MSc. (Pharmaceutical Chemistry) Syllabus

- **In Semester I, Two core papers are compulsory**

First Year- SEMESTER I

Core Papers

Module Code	Subjects
PCC1	Physical Chemistry concepts in Pharmaceuticals
PCC2	Organic Chemistry I

Two elective papers to be selected from the list given below.

Elective Papers

Module Code	Subjects
PCE1	Computers in Pharmaceutical Chemistry
PCE2	Biological Chemistry
PCE3	Herbal drug Technology and Cosmeticology

First Year- SEMESTER II

Core Papers

Module Code	Subjects
PCC3	Analytical Techniques I
PCC4	Pharmaceutical dosage forms, formulation and development

Two elective papers to be selected from the list given below.

Elective Papers

Module Code	Subjects
PCE4	Regulatory guidelines in Pharmaceutical Manufacturing
PCE5	Drug Design
PCE6	Chemistry of Natural products
PCE7	Toxicology and Environmental Chemistry

- **In Semester III, Two core papers are compulsory**

Second Year- SEMESTER III

Core Papers

Module Code	Subjects
PCC5	Organic Chemistry II
PCC6	Pharmaceutical Chemistry I

Two elective papers to be selected from the list given below.

Elective Papers

Module Code	Subjects
PCE8	Pharmaceutical stability programme, Statistics and management
PCE9	Synthetic methods in Organic Chemistry
PCE10	Fundamentals in clinical trials
PCE11	Pharmaceutical Plant Design and Operations

- **In Semester IV, Three core papers are compulsory.**

Second Year- SEMESTER IV

Core Papers

Module Code	Subjects
PCC7	Analytical Techniques II
PCC8	Pharmaceutical Chemistry II
PCC9	Industrial Training/Equivalent Project work in the institution

PCC9 may be started at the end of Semester II

Two elective papers to be selected from the list given below.

Elective Papers

Module Code	Subjects
PCE12	Fundamentals of Quality Assurance
PCE13	Polymers in Pharmaceuticals and novel drug delivery systems

Semester I

PCC1
Physical Chemistry Concepts in Pharmaceuticals (40L)

Theory

Importance of chemistry in pharmacy. Important terminologies: Pharmacodynamics, Pharmacokinetics,Pharmacopoeia(IP,BP,USP)**(Ref7)** **(2L)**

Surface Chemistry:Colloids, Colloidal System and their pharmaceutical applications. Types of solutions and their properties, Solid and Crystalline State-Formation of solids, types of solids, nature of amorphous and crystalline solids, crystal systems, determination of crystal structure, polymorphism.**(Ref 2,3,10)** **(5L)**

Physical properties of drug molecule: Importance of studying physical properties.Refractive index- Definition, explanation, formula, importance, determination, specific & molar refraction. Optical activity\rotation- monochromatic & polychromatic light, PPL, optical activity, angle of rotation, specific rotation & its examples, measurement of optical activity & its importance. Dielectric constant & Induced Polarization- Dielectric constant explanation & determination, Importance of Dielectric constant. Induced polarization. Permanent dipole moment- explanation & importance. **(Ref.2,3,4,10,14)** **(5L)**

Rheology of pharmaceutical systems: Introduction, Definition, Applications, concept of viscosity, Newton's law offlow, Kinematic, Relative, Specific, Reduced & Intrinsic viscosity. Newtonian system, Non- Newtonian system- Plastic flow, Pseudoplastic flow, Dilatent flow. Thixotropy, Brief explanation of Bulges & Spurs, rheopexy, measurement of thixotropy and its applications, Negative thixotropy. Viscosity measurements- selection of viscometer for Newtonian and non Newtonian system , Viscoelasticity & its applications**. (Ref.2,3,10,14)** **(5L)**

Chemical Kinetics- Rates and order of reactions, pharmaceutical applications- **Micromeritics**-Introduction to fundamental and derived properties, methods to determine particle size, shape and surface area, density and bulkiness, flow properties compaction. Interfacial phenomenon: Surface tension and surface free energy. **(Ref.2,3,4,10)** **(5L)**

Isotopic Dilution analysis : principle and applications, Neutron activation analysis : Principle, advantages and limitations, Scintillation counters :Body scanning. **(Ref.4,5,6,10)** **(6L)**

Introduction to radiopharmaceuticals. Properties of various types of radiopharmaceuticals, Radiopharmaceuticals as diagnostics, as therapeutics, for research and sterilization**.** **(Ref. 1,8,9,10)** **(6L)**

Physico Chemical Properties and drug action

The following physico chemical properties of drugs to be studied

(a) Partition coefficient, (b) solubility, (c) surface activity, (d) degree of ionization. Importance of the following: a) Solubility, b) stabilization of biopolymers, c) Drug – receptor interaction, d) Drug protein binding- hydrogen bonding, hydrophobic interaction, charge transfer complexation, ionic bonding, covalent bonding & chelation. Stereochemical properties and drug action. Drug metabolism,general pathway**.(11-13) (6L)**

References

1) Practical Pharmaceutical Chemistry Vol I &II by Beckett and Stenlake.
2) Physical Pharmacy and Pharmaceutical Sciences by Martins, Patrick J. Sinko, Lippincott. William and Wilkins.
3) Cooper and Gunn's Tutorial Pharmacy ,6th edition by S.J. Carter, CBS Publisher Ltd.
4) Instrumental method of Analysis : Hubert H ., Willard ,7th edition.
5) Physical Chemistry- Bahl and Tuli
6) Text Book of Physical Pharmaceutics, IInd edition, Vallabh Prakashan-.C.V.S. Subramanyam.
7) Medicinal Chemistry (Organic Pharmaceutical Chemistry), G.R Chatwal, Himalaya Publishing house.
8) Radiopharmaceuticals in modern pharmacy and nuclear medicine, Richard J. Kowalsky, Steven W. Falen, Oct.2004, 2nd edn., Amer Pharmacists association.
9) Radiopharmaceuticals-Adrian D. Nunn, Marcel Dekker Publishers.
10) Physical Pharmacy- Physical Chemical principles in the pharmaceutical sciences, Alfred Martins, James Swarbrick, Arthur Cammarata ,3rd edition Indian edition, K.M.Varghese Publishing House.
11) Wilson & Gisvold; Text book of Medicinal Chemistry, Philadelphia Williams & Lippinctt Wilkins.
12) Textbook of Pharmaceutical Chemistry by ,Jayshree Ghosh, S. Chand & company Ltd.
13) Pharmaceutical Chemistry by Dr. S. Lakshmi, Sultanchand & Sons.
14) Physical Chemistry by Arnikar and GurjarS.Chand and Sons.

Practicals (10)

1) Chemical Kinetic experiment :
    a) To determine the order of reaction between $K_2S_2O_8$ & KI by graphical method.
    b) Determination of the velocity constant of hydrolysis of an ester uing NaOH by conductometry method.
    c) Kinetics of iodination of acetone in presence of strong acid etc.
2) Specific gravity measurement (Indian Pharmacopoeia)

    Ethanol, acetone, cough syrup using Ostwald pycnometer

3) Preparation of buffer solutions, Measurement of pH and calibration of pHmeter IP/BP. pH=4, pH= 7, pH=10, pH= 9.2. **(4)**
4) Saponification value of castor oil (IP)
5) Acid value of castor oil (IP)
6) Viscosity Determination: Using Ostwald Viscometer, **(2)**
    a. Viscosity of a hydroxylpropylmethyl cellulose
    b. Viscosity of Polyethylene glycol
7) To determine partition coefficient of drug using octanol-water system.
8) To determine the interfacial tension between two liquids using Ostwald's Stalagnometer.
9) Determination of specific surface area of Talc/ charcoal by adsorption method.
10) Analysis of Phenobarbital potentiometrically.
11) Separation and determination of Fe(III) and Mg(II)/ Zn(II) using ethyl acetate as solvent.
12) Determination of the hydrolysis constant of a salt of strong acid and weak base conductometrically. (Aniline hydrochloride)
13) Verification of Ostwaltd's dilution law and determination of dissociation constant of weak monobasic acid (benzoic acid).

References

1) K.A. Connors: Text book of pharmaceutical analysis , 3rd edition , Wiley-interscience Publication 1999.
2) Indian Pharmacopoeia, British Pharmacopoeia.
3) Practical Physical Chemistry, A.M. James and F.E. Prichard, Longman.
4) Vogel's Textbook of Quantitative Analysis, revised, J. Basset, R.C. Denney, G.H. Jeffery and J. Mendham, ELBS.
5) Experimental physical pharmacy- Dr. Derle D. V.
6) Practical Physical Pharmacy- H. N. More and A. A. Hajare.
7) Physical pharmacy- Practical Text- Guru Prasad Mohanta, Prabalkumar Manna.
8) Practical Physical Chemistry : B. Viswanathan and P.S. Raghavan
9) Post- graduate Chemistry Practicals- S.S.Kelker, H.N.Patel, S.P. Turakhia, A.G.Gadre, Himalaya Publishing House.

PCC2
Organic Chemistry I (40L)

Theory
Chemical Bonding in Organic Molecules: Covalent, Ionic, Hydrogen, Vander waals, ion-dipole bonds with examples . **(7)** **(3L)**

Aromaticity in benzenoid non-Benzenoid compounds, alternate and non alternate hydrocarbon, compounds:,Huckels rule**.Molecular Properties of organic molecules:** Hydrophilicity, Hydrophobicity, acidity, basicity, Electronic effects-(Inductive, resonance, mesomeric), Steric effect**. (7)** **(6L)**

Stereochemistry
Stereochemical Principles – Enantiomeric relationships, diastereomeric Relationships, R and S, E and Z nomenclature, dynamic stereochemistry, prochiral relationships,

Stereospecific and stereoslective reactions. Stereochemistry of compounds containing phosphorus, sulphur and nitrogen. Introduction of optical activity in the absence of chiral carbon (biphenyl, allenes, spiranes and helical structures). Conformation of acyclicmolecules and shape of six membered rings**. (6,8) (8L)**

Types of Mechanism and reaction intermediate

Homolysis, Heterolysis, Classification of reactions (addition, elimination, substitution etc.), generation structure, stability and reactivity of carbocation, Carbanions, free radicals, Carbenes and nitrenes. **(1-5,7) (7L)**

Understanding Organic Reaction Mechanisms: Aliphatic Nucleophilic substitution-The SN2, SN1, mixed SN1 and SN2 and SET mechanism. Nucleophilic substitution at an allylic aliphatic trigonal and vinylic carbon. Reactivity effects of structure, attacking nucleophile, leaving group, and reaction. Medium, phase transfer catalyst and ultrasound, ambident nucleophile, Regioselectivity.
(1-5,7) (8L)

Electrophilic Aromatic Substitution: The arenium ion mechanism, orientation and reactivity, energy profile diagram. The ortho/para ratio, ipso attack, orientation in other ring systems. Diazonium coupling, Vilsmeier reaction, Gatterman-Koch reaction.**(1-5,7) (4L)**

Aromatic Nucleophilic substitution: The SNAr, SN1, Benzyne and SRN1 mechanisms, reactivity effects of substrate structure, leaving group and attacking nucleophile.**(1-5,7) (4L)**

References:

1) Modern Synthetic Reaction, by H.O.House, W.A. Benjamin INC 1972.
2) Modern methods of Organic Synthesis , by W. Carruthers, Cambridge University Press.
3) Organic Synthesis, by Michael B Smith , 2nd edition, London, McGraw Hill 2002.
4) Modern Organic Synthesis An Introduction, George S. Zueifel, Michael H . Nantz , New York.
5) Oxidation & Reduction in Organic Synthesis, Timothy T. Donohoe, Oxford-Oxford University Press 2000.
6) Sterochemistry – Conformation and mechanism, P.S. Kalsi, New age International(P), Ltd Publishers.
7) J. March (Ed. V) Adv. Organic Chemistry.
8) Stereochemistry of organic compounds by D. Nasipuri.

Practicals (10)

1. Techniques: Crystallization, fractional crystallization.
2. Ternary mixture separations 5examples.
   a) Solid-Solid-Solid
   b) Solid-Solid-Liquid.
   c) Solid-Liquid-Liquid.
   d) Liquid-Liquid-Liquid
3. Single stage preparations involving different type of reactions.
   1) Acetophenone to benzalacetophenone (chalcone)

2) Anthranillic acid to o-iodobenzoic acid.
3) Cyclohexanone to adipic acid
4) Anthranillic acid to o-chlorobenzoic acid.
5) Benzaldehyde to Cinnamic acid
6) benzaldehyde to dibenzalacetone

4. Preparation of the following derivatives- benzoyl of phenol and amine, 2,4-DNP of ketone, oxime of ketone, anilide of amine, amide of acid and aryloxy acetic acid of acid.

References:

1) Vogel's text book of Practical Organic Chemistry, ELBS Publishers
2) Advanced Organic Chemistry Practicals by Vishnoi

PCE1 Computers in Pharmaceutical Chemistry (40L)

Mathematics- Various functions and function plotting (exponential, logarithmic, trigonometric, etc), functions of many variables. Basic rules of differentiation and integration, partial differentiation, critical points of a function. Regression methods and curve fitting. Linear equations, vectors, matrices and determinants. Numerical methods. Probability (permutations and combinations**).(1,2) (15L)**

Brief introduction to the need of computers for chemistry. Computers for Analytical Chemists- Introduction to computers: Organization of computers, CPU, Computer memory, I/O devices, information storage, software components, Types of computers, Programming languages, Computer programs, Stored program concept, Operating systems, Algorithm, program flow charts**.(3-4) (10L)**

Application of computers in chemistry: Programming in high level language (BASIC/FORTRAN/C) to handle various numerical methods in applicable in chemistry such as least square fit, solution to simultaneous equations, interpolation, extrapolation, data smoothing, numerical differentiation and integrations etc. Application of computer in store management, production and control **(3-4) (15L)**

References:

1) Mathematics for science and engineering, P.L. Alger, McGraw-Hill, New York (1963).
2) Principles of Mathematics, C.B. Allendoerfer and C.O. Oakley, Mc.Graw-Hill, New York (1963).
3) Computers in chemistry, K.V. Raman, Tata Mc.Graw-Hill, 1993.
4) Computers for Chemists, S.K Pundir, Anshu bansal, A pragate prakashan.

Practicals (10)

Use of software packages in chemistry: Spread sheet application, least square fit, data plotting, simulations of potentiometric titration and end point locations etc.

1. To generate a mark sheet to learn various features of spreadsheets.

2. To generate a plot for a given function (functions such linear, exponential, parabolic, trigonometric, exponentials etc.

3. To generate a derivative plot for pH-metry and potentiometric experiments.

4. To write a computer program to obtain a slope and intercept for linear data using least square fit.

PCE2 Biological Chemistry (40L)

Biochemistry (Ref.1-12)

Introduction to biochemistry: Scope of the subject in pharmaceutical sciences, biochemical reactions, highlights of prokaryotic and eukaryotic cell metabolism. **2L**

Amino Acids and Proteins: Structural and functional classification of proteins, structure, physicochemical properties, configuration and optical properties of amino acids. Colour reactions of proteins and amino acids. Purification of proteins, amino acid sequence determination, peptide bond. Ramchandran plot. Primary, secondary, tertiary and quaternary structure of proteins. Three dimensional structure of proteins. **4L**

Nucleic acids: Chemical composition as genetic material, nucleosides, nucleotides, structure, biochemical function, replication, transcription, translation, flow of genetic information, genetic code, gene, gene expression, genetic disorder, DNA recombination, gene therapy. **3L**

Principles of coordination chemistry in proteins and nucleic acid. 2L

Enzymes: Introduction, classification (according to the reaction catalysis and sources) structure of enzyme, co-factors, active sites, binding site, Km, Vmax, enzyme kinetic, double reciprocal plot, effect of substrate, pH ionic strength, concentration, temperature on rate of enzyme reactions, enzyme inhibition (competitive, non-competitive, uncompetitive and irreversible). Manufacturing of medical compounds by enzymatic reactions, penicillin acylase for the production of 6-APA, therapeutic uses of enzymes. **3L**

Drug Metabolism: Definition and concepts, types of metabolic reactions effecting xenobiotics, biological factors effecting drug metabolism, biotransformation, metabolic conjugate reactions, significance of drug metabolism in medicinal chemistry. **2L**

Carbohydrates and Metabolism: Configuration and chemical transformation of carbohydrates, absolute configuration of carbohydrates, general concepts, energetics and control in metabolic pathways. Glycolysis and citric acid cycle, phospho and glycolipids. **2L**

Electron transport chain: Biological oxidations, concept of redox potential, energy rich compounds, substrate level phosphorylation, respiratory chain and oxidative phosphorylation. **2L**

Microbiology (Ref.13-19)

Introduction and History of Microbiology and its application in Pharmacy and medicine. **2L**

Classification of micro-organisms and their study based on morphological, physiological and biochemical properties. Study of bacteria, yeasts, moulds, viruses, rickettisia, algae and protozoa with respect to their morphology, cell characterization,

habitats, nutrition, reproduction and cultivation, growth phases of bacteria, measurements of growth and factors affecting their growth. **4L**
Brief introduction to principles of i) sterilization and disinfection, ii)aseptic technique. iii) Microscopy including staining techniques. **3L**

Culture media studies: Isolation and identification of pure cultures of bacteria including biochemical, serological and virologocal technique. Study of culture media such as cultivation storage media, enrichment media, differential medium and media for special purposes. **3L**
Microbial mutation: Study of microbial mutation including types of mutation, mutagenic agents, mechanism of mutation, methods of prevention of mutation. **2L**
Introduction to microbial drug resistance. Flora of normal body. Study of microflora of air, water and soil with particular emphasis on pathogenic micro-organisms. **3L**
Medical Microbiology: Introduction to pathogenic micro organisms of common occurrence with special reference with special reference to tropical diseases. Mycobacterium sp., Salmonella sp. Shigella sp. Staphylococcus sp. Klebsiella sp. E. Coli, Pseudomonas, Clostridium-study of fungal infections, protozoal infections like amoebic dysentery, malaria, Kala Azar and their detection. **3L**

Practicals: (10)

1) Staining Methods
2) Sterilization methods
3) Sterility Testing
4) Pyrogen Testing
5) Microbiological Assays**.**

References:

1. Principles of Biochemistry, Albert Lehninger (CBS publisher and distributors Pvt. Ltd. Delhi)
2. Biochemistry, Lubert Stryer, W H (Freeman and Co., New York).
3. Harpers's Biochemistry by R. K. Murray, D.L. Granner, P.A. Mayes (Prentice Hall International Inc.)
4. An introduction to practical biochemistry, Davis T. Plummer (Tata McGraw Hill, Publishing Co. Ltd., New Delhi).
5. Practical Clinical Biochemistry, Harold Varley (CBS Publishers and distributors, Delhi).
6. Molecular biology, J. D. Watson (The Benjamin/Cummings Company, Inc.)
7. Biochemistry, Zubay
8. Outlines of Biochemistry, E.E. Conn, P.K. Stump.
9. Harper's review of Biochemistry by David W. Martin, Peter A. Mayes, Victor W. Rodwell & Associates
10. Text Book of Biochemistry by Benjamin Harrow, Abraham
11. Biochemistry by Lubert Stryer.
12. Biological Chemistry: Inorganic elements in the chemistry of life-Introduction and guide: W. Kaim, B Schewedenski, VCH, (1991)
13. Fundamentals of Microbiology - Frobisher
14. Microbiology - Pelczar and Reed
15. Medical Microbiology - Cruickshank
16. Pharmaceutical Microbiology - Hugo and Russel
17. Benttey's text book of Pharmaceutics - Collins & Lyn

18. Industrial Microbiology - Patel (MacMillan)
19. Cooper & Gunns Tutorial Pharmacy –S.J.Cater, CBS publishers & Distributors

PCE3

Herbal Drug Technology and Cosmeticology

Development of Ayurvedic and Herbal formulations and their evaluation by physical methods, chemical methods and microscopical techniques. Application of various chromatographic methods in separation and identification of marker compounds in the formulations. Fingerprinting techniques and its importance. Development of analytical techniques for the estimation of markers present in the Herbal and classical formulations. Evaluation of Herbal drugs and formulations by Biological methods. General animal models for screening of Herbal drugs and formulations. Toxicological evaluations of herbal drugs and formulations. WHO and Indian regulatory requirements of Clinical trials for herbal formulations. Schedule T requirements and other regulatory requirements for the manufacturing of Herbal and Ayurvedic products.

(Ref.1-4) (20L)

Introduction to cosmeticology , Fundamentals of cosmetic science, structure and functions of skin and hair, Formulation, preparation and packaging of cosmetics for skin - Sunscreen, moisturizers, cold cream, and vanishing cream, like nail polish, lipsticks. Formulation, preparation and packaging of cosmetics for hair - Shampoo and conditioners**. (Ref.5-9) (20L)**

References:

1) Indian Herbal Pharmacopoeia.

2) Methods in Pharmacology by Arnold Schwartz.

3) Drug discovery & Evaluation by H. Gerhard Vogel.

4) Evaluation of drug Activities – Laurance & Bachrach

5) Cosmeticology Vol I & II by Sagarin
6) Cosmeticology by Thomson.
7) Harry's Cosmeticology - Longman Scientific Co.
8) Formulation and Function of Cosmetics-So Jellineck
9) Modern Cosmetics-E. Thomessen Wiley Inter science

Practicals: (10)

1) Herbal Drug Formulation experiments (5)

2) Preparation of Asaras, Arishtas.

3) Preparation of a face cream, face powders, lipsticks, nail polish, lotions etc.

References:

1) Indian Herbal Pharmacopoeia.
2) Harry's Cosmeticology - Longman Scientific Co.
3) Formulation and Function of Cosmetics-So Jellineck

Semester II

PCC3 (Core)
Analytical Techniques I (40L)

Theory

Role of Analysis, Classification of analytical methods–classical and instrumental. Selecting an analytical method, Analytical Method validation. Sensitivity & Detection limits, Precision & Accuracy, comparison of standards, standard addition & subtraction, Data plotting. Neatness and cleanliness. Laboratory operations and practices. Analytical balance. Techniques of weighing, errors. **(Ref. 4, 6, 7) (6L)**

Sampling- of raw materials, intermediates and finished products. Testing of packing material. Sample preparations – dissolution technology and decomposition. Interpretation and presentation of results: Storage of samples.**(Ref.2, 3, 9) (4L)**

Stoichiometric calculations and various ways of expressing concentrations. Introduction to analytical chemistry- Glassware, reagent, calibration. Wet analytical techniques: Reference standards, workings of standards.**(Ref.2,3,5,6,9) (5L)**

Titrimetric analysis- Introduction to acid – base titrations, precipitation and complex formation, oxidation – reduction titrations. Potentiometric and conductometric titrations. General information on Techniques of Quantitative Pharmaceutical analysis and variables in quantitative analysis**.** **(Ref.2,3,5,6,9) (5L)**

Analysis of drugs in solid state- Concepts of particle size, size distribution shown as cumulative undersize curve. Thermal methods of analysis : basic principle, differential thermal analysis and differential scanning, calorimetry. Differential thermal analysis, apparatus and methodology, factors affecting DTA results, quantitative DTA, interpretation of results. Applications to detect polymorphism and pseudopolymorphism in pharmaceuticals by DSC and DTA. **(Ref.1,8) (8L)**

Solvent Extraction: The Distribution Coefficient and Ratio, The percent extracted, Solvent extraction of metals, Analytical Separations, Multiple batch Extractions, Countercurrent Distribution, Application of solvent extractions**. (Ref.2,3) (4L)**

Assessing Analytical Data- Accuracy and Precision. Types of errors and ways of expressing accuracy. Propagation of errors and significant figures, standard deviation, Confidence Limit. Test of Significance. Statistical Quality Control, Statistics for small Data Sets. Linear Least Squares. Correlation coefficients.**(Ref.2,3,5,6,7) (6L)**

Assay of Drugs: Introduction to Chemical, Biological and immunological. **(1) (2L)**

References:

1) Pharmaceutical Chemistry by S. Lakshmi, Chand and Sons company.
2) Practical Pharmaceutical Chemistry, Vol I& II by Beckett and Stenlake.
3) K.A Connors Text book of Pharmaceutical analysis, 3rd edition, Wiley Interscience Publication 1990.
4) John of Kennedy, Principle of analytical Chemistry. 2nd edition, Saunders college Publishing ,1990, New York.
5) J. W. Munson, pharmaceutical Analysis , Modern methods, Part A &B, 2001, Marcel Dekker.
6) Principles of Instrumental analysis : A. Skoog, James, 5th edition, Saunders college Publishing.
7) Analytical Chemistry by Gary Christian, 6th edition, Wiley Publishing House.
8) Physical Pharmacy and Pharmaceutical Sciences by Martins, Patrick J. Sinko, Lippincott. William and Wilkins.
10) Vogel's Practical Textbook for Quantitative analysis, 6th Edition.
11) A book on Association of Organic and agricultural chemistry.

Practicals (10)

1) Calibration of UV/VIS Spectrophotometer as per I.P.
2) Analysis of Vitamin C in juices and squashes.
3) Assay by titration of the following: (Ibuprofen, aspirin, Milk of Magnesia, microcrystalline cellulose, paracetamol, zinc sulphate, zinc chloride)
4) Analysis of antacid.
5) Analysis and purity of working standards. (NaCl, $CaCO_3$)
6) Complexometric titration using EDTA: (Ca, Ni, Cu analysis).
7) Determination of Percentage of chloroquine phosphate using solvent extraction.
8) Dosage content in tablets by solvent extraction (Senade Tablets)
9) Standardization of potassium permanganate and analysis of hydrogen peroxide.
10) Determination of acetic acid in Vinegar by conductometric titration.
11) Estimation of Benzoic acid in ointment by titrimetry.
12) Estimation of Ascorbic acid in tablets by iodometry.
13) Analysis of Ephedrine titrimetrically.
14) Analysis of tartaric acid sample.
15) Determination of total hardness of water.
16) Determination of Calcium in Ringer's solution (Chlorides of Na, K and Ca)
17) To calculate the purity of NaCl. (Precipitation titration).
18) Estimation of acetyl salicylic acid in the given aspirin tablet by titrating against 0.1N alcoholic KOH potentiometrically.

References:

1) K.A Connors Text book of Pharmaceutical analysis, 3rd edition, Wiley Interscience Publication 1990.
2) Vogel 's text book of quantitative chemical analysis revised by G.H. Jeffery , J. Bassett, J. Mendhan, R.C. Denny , 6th Edition.
3) I.P., USP, B.P. European Pharmacopoeia.

PCC4(Core) **Pharmaceutical dosage forms, formulation and development I (40L)**

Theory

Introduction to drug dosage Forms & Drug Delivery system – Definatio of Common terms. Drug Regulation and control, pharmacopoeias-formularies, sources of drug, drug nomenclature, routes of administration of drugs products, need for a dosage form, classification of dosage forms & brief description, study of excipients. **(6L)**

Product Development: Preformulation studies, objectives ,factors to be considered,study protocol.Brief discussion on various parameters to be investigated. formulation and development of the dosage form/drug delivery system-general consideration. **(10L)** .

Pilot plant–scale up techniques, General Consideration**.(4L)**

Pharmaceutical manufacturing operations-Brief discussion on unit operations and types of equipments/ machines used. Unit operations like size reduction, mixing/blending, drying, compression etc**.(10L)**

Dosage forms-formulation components , manufacturing and QC: Liquids-monophase& biophase including ENT preparation.Semisolid eg. Ointment, creams , gels etc.Solid dosage forms eg. Tablets, capsules, granules,& powders.Sterile dosage forms eg. Injectables and ophthalmic preparations**.** **(10L)**

References:

1) Ansels pharmaceutical Dosage forms and Drug Delivery System by Allen Popvich and Ansel ,Indian edition-B.I. Publication Pvt . Ltd.

2) The theory and practice of industrial pharmacy by Lachman Varghese

Publishing House , Mumbai.

3) Modern Pharmaceutics by Gilbert. Banker, Marcel Dekker, Inc.

4) Cooper & Gunns Dispensing for Pharmaceuticals students edited by S.J.Carter,12th edition CBS publishers & Distributors, Delhi.

5) Remington's Pharmaceuticals Sciences- Mack Publishers.

6) Pharmaceutics Science of Dosage forms and design By Aulton ELBS edition.

Practicals (10)

Preparation of pharmaceutical dosage forms: i) Liquid dosage form, ii) Semi-solid dosage form iii) Solid dosage form.(Atleast one representative product) And their Quality control Analysis other then Assays.

Liquid Paraffin Emulsion, simple syrup, aqueous iodine, tincture of iodine, strong iodine, calamine lotion IP, phenyl, merbromine solution, non-staining ointment cum methyl salicylate (Iodex), sulphur ointment, Dill water concentrated IP, Non-staining iodine ointment, Liniment, cresol

with soap solution. One representative preparation under sterile dosage form.

References

1) IP/BP/USP/BPC.

2) Benthey's Book of Pharmaceutics by Paulings.

3) Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi

4) Pharmaceutics –II (Practical note book) Second edition ,A.K.Gupta, CBS Publishing Distributions.

5) Cooper & Gunns Dispensing for Pharmaceuticals students edited by S.J.Carter,12th edition CBS publishers & Distributors, Delhi.

PCE4 Regulatory Guidelines in Pharmaceutical Manufacturing (50L)

Good Manufacturing Practices History of GMP, drug laws and regulations, Essential elements of GMP regulations, GMP expectations, Characteristics of GMP products, Legal consequences of GMP non-compliance, Role of quality assurance in the pharmaceutical industry, Personnel responsibilities in GMP environment, Role of procedures: SOPs, documentation, logs in GMP environment, Function and importance of specifications, Five "Ps" of GMP; "Product", "Premise", "People", "Procedure", and "Process", GMP requirements for building, facilities, and equipment. **(25L)**

Good Laboratory Practices and Good Clinical Practices: History and the reasoning behind the GLPs, Essential and required Good Laboratory Practices GLPs, GLP and GMP Regulations for an analytical laboratory, 21 CFR Part 11, Critical operational elements of analytical laboratories, Review GLPs and GMPs and their regulations for analytical labs, Roles and responsibilities of personnel, Appropriate design and placement of laboratory equipment, Requirements for maintenance and calibration. ICH guidelines involved. Introduction to GCP and principles governing GCP. **(25L)**

References:

1) Good Manufacturing practices for pharmaceutical- A plan for Quality control, 4th Edn revised and expanded, Sidney Willig, James Stoker, Marcel Dekker.

2) Good Laboratory Practice regulations, Sandy Weinberg (3rd edn), Marcel Dekker.

3) Quality Assurance and Quality Management in Pharma Industry, Prof. Y. Anjanayuli, Dr. R. Marayya, Pharma Book Syndicate.

4) Good pharmaceutical manufacturing practice, by Sharp John.

5) ICH guidelines

6) A textbook of clinical pharmacy practice-essential concepts and skills, Parthasarathi, Nyfort-hansen Nahata, Publisher: Orient Longman.
7) Quality Assurance of pharmaceuticals-A compendium of guidelines and related materials, Vol I, Pharma Book Syndicate.
8) Pharmaceutical Pre-approval inspections-guide to regulatory success, 2nd edn,-Martin D, III(edt) Hynes, Informa Healthcare.
9) Drugs & Cosmetics Act, 1940 and Rules, 1945.
10) WHO Techical Report Series-885 by World Health Organisation. (35th report).
11) Good Manufacturing Practices, Philosophy and Applications by John Sharp, Inter Pharma Press, IL 60089,USA.
12) Quality Assurance Guide (Vol I & Vol II) by Organisation of Pharmaceutical producers of India.

PCE5

Drug Design (50L)

Development of new drugs: Introduction, procedure followed in drug design, the search for lead compounds, molecular modification of lead compounds, prodrugs and soft drugs, prodrug; introduction, prodrug formation of compounds containing various chemical groups, multiple prodrug formation, soft drugs; design of soft drugs. **(Ref.1-4,14) (8L)**

Structure-Activity Relationship (SAR): Factors effecting bioactivity, resonance, inductive effect, isoterism, bioisosterism, spatial considerations, biological properties of simple functional groups, theories of drug activity, occupancy theory, rate theory, induced-fit theory, quantitative structure-activity relationship(QSAR): history and development of QSAR, drug receptor interactions, the additivity of group contributions, physico-chemical parameters, lipophilicity parameters, electronic parameter, ionization constants, steric parameters, chelation parameters, redox potential, indicator-variables, quantitative models, Hansch analysis.
Free-Wilson analysis, their application, relationship between Hansch and Free-Wilson analysis (the mixed approach), non-linear relationship, introduction to other QSAR approaches**.(Ref.1-9,11,14) (15L)**

Design of Enzyme Inhibitors, 9-alkylpurines, 9-mercaptopurines and allopurines, active side directed irreversible enzyme inhibition, suicide enzyme inactivators. Introduction to molecular modeling using computers, uses of molecular modeling manual use, further computer programming. **(Ref.9-10,13,14) (8L)**

Structure-based drug design: Process of structure based drug design, deactivation of certain drugs necessary for T cell functioning, determination of the active site with special reference to chymotryspin, design of inhibitors**. (Ref.10,14) (6L)**

Introduction to Combinatorial Chemistry and high throughput screening. (**3L)**

Patents -Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. **(Ref.14-16) (4L)**

Bioinformatics in structure based drug design. Introduction, rational drug design, structure based drug design, lead optimization. **(Ref.17-18) (4L)**

Current trends in the field of drug discovery and design. **(2L)**

References

1. An Introduction to Drug Design by S.S. Pandeya and J.R. Dimmock, New AgeInternational (P) Ltd. Publishers.
2. Burgers Medicinal Chemistry and Drug Discovery, Vol I (Ch 9 and 14), Ed. M.E. Wolff John Wiley.
3. Introduction to Medicinal Chemistry, Alen-Gringauz, Wiley-VCH, D. Lednicer and L.A. Mitscher, The Organic Chemistry of Drug Synthesis, Vol. I to V, John Wiley.
4. An Introduction to Drug Design by S.S. Pandeya and J.R. Dimmock, new Age International (P) Ltd. Publishers.
5. Burgers Medicinal Chemistry and Drug Discovery, Vol I (Ch 9 and 14); Ed. M.E. Wolff, John Wiley.
6. Introduction to Medicinal Chemistry, Alen-Gringauz, Wiley-VCH
7. The Organic Chemistry to Drug Synthesis by D. Lednicer and L.A. Mitscher. Vol.IV John Wiley.
8) Organic Chemistry of drug design and drug action-R.B. Silverman (1993) Acad. Press.
9) Molecular Modelling, Principles and applications-Andrew Leach (Longman 1998).
10) Statistical methods in Biology – Norman Bailey (1995) Cambridge.
11) A text book of Drug design and development IIN Edn. Povl. Krogsgaard-Larsen Tommy L. and U. Madsen (1996) Harwood Acad. Publishers.
Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6 Marcel Inc.,N.Y.
12) G. Jolles and R.H. Wooldridge, Drug Design – Fact of Fantasy? Academic Press, 1984 .
13) E.B.Roche, Design of Biopharmaceutical properties through prodrug and analogs, Am. Pharm. Assoc. Academy of Pharm. Sci. 1977.
14) An Introduction to Medicinal Chemistry, 2nd edition, Grahan L. Patrick (Indian edition) Oxford university press
15)N.R. Subbaran, what everyone should know about Patent, Pharma Book Syndicate (2nd edition).
16) Current Patent Acts of various countries.
17) Patents for Chemicals Pharmaceuticals & Biotechnology 4th edition , Philip W Grubb- Oxford University Press.
18) Bioinformatics in structure based drug design: Richard M.Casey.
19) Bioinformatics and drug discovery: By Richard Larson, Humana Press.

PCE6

Chemistry of Natural products (40L)

1) Structural elucidation by classical methods: Terpenoids: Cedrene, Alkaloids: Morphine, Steroids: Cholesterol. **(6L)**
2) Structure elucidation of terpenoids:α and β vetinones and hormones: Cecropia JH by combination of physical and chemical methods. **(7L)**
3) Structure elucidation of Brevicomin, Eucomin and Eucomol by spectral methods. **(5L)**
4) Synthesis of selected natural products: Terpenoids: Longifolene (Corey Synthesis), Alkaloids: Reserpine (Woodward Synthesis), Hormones: Cecropia JH (Edward Synthesis), Antibiotics: Cephalosporin (Woodward synthesis), Prostaglandins: Prostaglandins-E2 (Corey Synthesis). **(7L)**

5) Introduction to Biogenesis and Biosynthesis. Biogenesis of secondary metabolites: Application of tracer techniques in evaluation of biogenetic pathways of secondary metabolites. **(5L)**
6) Natural products used as colour pigments, excipients, biopolymers, photosensitizing agents, flavours, biofuels. **(5L)**
7) Determination of stereochemistry (spectral and chemical methods) **(5L)** Terpenoids: Menthol and Hardwikic Acid, Alkaloid: Reserpine

References:

1) K. Natkanish, Natural product chemistry, Acad Press.
2) I. Fleming, Selected organic synthesis, John Wiley and Sons.
3) J. Apsimon, Total Synthesis of natural products, John Wiley and Sons.
4) D.R. Dalton, The Alkaloids, Marcel Dekker.
5) I.L. Finar, Stereochemistry and Chemistry of natural products.
6) Agrawal O.P., Chemistry of Organic Natural Product, Goel Publication House, UP.
7) E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company.
8) Pridham J B, Swain T, Biosynthetic pathway in higher plants, Academic Press, New York.
9) Bardon and Oils, Comprehensive organic Chemistry.
10) J. Corey and Xue-men Cheng, Wiley Interscience.
11) K.C. Nicolau and E.J. Sorensen, Classics in Total Synthesis

Practicals: **(10)**

1) Microscale extraction of Caffeine from tea, coffee etc. and purification by microscale sublimation.
2) Characterization of pure caffeine by IR.
3) Isolation of Cinnamaldehyde from Cinnamon by microscale steam distillation.
4) Characterization and interpretation of isolated Cinnamaldehyde by IR.
5) Enzymatic reduction of ethylacetoacetae using Baker's yeast.
6) Thin layer Chromatography for separation of mixtures of natural products/Market Formulations. (2)
7) Column chromatography of two component mixture of natural products/Market Formulations.(4)
8) Conversion of camphene to isobornyl acetate
9) Hydrolysis of isobornyl acetate to isoborneol
10) Oxidation of isoborneol to Camphor.

References:

1) D.W.Mayo, R.M. Pike and P.K. Trumper, Microscale Organic laboratory, John Wiley and Sons, 3rd Edn, 1994.
2) D.L. Pavia G.M. Lampman and G.S. Kriz, Introduction to organic laboratory techniques, Saunders college published, 2nd edn, 1995.
3) O.R.Rodig, C.E. Bell, Jr. A.K. Clark, Organic Chemistry Laboratory, Saunders college Publishing, 1990.

PCE7

Toxicology and Environmental Chemistry (50L)

Toxicology: Definition and types of toxicology, Basic principles of toxicology, Carcinogenicity, mutagenicity, teratogenicity, acute, sub acute and chronic toxicity. Pre-clinical valuation of drugs. Drugs and pregnancy. Drug addiction and drug habit/ dependence drug abuse, physical dependence, psychological dependence. **(8L)**

Detailed toxicity(mild/moderate/severe toxicology wherever applicable) and treatment of drugs such as salicylates/ paracetamol, opium, quinine, ethyl alcohol, nicotine/digitalis, barbiturates, etc**.** **(4L)**

Toxic chemicals in the environment, impact of toxic chemicals on enzymes. Biochemical effects of arsenic, lead mercury, cadmium, carbon monoxide, sulphurdioxide, pesticides and carcinogens**.** **(8L)**

Air and Air Pollution: Green house effect, Acid rain, Ozone hole phenomenon, Source & toxic effects of Pb and Cd. Sources-stationary and transportation sources of air pollution, classification of air pollutants-sources, effects and control of CO, SO2, NOx, HC as gaseous pollutants, suspended particulate matter aerosols, photochemical air pollution, sampling of air pollutants-gaseous and particulate, analysis of air pollutants, stack monitoring. **(12L)**

Water and Water Pollution: Water quality parameters and their analysis-colour, temperature, transparency, turbidity, pH, TDS, DO, free CO2, total hardness, Ca & Mg hardness, alkalionity, chloride, sulphate, ammonia, nitrite, NO3, organic N. phosphorus (total inorganic-organic), silica, BOD, COD, DO.

Sources of water pollution-soild waste, industrial, agricultural, oil, radiaoactive waste, thermal pollution, sampling of water pollutants. **(12L)**

Soil and Soil Pollution: Definition, component of soil, fertility management of soils, soil sediment analysis-physical and chemical parameters. Soil pollution-sources, detrimental effects and control. **(6L)**

References:

1. A.K. De, Environment Chemistry, Wiley Eastern Ltd., New Delhi.
2. R.K. Trivedy and P.K. Goel, Chemical and Biological Methods for Water Pollution Studies, Environment Publications, Karad (India)
3. S.L. Chopra and J.S. Kanwar, Analytical Agricultural Chemistry, Kalyani Publishers, New Delhi.
4) Thad Godish, Air Quality.
5. S.P. Mahajan, Pollution control in Process Industries, 1994.
6. Harry Freeman, Hazardous Waste Minimization, 1990.
7. Metcalf and Eddy, Waste Water Engineering, 1993
8. Herfindale.E.T. and Hirschmann,J.L.; Clinical Pharmacy and Therapeutics.

Semester III

PCC5

Organic Chemistry II (40L)

1) **Oxidation (Ref.1,2,7,8)** (**4L)**
Mechanisms,stereochemical aspects and applications of: Oppenaur oxidation, aromatization, dehydrogenation, ozonolysis, oxidation using peracids and peroxides.

2) **Reduction (Ref.1,2,7,8)**
Mechanisms,stereochemical aspects and applications of: Catalytic Hydrogenation, (Pt, Pd, Ni catalysts and Wilkinson's catalyst. Homogeneous and heterogeneous catalysis. Introduction to metal hydride reagents. Birch reduction. **(4L)**

3) **Rearrangements: Mechanism, synthetic applications and stereochemistry**
Beckmann, Hofmann, Curtius, Wolf, Schmidt, Loffmann, Baeyer-Villiger, Sommelet, Favorskii, Pinacol-Pinacolone, Benzil-Benzilic acid, Claisen and Cope rearrangement. **(Ref.2,3,4,5,6)** (**10L)**

4) **Addition to Carbon-hetero Multiple bonds** **(6L)**
Addition of Grignard reagent, organozinc, organo copper and organo lithium reagents to carbonyl and unsaturated carbonyl compounds. **(Ref.2,3,4,5,6)**

5). **Addition to Carbon-Carbon multiple bonds** (**6L)**
Mechanistic and stereochemical aspects of addition reactions involving electrophiles, nucleophiles and free radicals, region and chemoselectivity, orientation and reactivity, hydrogenation of double bond and triple bonds, hydrogenation of aromatic ring, hydroboration, Michael reaction**.**
(Ref.2,3,4,5,6,9)

6). **Elimination reactions**
The E2, E1and E1cB mechanism and their spectrum, orientation of the double bond. Reactivity effects of the substrate, structures, attacking base the leaving group and the medium. Mechanism and orientation in pyrolytic elimination. (**5L)**
(Ref.2,3,4,5,6,9)

7) **Carbanions** Formation and stability, mechanism of important reactions, summary of esterification and ester hydrolysis. **(5L)**
(Ref.2,3,4,5,6,9)

References:

1. Carey and Sundberg, (Ed.III), Part B- Adv. Organic Chemistry
2. H.O. House, Synthetic Organic Chemistry
3. Gould E.S. Mechanism and structure in Organic chemistry
4. Norman R.O.C. Organic Chemistry.
5. J. March (Ed. V) Adv. Organic Chemistry.
6. S.H. Pine, Organic Chemistry, 5th edition, McgrawHill, International Edition.
7. Some Modern methods of Organic Synthesis, W. Carruthers, Cambrige university Press, New Delhi, 2003.
8. Oxidation & Reduction in Organic Synthesis, Timothy T Donohoe, Oxford- Oxford University Press 2000.
9. Organic Chemistry, Morrison and Boyd.

Practicals:(10)

1. Ternary mixture separations. (3)
   Separation and Characterization of the three components:
   a) Solid-Solid-Solid
   b) Solid-Solid-Liquid.
   c) Solid-Liquid-Liquid.
   d) Liquid-Liquid-Liquid
2. Three stage preparations (7)
   a) Cyclohexanone-Cyclohexanone Oxime- Caprolactam.
   b) Phthalic Anhydride –Phthalimide- Anthanilic Acid.
   c) Anthranilic Acid-Phenyl Glycine-ortho carboxylic acid Indigo.
   d) Phthalic Anhydride- o-benzoyl benzoic acid- Anthraquinone.
   e) Chlorobenzene- 2,4-dinitrochlorobenzene 2,4-dinitrophenol.
   f) o-aminophenol –Schiff's base-benzoxazole.
   g) Acetopheneone.- Acetophenone oxime –Acetanilide.
   h) o-Chlorobenzoic acid - N-phenylanthranilic acid - acridone.
   i) Nitrobenzene -m-dinitrobenzene- m-nitroaniline
   j) Phenol - allylphenyl ether-+ o-allylphenol
   k) Phenol - salicylaldehyde -~ coumarin

References:

1) Vogel's text book of Practical Organic Chemistry, ELBS Publishers
2) Advanced Organic Chemistry Practicals by N.K. Vishnoi, Vikas Publishing House, 2nd revised edition.

PCC6 (Core)
Pharmaceutical Chemistry I (40L)

Drugs -Nomenclature, Classification, Naming of drugs: code number, chemical name, brand name/trade name/optical name/common name, synonyms. **(2L)**
Chemical structure and Chemoactivity of drugs (effect of various functional groups on the chemical activity of drugs). Physico-Chemical properties of Drugs affecting pharmacological action of drug (Partition Coefficient, solubility, degree of ionization, surface activity, electronic effect, steric effect, cis-trans isomers). **(2,6,7)** **(3L)**

Development of the following drugs including structure activity relationship (S.A.R.), mechanisms of action, chemical nomenclature, generic names and side effects
(Any 3 in each class) (outline of synthesis only of those marked$) (Ref.1-8)

1. **Antiseptics and Disinfectants**: Alcohols, substituted phenols, methenamine mandalate, DDT[s], p-hydroxy-benzoic acid esters, Chloramine-T, Dichloramine-T, 8-hydroxy quinoline derivatives, Acridine derivatives, Mercurials like

(Mercurochrome, Thiomersal, Nitromersal) and Nitrofurantoin derivative[s] , Bromopal, Triclosan,HalazoneS. (**3L)**

2. **Antitubercular and Antileprotic drugs** (acid fast)
Aminosalicylic acid, PAS[s], Isoniazid[s], Pyrazinamide, Ethionamide, Ethambutol[s], Streptomycin, Thiacetazone, Rifampisin, Cycloserine, Dapsone[s] and derivatives, Clofazimine and important drug combinations. **(3L)**

3. **Antimalarials**: Life cycle of parasite, drug acting on different stages- Quinine, Mefloquine, Chloroquine[s], Hydroxyquinoline, Amodiaquine, Sontoquine, Quinacrine, Primaquine, Pentaquine, Isopentaquine, Pyrimethamine, Trimethoprim, Proguanil, Cycloguanil[s], Drug combinations, Artemisine, Halofantrine. (**3L)**

4. **Antiamoebics**: General aspect of infection, Life cycle of parasite, Hydroxyl quinolines, Metronidazole[s], Tinidazole[s], Diloxanide[s], Lucanthone, Hycanthone, Emetin, Dehydremetin, Secnidazole, Quinfamide. (**3L)**

5.**Anthelmentics**:Piperazine, Diethycarbamazine, Antimony compounds, Stilbophen[s], Niridazole, Lucanthone, Hydrolucanthone, Niclosamide, Mebendazole[s], Thiabendazole, Ivermectin, Tetramisol, Pyrantel pamoate, Praziquantel[s], Oxamniqine. (**3L)**

6. **Antitrypanosomiacs**: Suramin[s], arsenicals, nitroheterocyclics and pentamidine. (**1L)**

7.**Antifungal**:Antibiotics like Griseofulvin, Amphotericin, Nystatin, Tolnaflate[s],Flucytosine, Ciclopirox, Clotrimazole[s], Miconazole. (**2L)**

8.**Antivirals including drugs acting on HIV**: Idoxuridines[s], Vidarabine, Amantadine Hydrochloride[s], Methisazone, Interferon, Enviroxime, AZT, Acylclovir[s], Cytarabine. (**3L)**

9.**Antineoplastics**: Methotrexate, 6-Mercaptopurine[s], 6-Thioguanine, Cytarbine, 5-fluorouracil[s], Dacarbazine, Mechlorethamine, Thiotepa, Chlorombucil[s], Procarbazine, Mithramycin, Bleomycin, Doxorubicin, Vinblastine, Vincristine, Taxol, Cisplatin, Cyclophosphamide[s], Tamoxifen. (**2L)**

10. **Sulfonamides and other antifolics**: Sulfonamides and other para-aminobenzoic acid antagonist, Sulfacetamide, Sulfamerazines, Sulfathiazole[s], Sulfaguanidine, Sulfamethoxazole[s], Trimethoprim[s] and related products Sulfadimethoxine, Pthalyl sulphathiazole, Sulfadimidine. (**2L)**

11. **Newer antibacterial agents**: Quinoline carboxylic acids such as Ciprafloxacin, Temafloxacin. (**1L)**

12.**Hypoglycemics**:Insulin and various sulfonyl ureas like tolbutamide,Chlorpropamide, Tolazamide[s] ,Azepinamide, Phenformin[s], Glipizide[s], Biguanidines,Glyburide, Synthetic sweeteners. **(1L)**

13. **Diagnostic agents**
Inorganic compounds- Iodoxyl[s], Iodipamide, Iopanoic acid, Diatrizoic acid,Sodiumlipodate, Iodophendylate. **(1L)**
Dyes- Rose Bengal, Fluorescein, Phenolsulfopthalein, Bromosulfopthalein, Aminohippuric acid, Indigocarmine, Congo red, Evans blue[s]. **(1L)**

14. **Anticoagulants:**
Heparin, Coumarin derivatives like warfarin, Dicoumarol, Fenflucoumarin. **(1L)**

15. **Antilipidemics:synthesis** and S.A.R. of Clofibrate[s], Nicotinic acid, Boxidine[s], cholesterol lowering agents. **(1L)**

16.**Diuretics**: Acid forming osmatic diuretics, Mercurials – Meralurides, Mercurophylline[s], Chloromerodin, Sulfonamides – Acetazolamide[s], Methezolamide, Dichlorphenamide[s], Benzothiadiazones – Chlorthiazide[s], Hydrochlorthiazide, Benzthiazide, Flumethiazide and others like Spironolactone, Ethacrynic acid. **(2L)**

17.**Local anaesthetics**: Cocaine, Ecgonine, Benzocaine[s], Procaine[s] Teracaine, Lidocaine, Tetrodotoxin. **(1L)**

18. **Purgatives and cathartics**: Phenolphthalein, Bisacodyl, Paraffins, Castor oil. **(1L)**

References:

1) Foye's principles of medicinal chemistry, 5th edition, David A. Williams and Thomas L. Lemke, Lippincott Williams and Wilkins.

2) Medicinal Chemistry (Organic Pharmaceutical Chemistry),

G.R Chatwal, Himalaya Publishing house.

3) Wilson & Gisvold; Text book of Medicinal Chemistry, Philadelphia Williams & Lippinctt Wilkins.

4) Burger, Medicinal Chemistry (John Wiley & Sons N.Y).

5) Medicinal Chemistry, D. Shriram, P. Yogeshwari, Pearson Education.
6) Textbook of Pharmaceutical Chemistry by ,Jayshree Ghosh, S. Chand & company Ltd.

7) Pharmaceutical Chemistry by Dr. S. Lakshmi, Sultanchand & Sons.
8) Drug Synthesis by Gogte

Practicals (10)

1) IP Monograph of important drugs and excipients (min. 3 including excipients)

2) Assay of drugs official in various pharmacopoeias (Any 4). This should cover titrimetric, spectro-photometric (including flamephotometric) methods, HPLC etc. The titrimetric methods should include conductometric, and potentiometric end-point determination.

References

Indian Pharmacopoeia/British Pharmacopoeia/ United States Pharamacopoea.

PCE8

Pharmaceutical Stability Program, Statistics and Management (50L)

Pharmaceutical Stability Program : Basic concept and objectives of stability study . Fundamentals of stability testing requirements. Basic concept and objectives of stability study.- Order of reaction and their applications in predicting shelf life and half-life of Pharmaceutical formulations.- Review ICH process and ICH updates on stability Common terminology and acronyms Review current Q1A, Q1B, Q1D, Q1F, Q2, Q3 and Q6 guidelines Determine stability requirements for OTC products Stability SOPs Stability protocols and data Design of a compliant bracketing and matrixing ICH guidelines on bracketing and matrixing Stability testing laboratory Design and validation stability test procedures Stability data management system Investigation procedures of OOS stability results FDA inspection of stability labs. **(Ref.1-4)** (**20L)**

Pharmaceutical Statistics: Importance of statistics, biostatistics? Application of following topics of statistics in biological and pharmaceutical sciences. Mean, Median and Mode, Standard Deviation and Coefficient of variation, Students t-test, One way ANOVA, Chi-square test, Probability, Frequency distribution, Regression analysis, Bioavailability – Cross-over study, Wilcoxon signed rank test, Introduction to control charts. Analysis of variance: One-way classification, two-way classification, partitioning of sign of squares and degrees of freedom. Multiple compression tests such as LSD. The analysis of variance models. FDA requirements for OOS (Out of specification) results and how to best investigate OOS results, Confidence intervals and tolerance intervals, Statistical Process Control (SPC), Control charts, Statistically sound sampling plan, Relationship between sample size, statistical precision, and statistical power. **(Ref.5,6)** (**20L)**

Pharmaceutical Management: Nature and Principles of Management, Planning, decision making, Organising-Authority, Responsibilities, Hierarchy, Directing: Controlling: Leadership (Qualities, Group dynamics): Motivation (Financial and Non-financial, x and y theory, Z theory, Morale): Financial Management (Sources): Marketing Management (Marketing Mix): Human Resource Management: Cost Accounting (Principles, cost-sheet)-Office management**:(Ref.7-9)** **(10L)**

References:

1) J.T.Carstensen, "Drug Stability: Principles & Practices", Drugs & Pharm Sci. series ,Vol 43, Marcel Dekker Inc., N.Y.
2) Modern Pharmaceutics by G. S. Banker.
3) Stability of drugs & dosage forms- Sumie Yoshika & Valenino,J-Stella Springer International edition.
4) Drug stability, revised and expanded, 3rd edition, Jens T. Carstensen, Informa HealthCare.
5) Pharmaceutical Statistics by Stds Boldon , Marcel Dekker Inc.
6) Basics Statistics & Pharmaceutical Statistical applications by James E. De Muth , Marcel Dekker Inc.
7) Pharmaceutical Management, Vidya Sagar, Pharma Book Syndicate.
8) Management, Kotler, Wiley Publishers.
9) Pharmaceutical Project Management, 2nd Edn, Anthony Kennedy, Informa Health Care.

PCE9

Synthetic Methods in Organic Chemistry (50L)

1) Introduction to Chemistry of Enolates: Preparation and Properties, E/Z-nomenclature in enolate formation**.** **(Ref.1-3)** **(4L)**
2) Alkylation of reactive acidic methylene groups. Dianions in synthesis, O-alkylation vs C-alkylation and electrophilic reagents. Stork Enamine alkylation reactions and asymmetric enamine synthesis. **(Ref.1-3,6)** **(3L)**
3) The application of the following condensation reactions in organic synthesis: The Aldol reaction, Mukaiyama reaction, Claisen reaction, Perkin reaction, Diekmann Condensation, Knoevanagel condensation and Doebner Condensation. Stobbe Condensation, Darzens Glycidic ester condensation, Michael Addition, Robinson Annulation, Sakurai reaction. **(Ref.7,9,13)** **(7L)**
4) **Important reagents in Organic Synthesis**: N-Bromo Succinimide, Selenium dioxide, lithium diisopropylamide, osmium tetraoxide, dicyclohexylcarbodiimide, periodic acid, lead tetracetate,DDQ,DMSO**.** . **(Ref.2,3,5,7,13)** **(5L)**
5) **Synthetic Utility of the following Name reactions**: Mannich , Hofmann-Loffler-Freytag, Sharpless asymmetric epoxidation, Nef, Mitsunobu, Intramolecular Friedal Crafts Cyclisation, Olefin Metathesis and dihydroxylation **(Ref.7,9)** **(8L)**
6) **The Chemistry of Ylides**: Phosphorus, Sulfur and Nitrogen, Their preparation, Wittig reaction, mechanism and stereochemistry, Peterson olefination, Stevens and Sommelet rearrangement. **(Ref.7,9)** **(4L)**
7) **Retrosynthetic Analysis**: The disconnection approach, Synthesis of target molecules. **Synthone approach** Definition, terms and abbreviation, rules and guidelines used in synthesis of following drugs. (Any 3) Rosiglitazone, Trimethoprim, Terfenadine, Ibuprofen, Fentanyl, Midazolam, Ciprofloxacine, Captopril, Diclofenac, Losartan. **(Ref.14-15,21)** **(7L)**
8) **Protecting groups in Organic Synthesis**: Introduction and the need for protecting groups in synthesis. Protecting groups for important functional groups. **(Ref.1,7,14)** **(4L)**

9) **Modern techniques in Organic synthesis**: **Green Chemistry:** Water as solvent, ionic liquids, supercritical liquids, Supported reagents and catalysts, Solvent free reactions, activation by Microwave, Ultrasound etc. Using Phase transfer catalysts for synthesis. Mechanism of PTC. Advantages and applications in Organic Synthesis. Polymer supported reagents- Introduction, advantages and applications. Microwave assisted synthesis.
(Ref.5, 8,16-20) **(8L)**

References:

1) Advanced Organic Chemistry-Reaction Mechanisms, R. Bruckner, Harcourt, Aca.Press, 2002.
2) Organic Syntheses, M.B. Smith, McGraw Hill, International Edn, New York, Press, new Delhi, 2003.
3) Organic Synthesis-Concepts, Methods, Starting Materials, J. Fuhrhop and G. Penxlin, VCH Publishers, 1994.
4) Some Modern methods of Organic Synthesis, W. Carruthers, cambrige university Press, New Delhi, 2003.
5) Organic Synthesis-Special Techniques, V.K. Ahluwalia and R. Aggarwal, Narosa Publishing House, New Delhi, 2001.
6) Stereoselective synthesis, M. Nogradi, VCH Publisher, Inc. New York, 1994.
7) Modern Synthetic Reactions, H.O. House, W.A. Benjamin, New York.
8) Phase Transfer Catalysis, Waber and Gokel, springer-verlag, 1977.
9) Named Organic Reactions, T. Laue and A. Plagens, John Wiley, 2005.
10) Norman, Principles of Organic Chemistry, Carey and Sundberg, Organic Chemistry Part A & B.
12) Beuhler and Pearson – Organic Chemistry – Part A & B.
13) Sykes- A Guidebook to Mechanism in Organic Chemistry.
14) Stuart Warren – Organic Synthesis – The Disconnection Approach (John Wiley & Sons).
15) Ledinicer, Organic Drug Synthesis Vol 1,2,3,4,(John Wiley & sons N.Y).
16) Kappe, C. O. & Stadler, A. Microwaves in Organic and Medicinal Chemistry (Wiley-VCH,Weinheim) **2005**
17) New trends in Green Chemistry, V.K.Ahluwalia and M.Kidwai, Kluwer Academic Publishers.
18) Methods and Reagents for Green Chemistry: An Introduction, Pietro Tundo (Editor), Alvise Perosa, Fulvio Zecchini, ISBN
19) Green Chemistry Theory & Practice by Paul T. Anastas and John C. Warner.
20) Organic Chemistry Laboratory standard & Microscale experiments, Bell C.E. Clark, Taber D. F. Rodig O.R, Saunders College Publishing Philadelphia 2nh edition 1997.
21) Drug Synthesis by Gogte.

PCE10

Basic Fundamentals in Clinical Trials (50L)

(Ref. 1-7)

Introduction to clinical Trial

History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments. (**4L)**

Regulatory affairs in clinical trials

IND, NDA, ANDA- Parts and contents, Safety monitory boards, FDA in various countries including India. (**5L)**

Ethical issues in clinical trials

Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report. (**4L)**

Clinical trial design

Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls. (**10L)**

Clinical trial protocol Development

Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial. (**5L)**

Good Clinical Practice

Concept, importance, and GCP guidelines including ICH guidelines. (**5L)**

Management of Clinical trials

Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials. (**8L)**

Bioavailability, bioequivalence and Therapeutic Drug Monitoring

Concept, organization, advantages, special issues, applications, bioequivalence. (**4L)**

Data analysis issues in Clinical Trials

Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials. (**5L)**

References:

1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc Graw-Hill
3. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
6. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York.
7. WHO guidelines,US FDA guidelines (Web sources)

PCE11 Pharmaceutical Plant Design and Operations (50L)

Regulatory requirements of Pharma facilities with reference to cGMP, revised schedule M and Factory Act. (**8L)**

Design, layout and operational facilities with services and utilities for Tablets, Capsules, Liquid orals, Ointments and Dry syrups. (**8L)**

Design, layout and operational facilities with services and utilities for sterile products powders ready for reconstitution. (**8L)**

Design and operation of Q.C. Laboratory (**6L)**

Design of utility services - Water - stream- Compressed air and other gases (**5L)**

Design of effluent treatment plant (**5L)**

Designing of plant support services like security office, vehicle parking, fuel storage, canteen and cooking, garden and horticulture, scrap yards, Administrative block and training centre, sports and entertainment block, resident managers bungalow, residences for essential service staff, toilet facilities, medical services, crush. (**10L)**

References:

1. Project Management by Clifford F. Gray and Erik W. Larson Publisher: McGraw Hill company.
2. Pharmaceutical Production facilities: Design and applications by Graham Cole. Publisher: Taylor & Francis
3. Production/Operations Management by: El wood Bufa Publisher: Wiley Eastern Limited (New Delhi)
4. S. J. Turco; Sterile Dosage Forms: their Preparation and Clinical Applications; Lee and Febiger.
5. N. K. Jain; Controlled and novel drug delivery: CBS Publication.
6. J. R. Robinson and H. L. Lee; Controlled Drug Delivery: Fundamentals and Applications; Marcel Dekker.
7. F.J. Carleton and J.P.Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.
8. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.
9. N.A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.
10. Planning and control by: Samuel Eilon Publisher: Universal book corporation, Mumbai.

Semester IV

PCC7

Analytical Techniques II (40L)

Instrumental analytical techniques: Theory and principle, operation, calibration, interpretation of results, applications of following analytical instrumental techniques.

Spectroscopy:Ultra-violet-visible, infra-Red, near Infrared,Nuclear magnetic Resonance, Microwave. **Mass Spectrometry, Atomic absorption spectrometry (Ref. 1-5,7-9,11-12,14-15) (12L)**

Chromatography: Thin layer chromatography, High performance liquid chromatography, gas liquid chromatography, gas chromatography, hptlc, **(12L)**

(Ref.1-4, 6-9,13,16,18)

Potentiometry, polarography, amperometry, coulometry conductometry, refractometry, Fluorimetry, X-ray Crystallography, flame photometry. **(10L)**

(Ref.1-4,7-9)

Analytical method development, demonstration of use of statistical treatment for validation of analytical method by titrimetric method The applications of techniques in the identification of bulk pharmaceuticals, detection of impurities and quality assurance, structural elucidation and drug regulation**.** **(Ref.7,10,16,17) (6L)**

References:

1) John of Kennedy, Principle of analytical Chemistry. 2nd edition, Saunders college Publishing ,1990, New York.

2) J. W. Munson, pharmaceutical Analysis , Modern methods Part A &B, 2001, Marcel Dekker.

3) Principles of Instrumental analysis : A. Skoog, James, 5th edition, Saunders college Publishing.

4) Analytical Chemistry by Gary Christian ,6th edition, Wiley Publishing House.

5) Spectrometric identification of organic compounds: Robert M. Silverstein et al,4th edition 1981, John & Wiley Sons.

6) Chromatographic Analysis of Pharmaceutical , John A. Adamovics, 2nd edition.

7) Practical Pharmaceutical chemistry Part II : A.H. Beckett , J. B. Stenlake, (4th Edition), CBS Publishers Ltd.

8) Instrumental method of Chemical analysis : G. R. Chatwal, Himalaya Publishers Ltd.

9) Instrumental method of Analysis : Hubert H ., Willard ,7th edition.

CBS Publishers.

10) Indian Pharmacopoeia, British Pharmacopoeia.

11) Spectroscopy of Organic Compounds : P.S. Kalsi, New

Age International (P), Ltd. Publishers.

12) Organic Spectroscopy : William Kemp.ELBS, McMillan London 1991.

13) Techniques and Practice of Chromatography : Raymond P.W. Scott,

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14) Fundamentals of molecular spectroscopy 4th edition , C.N & E.M. Mckash ,Tata McGraw Hill.
15) Spectroscopic Methods in organic Chemistry 4th edition, D.H Williams & I- Fleming, McGraw Hill,NY 1989
16) HPLC in pharmaceutical industry, Stanley K. Lam, CRC Press.
17) Determination of Pharmaceutical formulation by P. D. Shethi.
18) Chromatographic analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition, Revised and expanded, Marcel Dekker.

Practicals (10)

(i) Determination of the velocity constant, order of the reaction and energy of activation for saponification of ethyl acetate by sodium hydroxide conductometrically.
(ii) Determination of solubility and solubility product of sparingly soluble salts (e.g. $PbSO_4$, $BaSO_4$) conductometrically.
(iii) Determination of strength of strong and weak acids in a given mixture conductometrically.
(iv) Determination of strengths of halides in a mixture potentiometrically.
(v) Assay of Dextrose Injection by polarimetry as per I.P. 1996.
(vi) Spectrophotometric determination of paracetamol in the tablet.
(vii) Determination and interpretation of IR/FTIR spectra of some pharmaceutical drugs. (two Drugs).
(viii) Determination of Na^+ and K^+ by flame photometry.
(ix) Separation of 2,4-dinitrophenylhydrazones by column chromatography.
(x) HPLC Analysis- Analysis of Analgesics in a commercial sample/tablet. Ibuprofen,
(xi) To determine the refractive indices of glycerin-water mixtures.
(xii) Determination of Vitamin B12 (Riboflavin) by Fluorimetry.
(xiii) Identification of Drugs and Impurities by TLC/HPTLC (Two Exp.)
(xiv) Determination of ephedrine hydrochloride in cough syrup at 225nm.
(xv) Determination of commercial Digitoxin at 490nm.
(xvi) Solvent extraction of Al / Mo using 8-hydroxy quinoline complex and determination by spectrophotometry.

(xvii) Separation and estimation of Fe and Al on a cation exchanger.
(xviii) Solvent extraction of ferric thiocyanate complex and determination by colorimetry.
(xix) To develop and validate the UV spectroscopic analytical method of any one drug.
(xx) To develop and validate the analytical method of any one drug using high performance liquid chromatography.

References: 1) K.A. Connors: Text book of pharmaceutical analysis,

3rd edition , Wiley- interscience Publication 1999.

2) Practical TLC by P. D. Shethi.

3) Practical HPLC by P. D. Shethi.

4) I.P., USP, B.P. European Pharmacopoeia.
5) Practical Pharmaceutical chemistry PartII:A.H.Beckett, J. B. Stenlake, (4th Edition), CBS Publishers Ltd.
6) Vogel's Textbook of Quantitative Analysis, 6th Edition, ELBS.
7) Post-graduate Chemistry Practicals- S.S.Kelker, H.N.Patel, S.P. Turakhia, A.G. Gadre, Himalaya Publishing House.

PCC8
Pharmaceutical Chemistry II (40L)

(4L)

Introduction to drug design. Drug design and QSAR,Drug/Drug interaction Chemistry Aspects, Drug evaluation (Long term use bioavailability social effect).

The following classes of drugs to be discussed in relation to a) Introduction to the rational development (if any) of the drugs including the principle of isosterism b) Mechanism of action c) Synthesis of some specific compounds d) Structure activity relationship e) Generic names f) Chemical nomenclature g) Prodrug concept h) Classification of drugs.(selected from below)

1) **Drugs acting on cholinergic nervous system**: Bethanechol, Carbachol, Methacholine, Neostigmine, Pyridostigmine, Demecarium, Physostigmine, Ambenonium chloride, Echothiophate iodide, Isofluorophate, Parathion, Paraoxon, Malathion, Pralidoxine, Atropine, Scopolamine, Hyoscyamine, Homotropine, Dicyclomine, Cyclopentolate, Tropicamide, Papaverine, Mecamylamine, Trimetaphan, Piperidolate, Hexamethonium chloride, Pentolinium tartarate, d-Tubocurarine chloride, Succinyl choline chloride, Endophonium bromide. (**4L)**

2) a] **Drugs acting on adrenergic nervous system**: Methyldopa, methyl-L-tyrosine, Guanethidine, Reserpine, Ephedrine, Phenylpropanolmine, amphetamine, Propylhexedrine, Tranylcypromine, Pragyline, Norepinephrine, Epinephrine, Tolazoline, Phentolamine, Pronetalol, Sotalol, Propanalol, Oxyprenalol, Practalol, Butaxamine, Atenolol, Labetalol, Metoprolol.

b] **General Anaesthetics**: Ether, Nitrous oxide, Halothane, Ultra short acting Barbiturates.

c] Hypotensive agents acting on vascular smooth muscles: Nitrites, Amylnitrites, Glyceryl nitrite, Sodium nitrite, Erythratyl tetranitrite, Mannitol tetranitrate, Pentaerytritol tetranitrate, Isosorbide mononitrate, Isosorbide dinitrate. (**5L)**

3) **Drugs acting on the central nervous system**:
   a] Hypnotics and sedatives: Chloral hydrate, Ethinamate, Glutethimide, Phenbarbital, Talbutal, Pentobarbital, Secobarbital, Hexobarbital, Thiopental, Nitrazepam, Bromozepam, Temazepam, Midazolam.
   b] Drugs acting as anticonvulsants: Phanytoin/Cimromide, Mephenytoin, phenacemide, Trimethadione, Paramethadione, Clonazepam, Phensuximide, Ethosuximide, Phenobarbital, Mephobarbital, (Classification of Barbiturates), Metharbital, Primidone, Carbamezepine, Sodium valproate.
   c] Psychotherapeutic agents: Phenothiazines such as Chloropromazine, Triflupromazine, Fluphenazine, Chlorodiazepoxide, Flurazepam, Oxazepam, Diazepam, Meprobamate, Aluronium, Imipramine, Desipramine, Amitriptyline, Nortriptyline, Doxepin, Phenelzine,Nialamide, Tranylcypromine, Pargyline, Fluoxetine, Loxapine, Molindone, Pimozide, amzenil.
   d] CNS stimulans: Phenmetrazine, Phendimetrazide, Fenfluramine, Phenidate, Nikethamide, Iproniazide, Picrotoxines, Tetrazole, Hydrazine derivatives (5 only), Amphetamine, Methamphetamine. (**8L)**

4) **Antihistaminics and antiemitics and antiulcer drugs**: Metoclopramide, Diphendydramine, Cinnarizine, Flumarizine, Doxylamine, Carbenoxamine, Triprolidine, Chloropheniramine, Methapyrilene, Cyclizine, Meclizine, Promethazine, Trimeprazine, Antazoline, Cyproheptdine, Terfenanadine, Domopeidone, Cimetidine, Omeprazole, Ranitidine, Fomatidine, Sumatriptan, Ondisitron. (**2L)**

5) **Cardivascular drugs and antihypertensive including antiarrythemic agents**, **calcium channel blockers**: Lanatosides ,B, C+, C. Strophanthin, Citoxin, Digoxin, Quinidine, Procainamide, Nifedepine, Amlodipine, Verapamil. Antihypertensive agents which elicit their action through autonomous nervous system previously described under 1 and 2, clonidine, diazoxide, hydralazine, ACE inhibitors- Enalapril and related drugs vasodialators such as Amyl nitrate, Nitroglycerine, Isoxsuprine, Nylidrin, Sodium nitroprusside. (**2L)**

6) **Vitamins: Water soluble vitamins and oil (fat) soluble vitamins** – Vitamin A, B1, B2, B6, B12, folic acid, Niacinamide, Vitamin C, Biotin, Vitamin K, Vitamin D, Vitamin E, Vitamine H1 (**2L)**

7) **Steroids**: a] Classification of steroids, configuration and conformation. b] Adrenocorticoids: Cortisol, Hydrocortisone acetate, Fludrocortisone acetate, Metamethasone, Triamcinolone, Methylprednilsolone, Dexmethasone,

Flucinolone acetonide, Prednisone, Predinosolone. c] Androgens and anabolic steroids: Testosterone, Fluoxymestrone d] Estrogens: Ethinyl, Estradiol, Mestranol, Chlorotrainsene, Estrone, Dienesterol, Diethylstilbestrol and other non-steroidal estrogens. e] Progestational agents: Progesterone, Norethindrone, Norgestrel, Imithisterone, f] Introduction into a steroid molecule the following functional groups: i) 17 alpha-fluro-11-beta hydroxy ii) 17-alpha-ethynl and 17 beta methyl iii) 16-alpha 17-beta acetonide g] Oral contraceptives h] Miscellaneous steroids: Fusidic acid,spironolactone etc. (**3L)**

8) **Analgesics, antipyretics and anti-inflammatory agents**: Aspirin, Sodium salicylate, Acetaminophen, Phenacetin, Phenylbutazone, Oxyphenabutazone, Ibuprofen, Indac, Naproxen, Colebieine, Probencid, Allopurinol, Ketorolac, Ketoprofen, Profen, Diclofenac, Oxycams like Piroxicam, Nimusulide. (**2L)**

9) **Narcotic analgesic agents**: Morphine, Oripavine, Codeine, Ethyl morphine, Hydroxycolenone, Metopan, Levarphanol, Dextromethorphan, Meperidine, Anileridine, Methadone, brief concepts, introduction to receptor outline of conformation of morphine and its relation to conformation of synthetic agents like Methadone, Meperidine, Dextropropoxyphene, Pentazocine. **(2L)**

10) **Non-narcotic analgesic agents**: Dextropropoxyphene and Ehtoheptarine, morphine antagonist n-allyl-nor morphine, Levellorphan, Nalxone. **(1L)**

11) Drugs used in Parkinsonism: Benzotronine mesylate, Procyclidine, Orphendine hydrochloride, Ethopropazine, Levodopa, Carbidopa, Beneerazide, Amantadine hydrochloride. **(1L)**

12) Drugs for Alzeimer's diseases: Serine, Velnacrine, Aniracetam, Sibopiridine. (**1L)**

13) Antibiotics: Penicillin and semisynthetic pencillins and Cepholosporins picillin,Amoxicillin, Cloxacillin, Dicloxacillin, Streptomycin, dehydrostreptomycin, Chloromphenicol, Tetracycline and derivatives, Erythromycin, photericin, Gentamycin, third generation antibiotics, Llavulanic acid. (**2L)**

14) Information in brief about new drug molecules. (**1L)**

References:

1) Foye's principles of medicinal chemistry, 5th edition, David A. Williams and Thomas L. Lemke, Lippincott Williams and Wilkins.

2) Medicinal Chemistry (Organic Pharmaceutical Chemistry),

G.R Chatwal, Himalaya Publishing house.

3) Wilson & Gisvold; Text book of Medicinal Chemistry, Philadelphia Williams & Lippinctt Wilkins.

4) Burger, Medicinal Chemistry (John Wiley & Sons N.Y).

5) Medicinal Chemistry, D. Shriram, P. Yogeshwari, Pearson Education.

. 6) Organic Chemistry of Drug synthesis-D Lednicer and L.A. Mitcher

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7) Drug of today, Drugs of future (Journal).

8). Principles of Medicinal Chemistry- Foye

9). Medicinal Chemistry-Burger.

10)Textbook of Pharmaceutical Chemistry by ,Jayshree Ghosh, S. Chand & company Ltd.

11)Pharmaceutical Chemistry by Dr. S. Lakshmi, Sultanchand & Sons.

Practicals: (10)

Synthesis of the few drugs.(Aspirin, Benzocaine, Lidocaine, Dilantin, Phenacetin, Paracetamol, Isoniazide, p-aminosalicylic acid, dicoumarol, Mefenamic acid, Hippuric acid)

References:

1) Organic Chemistry of Drug synthesis-D Lednicer and L.A. Mitcher

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2) Drug of today, Drugs of future (Journal).
3) Medicinal Chemistry, D. Shriram, P. Yogeshwari, Pearson Education.
4) IP, BP.
5) Vogel's Practical Texbook of Pharmaceutical and Medicinal Chemistry.

PCC9: Industrial training/equivalent project work in the institution

PCE12

Fundamentals in Ouality Assurance (50L)

Good documentation practices and technical writing, Drug Product approval, SOPs and BMRs: **(Ref.1-4) 25L**

Importance of documentation - a regulatory requirement Role, objective, and importance of Standard Operating Procedures (SOPs) Use of SOPs in the pharmaceutical industry. Application and role of corporate policies Role and application of technical guidelines. Role and objectives of analytical reports. Manufacturing and Packaging documents. Role, objective, and importance of

Certificate of Analysis (CofA), Certificate of Manufacturing (CofM), and Certificate of Packaging (CofP) Objective and importance of incident reports, Change control reports - their purpose and function, Stability process Investigation reports, Notice of change Regulations governing electronic records.

Calibration and Validation :(Ref.5-8) 25L

Validation and calibration of various instruments used for drug analysis such as UV-Visible Spectrophotometer, IR Spectrophotometer, Spectrofluorimeter, HPLC, HPTLC and GC. Regulatory requirements for analytical method validation International conference on harmonization (ICH) guideline Q2A: Validation of analytical procedures Linearity and range criteria and their role in instrumental method validation Detailed discussion on accuracy and precision role in the method validation Role of quantification limit and specificity -Limit of Detection (LOD) and Limit of Quantification (LOQ) Robustness & method validation Ruggedness of chromatographic method Ruggedness of sample preparation procedure Complete method validation package, analytical data, protocol, plan, revisions, and change controls. Overview of qualification of some instruments. Overview of installation, operation, and performance qualification (IQ, OQ, PQ) of analytical equipment.

References:

1) Lachman "The theory and practice of industrial pharmacy edition
2) Web resources in Pharmacy, In Pharma Publication , Bangalore
3) Schedule M"
4) WHOguideline
5) Michael E. Swartz, Analytical method development & validation.

6) Pharmaceutical Process Validation by Loftus & Nash.

7) Vogel textbook of quantitative chemical analysis.6th edition., J Mendham, RC Denny, JD banes, Thomas. ELBS.

8) Pharmaceutical Process Validation by Alfred H. Wachter, Informa Health care.

PCE13 <u>Polymers in Pharmaceuticals and novel drug delivery systems (50L)</u>

Classification, General methods of synthesis, properties, characterization and evaluation: Biodegradable polymers - Classification - Mechanism of biodegradation in the body. Polymer processing with respect to novel formulation design: Applications of polymers in novel drug delivery systems, Medical prosthetics and packaging. Classification- Indroduction, Types, characteristics, evaluation ,properties, Biodegradable polymers, non-biodegradable. Pharmaceutical application, Product formulation & design, Packaging case studies.
(Ref.1-10) (25L)

Introduction to Novel Drug delivery systems, drug delivery carriers, routes of administration, Recent advances in drug delivery systems. Theory of controlled release drug delivery systems. Microencapsulation – Methods of encapsulation.

Transdermal drug delivery systems – Theory, formulation, production and evaluation. Targetted drug delivery systems – concept of drug targeting, importance in therapeutics; Recent innovations in conventional dosage form like tablets, capsules, sterile dosage forms, pellets, Mucoadhesive system, GRDDS, peptide drug delivery, supercritical fluid technique, PEGylation, Nanoparticulate drug delivery. Future opportunities and challenges. **(Ref.3, 11-13)** **(25L)**

References:

1) U.S.Beans, A.K. Beckett & J.E.Caralem "Advances in Pharm Sci" Vol 1-4.

2) Modern Pharmaceutics By G.S. Banker.

3) Lisbeth Lliun & Stanley S Davis " Polymer in controlled drugs delivery" , Wright,Bristol (1987)

4) Analysis of polymer- An Introduction, J.R .Crompton, Pergamon Press, Oxford 1989.
5) Polymer Chemistry An Introduction, Malcolm P. Steven Publised New York, Oxford, Oxford University Press, 1990.
6) Biodegradable polymers as drug delivery systems-M. Charin, Informa HealthCare.

7) Practical Pharmaceutical Chemistry Vol I &II by Beckett and Stenlake, CBS Publishers Ltd.
8) Physical Pharmacy and Pharmaceutical Sciences by Martins, Patrick J. Sinko, Lippincott. William and Wilkins.
9) Cooper and Gunn's Tutorial Pharmacy ,6^{th} edition by S.J. Carter, CBS Publisher Ltd.
10) Indian Pharmacopoeia, British Pharmacopoeia.
11) J.R.Robinson and Vincent H.L. Lee, Controlled Drug Delivery, Drugs and Pharm. Sci. Series, Vol. 29, Marcel Dekker Inc. N.y.
12) J.R.Juliano, Drug Delivery Systems Oxford University Press, Oxford, 1980.
13) M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.