02**
2.	**Code of Pharmaceutical ethics** - Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath	**02**

3. **Drugs and Cosmetics Act, 1940 and its rules 1945.** **22**
   - Objectives, Definitions, Legal definitions of schedules to the act and rules
   - Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.
   - Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license. Detailed study of schedule M, N and Y. Offences and penalties
   - Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties
   - Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties
   - Administration of the act and rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government analysts, Licensing authorities, controlling authorities, Drug Inspectors

4. **Pharmacy Act –1948**. **05**
   Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and Penalties.
5. **Medicinal and Toilet Preparation Act –1955**. **04**
   Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations. Offences and Penalties.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**. **04**
   Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse,Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.** **02**
   Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
8. **Drug Price control Order & National Drug Policy (Current).** **02**
   - Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Implementation of prices Fixed/ revised.
   - **Pharmaceutical Policy 2002:** Objectives, Approaches in the review, Salient features of Pharmaceutical Policy 2002.
9. **Prevention Of Cruelty to animals Act-1960.**
   Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties **03**

10. **Patents & design Act-1970.**
    - Objectives, definitions, Types of patent, PCT, Patentable and not patentable inventions, Applications for patents, Term of patent, revocation of patents, compulsory licensing, Offences and penalties.
    - Registration of designs, copyright, prohibition of certain designs, cancellation of designs, Offences and penalties. **03**

11. **Brief study of prescription and Non-prescription Products. 01**

4. Assignments:

Format of the assignment

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

Case studies relating to

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

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory: 3 Hrs. /Week

1. **Scope and Objectives**: This course is designed to impart a fundamental knowledge on the structure and functions of the different drugs. The course gives details of Chemistry, Mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR) and uses of Chemotherapeutic Agents, Cardiovascular Drugs and synthesis of some important drugs. The course also covers modern techniques of drug design, which include Prodrug concept and combinatorial chemistry.

At the end of the course, students are able

1. To understand the chemistry of drugs with respect to their biological activity.
2. To know the metabolism, adverse effect and therapeutic activity of drugs.
3. To understand the different modern techniques of drug design.
4. To appreciate the SAR of some important drug classes.

2. Course materials:

Text books

a. Wilson and Giswolds, Text book of Organic and pharmaceutical chemistry
b. Principles of Medicinal chemistry- William O. Foye

Reference books

a. A I Vogel Text book of Practical Organic Chemistry

b. Text Book of organic chemistry by I. L. Finar
c. S.N. Pandeya, A Text Book of Medicinal Chemistry, S.G. Publisher, Varanasi, Vol I & II.

3. Lecture wise Programme:

	Topic	Hrs
I	Modern concept of rational drug design: A brief introduction to prodrug & drug latentiation, combinatorial chemistry, general pathways & factors affecting drug metabolism.	**04**
II	A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds (marked with asteric*), brand names of important marketed products and their side effects.	
1	**Anti-infective agents**: a)Local anti-infective agents: Alcohols: isopropyl alcohol Phenols: cresols, hexyl resorcinol Cationic surfactants: benzalkonium chloride, cetyl pyridinium bromide Nitrofurans: nitrofurazone, furazolidone. b)Antifungal agents: Azoles: miconazole, ketoconazole, fluconazole Miscellaneous: tolnaftate, naftifine Antifungal Antibiotics: amphotericin, nystatin, griseofulvin. c)Urinary tract anti-infectives: SAR of quinolone antibacterial agents, Norfloxacin, ciprofloxacin*, sparfloxacin, ofloxacin, d) Antitubercular agents: Management of tuberculosis, Synthetic anti TB agents: INH*, Pyrizinamide, ethambutol, Anti TB antibiotics: rifampin, capreomycin e)Antiviral agents and Anti AIDS agents: amantadine, acyclovir, trifluridine, zidovudine, stavudine f)Antiprotozoal agents: Introduction to protozoal diseases and causative organisms. Metronidazole, diloxanide furoate, dehydroemetine, nifurtimox g) Anthelmentics: Benzimidazoles: mebendazole, albendazole Piperazine, diethylcarbamazine, ivermectin	**15**
2	**Sulfonamides and sulfones** History and development of sulfonamides, SAR and mechanism of action of Sulfonamides, pK^a of Sulfas and Crystalluria. Sulfamethoxazole, sulfisoxazole, sulfacetamide*, sulfasalzine Folate reductase inhibitors: trimethoprim*, synergistic action of cotrimoxazole. Sulfones: dapsone	**05**
3	**Antimalarials:** Etiology of malaria, SAR and mechanism of action of quinoline Antimalarials Quinine sulphate, Chloroquine phosphate, amodiaquine, pamaquine*,	**05**

	primaquine, Quinacrine Chloroguanide, cycloguanil, pyrimethamine	
4	**Antibiotics** Historical background and classification of antibiotics. Beta lactam antibiotics: development of acid resistant and extended spectrum Penicillins. Penicillin G, ampicillin, amoxicillin, cloxacillin Beta lactamase inhibitors: clavulanic acid, thienamycin Cephalosporins: cephelexin, cefadroxil, cefuroxime Aminoglycosids: streptomycin, neomycin, amikacin, gentamicin Tetracyclines: Chemistry and SAR of tetracyclines, chlortetracycline, doxycycline, Minocycline. Macrolides: erythromycin, azithromycin Miscellaneous: clindamycin, bacitracin, chloramphenicol*	**12**
5.	**Antineoplastic agents** Historical background and classification of antineoplastic agents Alkylating agents: cyclophosphamide, mechlorethamine, cholrambucil Antimetabolites: mercaptopurine, flurouracil, methotrexate Antibiotics: dactinomycin, mitomycin, streptozocin Plant products: etoposide, taxol, vincristine and vinblastine Miscellaneous: cisplatin, interferons	**06**
6	**Cardiovascular agents** a)Antianginal agents and vasodilators Nitrovasodilators: amyl nitrite, isosorbide dinitrate Calcium channel blockers: verapamil, diltiazem b)Antiarrhythmic agents: Class I: quinidine, phenytoin, lidocaine, encainide Class II: beta blockers- propranolol Class III: amiodarone Class IV: Calcium channel blockers: verapamil, diltiazem c)Antihypertensive agents: betablockers: propranolol*, ACE inhibitors: captopril, enalapril Angiotensin antagonists: losartan Calcium channel blockers: nifedipine, amlodepine Adrenergic agents: clonidine, methyl dopa Adrenergic antagonists: prazosin, reserpine d)Antihyperlipidemic agents: types of hyperlipoproteinemia clofibrate, fenofibrate, cholestyramine, lovastatin, simvastatin e)Anticoagulants: warfarin, dicumarol, anisindione	**12**
7.	**Hypoglycemic agents:** History, development and SAR of sulfonylureas: tolbutamide*, chlorpropamide, glipizide Metaglinides: repaglinide Thiazolindiones: rosiglitazone, pioglitazone Biguanides: metformin, phenformin Miscellaneous: acarabose, miglitol	**03**
8.	**Thyroid and Antithyroid agents** L-thyroxine, L-threonine Propyl thiouracil, methimazole	**01**
9.	**Diuretics:**	**05**

Carbonic anhydrase inhibitors: acetazolmide*
Thiazide diuretics: SAR of thiazide diuretics, chlorthiazide, benzthiazide, xipamide, chlorthalidone
Loop diuretics: frusemide*, ethacrynic acid
Potassium sparing diuretics: spiranolactone,amiloride
Miscellaneous: mannitol

10. Diagnostic agents **02**

Iodipamide, diatriazoate sodium
Amino hippurate, sulfobromphthalein, fluorescein sodium

11 Steroidal Hormones and Adrenocorticoids **05**

Estrogens: estradiol, DES
Progestines: progesterone, norethindrone
Testosterone, nandralone
Betamethasone, prednisolone, beclomethasone

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical: 3 Hrs./Week

	List of experiment	No of classes
A.	**Assays of important drugs from the course content.**	8
	1. Assay of ascorbic acid by cerimetry	
	2. Assay of metronidazole by NAT	
	3. Assay of chloroquine phosphate by NAT	
	4. Assay of dapsone by diazotization	
	5. Assay of INH by bromometry	
	6. Assay of benzyl penicillin by iodometry	
	7. Assay of analgin by iodimetry	
	8. Assay of diclofenac by alkalimetry	
B.	**Preparation of medicinally important compounds or intermediates required for synthesis of drugs**	10
	1. Preparation of 7-hydroxy 4-methyl coumarin	
	2. Preparation of phenytoin from benzoin	
	3. Preparation of phenothiazine from diphenyl amine	
	4. Preparation of benzyl alcohol from benzaldehyde	
	5. Preparation of chlorbutanol	
	6. Preparation of eosin from resorcinol	
	7. Preparation of fluorescein from eosin	
	8. Preparation of triphenyl imidazole from benzoin	
	9. Preparation of 2,3 diphenyl quinoxaline from OPDA	
	10. Preparation of benztriazole from OPDA	
	11. Preparation of benzimidazoles from OPDA	
	12. Preparation of sulfanilamide from acetanilide	
	13. Preparation of INH	
	14. Preparation of cinnamic acid	
C.	**Monograph analysis of important drugs.**	5
	1. Monograph analysis of ibuprofen	
	2. Monograph analysis of aspirin	

3. Monograph analysis of caffeine
4. Monograph analysis of sulfanilamide
5. Monograph analysis of paracetamol

D. Determination of partition coefficients, dissociation constants of drug substances. 2

Scheme of Practical Examination

	Sessionals	Annual
Synopsis	04	10
Assay/Estimation	06	30
Preparation	06	20
Viva	04	10
Max Marks	20	70
Duration	03hrs	04hrs

- **** Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance)***

3. 6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory: 2 Hrs. /Week

1. **Scope and Objective:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

   Upon completion of the course student shall be able to (Know, do, appreciate) –
   1. understand the principle involved in formulation of various pharmaceutical dosage forms;
   2. prepare various pharmaceutical formulation;
   3. perform evaluation of pharmaceutical dosage forms; and
   4. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

2. Course materials

Text books (Theory)

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

Reference books (Theory)

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

3. Lecture wise programme:

Title of the topic

	Topic	Hrs
1.	Pharmaceutical dosage form- concept and classification	**03**
2.	**Tablets**: Formulation of different types of tablets, tablet excipients, granulation techniques, Tablet coating, Type of coating, quality control tests and evaluation for uncoated and coated tablets.	**10**
3.	**Capsules:** Production and filling of hard gelatin capsules, Raw materials for	**07**

shell, finishing. Production and filling of soft gelatin capsules, Importance of base adsorption, quality control tests for hard and soft gelatin capsules.

4. **Liquid orals**: Formulation, Manufacturing and evaluation of suspensions, emulsions and solutions. Instability problems in suspensions and emulsions. **06**
5. **Parenterals**: Definition, types, advantages and limitation, general formulation, vehicles, production procedure, production facilities, and controls. Formulation of injections, sterile powders, implants and long acting parenterals, emulsions and suspensions. Containers and closures pertinent to sterile preparations and Pharmacopoeial quality control tests, Sterilization and evaluation. **10**
6. **Semi – Solids**: Introduction and classification Factors affecting absorption, Packaging, storage and labeling. **06**
   Ointments: Types of Ointment Base Preparation of ointment.
   Gels: Types and formulation of Gels
7. **Definition and concept of Controlled and novel Drug delivery systems** with available examples, viz. transdermal, buccal, vaginal, nasal, implantable, ocular drug delivery systems **08**

3.6 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 (demonstration)

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Pharm. D. - Fourth Year

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	**(2)**	**(3)**	**(4)**	**(5)**
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
4.7	Pharmacotheraputics I & II*	3*	3*	1*
	Total hours	**15/18***	**12/15***	**6/7 = 33/40***

* Additional subject for Pharm.D (Post Baccalaureate) students

4.1 PHARMACOTHERAPEUTICS -III

Theory: 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

   At completion of this course it is expected that students will be able to understand:

   1. The pathophysiology of selected disease states and the rationale for drug therapy
   2. The therapeutic approach to management of these diseases
   3. The importance of preparation of individualised therapeutic plans based on diagnosis
   4. 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)
   5. Describe the pathophysiology of selected disease states and explain the rationale for drug therapy
   6. Summarize the therapeutic approach to management of these diseases including reference to the latest available evidence
   7. Discuss the controversies in drug therapy
   8. Discuss the preparation of individualised therapeutic plans based on diagnosis
   9. 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)

2. **Course Materials:**

   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 - Robbins 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.

3. Lecture wise Programme

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

	Topic	Hrs
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.	20
2	**Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.	12
3	**Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,	16
4	**Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders	14
5	Pain management including Pain pathways, neuralgias, headaches.	08
6	**Evidence Based Medicine**	05

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

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

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

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

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25

Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

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

   Upon completion of the course, the student shall be able to –
   1. Know Various Drug Distribution Methods;
   2. Know The Professional Practice Management Skills In Hospital Pharmacies;
   3. Provide Unbiased Drug Information To The Doctors;
   4. Know The Manufacturing Practices Of Various Formulations In Hospital Set Up;
   5. Appreciate The Practice Based Research Methods; And
   6. Appreciate the stores management and inventory control.

2. **Course materials:**

   Text books: (latest editions)
   a. Hospital pharmacy by William .E. Hassan
   b. A text book of Hospital Pharmacy by 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.

3. **Lecture wise programme:**

	Topics	Hrs
1	**Hospital - its Organisation and functions**	**01**
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	**05**
3	**The Budget – Preparation and implementation**	**01**

4	**Hospital drug policy**	**12**
	a) Pharmacy and Therapeutic Committee (PTC)	
	b) Hospital formulary	
	c) Hospital committees	
	- Infection committee	
	- Research and ethical committee	
	d) Development of therapeutic guidelines	
	e) Hospital pharmacy communication - Newsletter	
5	**Hospital pharmacy services**	
	a) Procurement & warehousing of drugs and Pharmaceuticals	**02**
	b) Inventory control**:** Definition, various methods of Inventory Control ABC, VED, EOQ, Lead time and safety stock	**03**
	c) Drug distribution in the hospital i) Individual prescription method	**03**
	ii) Floor stock method	
	iii) Unit dose drug distribution method	
	d) Distribution of Narcotic and other controlled substances	**02**
	e) Central sterile supply services – Role of pharmacist	**02**
6	**Manufacture of Pharmaceutical preparations**	**12**
	a) Sterile formulations – large and small volume parenterals	**03**
	b) Manufacture of Ointments, Liquids, and creams	**03**
	c) Manufacturing of Tablets, granules, capsules, and powders	**03**
	d) Total parenteral nutrition	**03**
7	**Continuing professional development programs** Education and training	**02**
8	**Radio Pharmaceuticals – Handling and packaging**	**03**
9	**Professional Relations and practices of hospital pharmacist**	**02**

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical: 3 Hrs. /Week

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

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.

2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY

Theory: 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart the basic knowledge and skills that required for practice of pharmacy including provision of various clinical pharmacy services to patients and healthcare professionals in clinical settings.

   Upon completion of the course, student shall be able to

   1. Monitor drug therapy and resolve drug related problems
   2. Counsel the patients for safe and effective use of medications
   3. Assist healthcare professionals in detecting and managing medication errors including ADR
   4. Provide unbiased drug and poison information services
   5. Interpret, analyze and correlate the lab investigations

2. **Course Materials**

   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. Textbook of Clinical Pharmacy Practice; Essential concepts and skills, Dr. G.Parthasarathi, Karin Nyfort-Hansen, Milap Nahata, Orient Longman Pvt. Ltd.

   Reference Books

   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.

3 **Lecture wise programme**

	Topic	Hrs
1.	**Definitions, development and scope of clinical pharmacy**	**03**
2.	**Introduction to daily activities of a clinical pharmacist**	**13**
	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 counselling	
	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.	**03**
4.	**Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results** • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Microbiological culture sensitivity tests • Pulmonary Function Tests	**15**
5.	**Drug & Poison information** • Introduction to drug information resources available • Systematic approach in answering DI queries • Critical evaluation of drug information and literature • Preparation of written and verbal reports • Establishing a Drug Information Centre • Poisons information- organization & information resources	**08**
6	• **Pharmacovigilance** Scope, definition and aims of pharmacovigilance • Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used], • Reporting, evaluation, monitoring, preventing & management of ADRs • Role of pharmacist in management of ADR.	**10**
7	• Communication skills, including patient counseling techniques, medication history interview, presentation of cases.	**10**
8	• Pharmaceutical care concepts	**04**
9	• Critical evaluation of biomedical literature	**06**
10	• Medication errors	**03**

4.3 CLINICAL PHARMACY (PRACTICALS)

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

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

ASSIGNMENT

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

Drug information, Patient medication history interview, Patient medication counseling, Problem solving in Clinical Pharmacokinetics, Therapeutic drug monitoring and Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment

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

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and Objective :** This is an introductory course in statistics, research methodology and Computer application in hospital and community Pharmacy. This subject deals with Research methodology, Biostatics, epidemiology and Computer application and clinical studies.

   Research methodology deal about types of clinical study, designing, sample size determination and power of study Statistics deals about frequency distribution, graphics, averages, measures of dispersion, Correlation, regression, Parametric and non-parametric tests. Incidence and prevalence, relative risk, attributable risk

   Computer Application deals with application of Computer System in Hospital Pharmacy and Community Pharmacy

   Upon completion of the course the student shall be able to :
   1. Know the various statistical methods to solve different types of problems
   2. Operate various statistical software packages
   3. appreciate the importance of Computer in hospital and Community Pharmacy
   4. appreciate the statistical technique in solving the pharmaceutical problems

2. Course material:

Reference books:

a. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton 3rd and 4th edition, publisher Marcel Dekker Inc. NewYork.
b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006
c. Computer Application in Pharmacy – William E. Fassett, publisher – Lea & Febiger . Philadelphia

3. Lecture wise Programme

	Topic	**Hrs**
01	**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	**10**
02	**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, mean deviation, standard deviation, variance, coefficient of variation, standard error of mean.	**10**
2.2	**Data graphics** : Construction and labeling of graphs, histogram, Pie charts, scatter plots, semi-logarithmic graphs	**02**
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's test (one way ANOVA) d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient. e) Introduction to statistical software: SPSS, Epi Info, SAS.	**15**

2.4	**Statistical methods in epidemiology** Incidence and prevalence, relative risk, attributable risk	**05**
03	**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	**08**

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.
   At completion of this course it is expected that students will be able to -
   1. Define the basic concepts in biopharmaceutics and pharmacokinetics.
   2. Use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
   3. Critically evaluate biopharmaceutic studies involving drug product equivalency
   4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
   5. Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

2. **Course Materials**
   Text Books
   a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
   b. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
   c. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall Inernational edition.USA
   d. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi

   Reference Books
   a. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
   b. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.

c. Biopharmaceutics; By Swarbrick
d. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
e. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
f. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
g. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
h. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

3. Lecture wise programme

	Topics	Hrs
I	**Biopharmaceutics**	
1	Introduction to biopharmaceutics	**01**
2	**Absorption;** Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non *per OS* extra-vascular routes	**08**
3	**Distribution of drugs** Tissue permeability of drugs, binding of drugs, apparent volume of drug distribution, protein binding of drugs, factors affecting protein – drug binding. Kinetics of protein binding, Clinical significance of protein bin-drug binding.	**08**
4	**Drug Elimination.** Biotransformation of drugs, renal excretion of drugs , factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs	**06**
5	**Bioavailability and Bioequivalence:** Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro in-vivo* correlations, bioequivalence studies, methods to enhance the bioavailability.	**10**
II	**Pharmacokinetics**	
6	Introduction to Pharmacokinetics. Mathematical model. Drug levels in blood. Pharmacokinetic models, Compartment models, Noncompartment models, physiological models	**05**
7	**One compartment open model.** a. Intravenous Injection (Bolus) b. Intravenous infusion. c. extra vascular administrations, calculations of Ka, KE. From plasma and urinary excretion data	**15**
8	**Multicompartment models**: Two compartment open model. IV bolus, IV infusion and oral administration	**08**
9	**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	**05**
10	**Nonlinear Pharmacokinetics. a.** Introduction, **b**. Factors causing Non-linearity. **c**. Michaelis-menton method of estimating parameters	**05**
11	**Noncompartmental Pharmacokinetics**. Statistical Moment Theory,. MRT for various compartment models.Physiological Pharmacokinetic model	**04**

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

List of experiments

1. Improvement of dissolution characteristics of slightly soluble drugs by co-solvency
2. Improvement of dissolution characteristics of slightly soluble drugs by solid dispersion
3. Improvement of dissolution characteristics of slightly soluble drugs by use of surfactant
4. Comparison of dissolution studies of two different marketed products of same drug.
5. Influence of polymorphism on solubility and dissolution
6. Protein binding studies of a drug.
7. Calculation of bioavailability
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 elimination half-life for different drugs by using urinary elimination data and blood level data
11. Calculation of AUC and bioequivalence from the given data for two drugs
12. Absorption studies in animal inverted intestine using various drugs.
13. Studying metabolic pathways for different drugs based on elimination kinetics data
14. Calculation of renal clearance

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory: 2 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a thorough knowledge in the management of various poisoning cases thereby enabling the students to assist healthcare professionals / toxicologists in handling and managing the emergency cases.

   Upon completion of the course student shall be able to:

   1. Understand and deal with general principles involved in the management of poisoning
   2. Recognize the clinical symptoms and manage poisoning cases
   3. Educate public and healthcare professionals in the management of emergency cases

4. Minimize/ prevent the poisoning cases in local population

2. Course materials

Reference Books:

a. Matthew J Ellenhorn. Ellenhorns Medical Toxicology – Diagnosis and Treatment of Poisoning. Second edition. Williams and Willkins publication, London
b. Modern medical toxicology, Author V. V. Pillay, Publisher: JP Brothers
c. Pediatric toxicology diagnosis and management of the poisoned child, Timothy B, Erickson, William R. Athrens, Steven.E. AK, Cart K.Baun,Louis J.Ling. Mcgraw-Hill; 2005.
d. Lindsay Murray, Frank Dary, Mark little, Mikes Cadogan, editors. Toxicology handbook. Australia: Churchil Livingstone, Elsevier; 2007

3. Lecture wise programme

	Topic	Hrs
1	General principles involved in the management of poisoning	**02**
2	Antidotes and the clinical applications	**01**
3	Supportive care in clinical Toxicology	**02**
4	Gut Decontamination	**02**
5	Elimination Enhancement	**01**
6	Toxicokinetics.	**02**
7	Clinical symptoms and management of acute poisoning with the following agents	
	a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids	**05**
	b) Opiates overdose.	**01**
	c) Antidepressants	**03**
	d) Barbiturates and benzodiazepines	**04**
	e) Alcohol: ethanol, methanol	**02**
	f) Paracetamol and salicylates	**02**
	g) Non-steroidal anti-inflammatory drugs	**02**
	h) Hydrocarbons: Petroleum products and PEG.	**01**
	i) Caustics: inorganic acids and alkali	**01**
	j) Radiation poisoning	
8	Clinical symptoms and management of chronic poisoning with the following agents - Heavy metals: Arsenic, lead, mercury, iron, copper	**05**
9	Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snakebite injuries	**02**
10	Plants poisoning. Mushrooms, Mycotoxins	**02**
11	Food poisonings	**01**
12	Envenomations – Arthropod bites and stings	**01**
13	**Substance abuse:** Signs and symptoms of substance abuse and treatment of dependence	
	a) CNS stimulants : Amphetamine	**01**
	b) Opioids	**01**

c) CNS depressants **02**
d) Hallucinogens: LSD **01**
e) Cannabis group **02**
f) Tobacco **01**

4.7 PHARMACOTHERAPEUTICS I & II

Theory: 3 Hrs. /Week

1. Scope and Objectives: This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

At completion of this course it is expected that students will be able to understand:

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

2. Course materials

TEXT BOOKS

a. Clinical Pharmacy and Therapeutics – Walker and Whittlesea, 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.

3. Lecture wise Programme

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

	Topic	Hrs
1.	**Cardiovascular system** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidemia , Electrophysiology of heart and Arrhythmias.	**13**
2	**Respiratory system** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases.	**06**
3	**Endocrine system** Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis	**08**
4	**General prescribing guidelines for** Paediatric patients Geriatric patients 4.3 Pregnancy and breast feeding	**04**
5	**Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial.	**03**
6	**Introduction to rational drug use** Definition, Role of pharmacist Essential drug concept Rational drug formulations.	**02**
7	**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.	**18**
8	**Musculoskeletal disorders** Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.	**06**
9	**Renal system** Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders.	**05**
10	**Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis.	**06**
11	**Dermatology:** Psoriasis, Scabies, Eczema, Impetigo.	**04**

4.7 PHARMACOTHERAPEUTICS I & 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. A minimum of 15 cases should be presented and recorded covering most common diseases.

ASSIGNMENTS

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

Assignments

Format of the assignment

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

Scheme of Practical Examination

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

- **** Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance)***

Pharm. D. - Fifth Year

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	**8**	**20**	**4 = 32**

*** Attending ward rounds on daily basis.**

5.1 CLINICAL RESEARCH (THEORY)

Theory: 2 Hrs. /Week

1. **Scope and Objectives**: This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development.

   At completion of this course, it is expected that students will be able to:
   1. Know the concept of new drug development process.
   2. Understand the regulatory and ethical requirements.
   3. Conduct the clinical trials in accordance to regulatory and ethical requirements.
   4. Coordinate the clinical trials and promote quality drug trial research.

2. Course material

Text Books:

a. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward,Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
b. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
c. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

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.

3. Lecture wise programme

	Topics	Hrs
1	**1. Drug development process:** Introduction Various Approaches to drug discovery 1. Pharmacological 2. Toxicological 3. IND Application 4. Drug characterization 5. Dosage form	**06**
2.	**Clinical development of drug:**	
	1. Introduction to Clinical trials.	**02**
	2. Various phases of clinical trial.	**04**
	3. Methods of post marketing surveillance.	**02**
	4. Abbreviated New Drug Application submission.	**02**
	5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines.	**06**
	6. Challenges in the implementation of guidelines.	**02**
	7. Ethical guidelines in Clinical Research.	**01**
	8. Composition, responsibilities, procedures of IRB / IEC.	**01**
	9. Overview of regulatory environment in USA, Europe and India.	**08**
	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	**05**
	11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment).	**04**
	12. Informed consent Process.	**01**
	13. Data management and its components.	**03**
	14. Safety monitoring in clinical trials.	**03**

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Theory : 3 Hrs./Week

1. Scope and Objectives: This course is designed to impart knowledge regarding various methods and applications of pharmacoepidemiology and pharmacoeconomics in drug safety monitoring, drug approval and regulations.

Upon completion of this courset, it is expected that students will be able to -

1. Understand drugs use pattern and their outcome measures

2. Conduct pharmacoepidemiological studies
3. Adopt the tools effectively in evaluating risk and benefit of therapy
4. Conduct pharmacoeconomic studies and evaluate the cost-benefit ratio

1. Course Materials:

Reference Books

a. Pharmacoeconomics and outcomes: Applications for patient care, case studies. Authors:Graer DW,Lee J,OdomTD,et al. American college of clinical pharmacy-2003.
b. Introduction to Applied Pharmacoeconomics, F. Randy Vogenberg, New York; London: McGraw-Hill,
c. Pharmacoepidemiology Editor Brian L Storm, John Wiley and Sons, Ltd 4th edition, 2 copies
d. Clinical epidemiology- How to do clinical Practice Research. 3rd edition, Brian Haynes, David L Sachett, Lippinkot

3. Lecturewise programme:

	Topic	Hrs
1	**Pharmacoepidemiology :** **Definition and scope:** Origin and evaluation of Pharmacoepidemiology, need for pharmacoepidemiology, aims and applications of Pharmacoepidemiology.	**06**
2	**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	**06**
3	**Concept of risk in pharmacoepidemiology** Measurement of risk, attributable risk, relative risk, time-risk relationship and odds ratio	**06**
4	**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.	**22**
5	**Sources of data for pharmacoepidemiological studies** Ad Hoc data sources and automated data systems.	**04**
6	**Selected special applications of pharmacoepidemiology** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management and drug induced birth defects.	**08**
7	**Phrmacoeconomics:** Definition, history, needs of pharmacoeconomic evaluations Role in formulary management decisions	**02** **02**

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 and cost utility	**16**
Applications of Pharmacoeconomics	**03**
Software and case studies (assignment discussion)	**02**

5. 3 CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

Theory : 3 Hrs./Week

1. **Scope and Objectives:** This course is designed to make the students to understand and apply pharmacokinetic principles in designing / individualizing dosage regimen. Also, enable the students to interpret the plasma drug range, and hepatic / renal function in optimizing the drug therapy.

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

   1. Design the drug therapy regimen for individual patient
   2. Interpret and correlate the plasma drug concentration with patient's therapeutic outcome.
   3. Recommend dosage adjustment for patients with renal/ hepatic impairment
   4. Detect and manage drug –drug interactions

2. Course materials:

Reference Books

a. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring; Author: Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans Published by: Lippincott Williams & Wilkins, 2005
b. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology By Steven How-Yan Wong, Irving Sunshine, Published by CRC Press, 1996
c. Clinical pharmacokinetics, Author: Soraya Dhillon, Andrzej Kostrzewski, Publisher: Pharmaceutical Press
d. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
e. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel , Prentice Hall publication

3. Lecture wise Programme:

	Topics	Hrs
1	**Introduction to Clinical pharmacokinetics.**	**01**
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.	**07**

3	**Pharmacokinetics of Drug Interaction:** a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.	**03**
4	**Therapeutic Drug monitoring:** a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs). c. Indications for TDM, Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following conditions: Cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.	**20**
5	**Dosage adjustment in Renal and hepatic Disease.** a. Renal impairment b. Pharmacokinetic considerations c. General approach for dosage adjustment in Renal disease. d. Measurement of Glomerular Filtration rate. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Effect of Hepatic disease on pharmacokinetics.	**10**
6	**Population Pharmacokinetics.** a. Introduction to Bayesian Theory. b. Adaptive method or Dosing with feed back. c. Analysis of Population pharmacokinetic Data.	**05**
7	**Pharmacogenetics** a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. b. Genetic Polymorphism in Drug Transport and Drug Targets. c. Pharmacogenetics and Pharmacokinetics /Pharmacodynamic considerations	**04**

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