PONDICHERRY UNIVERSITY
Puducherry – 605 014.

BACHELOR OF PHARMACY [LATERAL ENTRY]
* B.PHARM. (LE) *

SYLLABUS AND REGULATIONS

2007 -08
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** * **
I. SHORT TITLE AND COMMENCEMENT

These regulations shall be called “THE REGULATIONS FOR THE BACHELOR OF PHARMACY (LATERAL ENTRY) DEGREE COURSE OF PONDICHERRY UNIVERSITY, Puducherry”.

They shall come into force from the academic year 2007-2008 session.

The regulation and syllabi are subject to modifications by the standing Under Graduate Board of Studies for paramedical courses from time to time.

II. REGULATIONS

1. ELIGIBILITY FOR ADMISSION:

Students who have acquired a Diploma in Pharmacy from Pharmacy Council of India recognized institutions and who are registered Pharmacist in any of the State Pharmacy Council are eligible for lateral entry to Pharmacy Degree programme.

2. DURATION OF THE COURSE AND COURSE OF STUDY:

a. The period of certified study and training of the B.Pharm. (LE) degree course shall be of Three academic years.

b. The candidates selected for B.Pharm.(LE) shall be admitted directly into II year of B.Pharm. (Regular System). The course of study of B.Pharm. (LE) will be six Semesters i.e. from III Semester to VIII Semester.

3. MEDIUM OF INSTRUCTION:

English shall be the medium of instruction for all the subjects of study and for examinations of the Course.

4. MINIMUM WORKING DAYS IN AN ACADEMIC YEAR:

Each academic year shall consist of not less than 180 working days (Minimum 90 working days per semester).
5. **REGISTRATION:**

A Candidate admitted into B.Pharm. (Lateral Entry) Degree course in any one of the affiliated institutions of the PONDICHERRY UNIVERSITY, Puducherry shall submit the prescribed application form for registration duly filled along with prescribed fee and declaration in the format, to the Academic Officer of this University through the affiliated institution within 60 days from the cut-off date prescribed for admission.

6. **ATTENDANCE REQUIRED FOR APPEARING EXAMINATION:**

   a) Examination will be conducted in both theory and practical as prescribed. Candidates will be permitted to appear for the University Examinations in the subject, only if they secure not less than 80% of attendance in each subject of the respective semester/year.

   b) A student who does not meet the minimum attendance requirement in a semester or year must repeat the course along with the next batch of students.

7. **CONDONATION FOR LACK OF ATTENDANCE:**

Condonation of shortage of attendance in aggregate up to 10% (between 70% and 80%) in each semester may be granted by the College Academic Committee and as per the regulations of University.

8. **INTERNAL ASSESSMENT:**

Internal assessment will be done in each subject of study and the marks will be awarded to the candidates as detailed in the scheme of examinations. The marks awarded will be on the basis of the candidate’s performance in the assignments, class tests, laboratory work, preparation and presentation of seminars as assessed by the teachers.

9. **EXAMINATIONS:**

The University Examinations will be conducted in the semester pattern for all the three years, each year consisting of two semesters.

The particulars of subjects for various examinations and distribution of marks are detailed in the Table II.

The examination for the main subjects will be conducted by the University and the marks for the non-examination subjects will be awarded by the subject handling faculty and forwarded to University by the concerned college.

The Pondicherry University practical examinations shall be jointly conducted by one internal and one external examiner duly appointed by the University.
10. **ELIGIBILITY / MAXIMUM DURATION FOR THE AWARD OF THE DEGREE:**

The candidates shall be eligible for the Degree of Bachelor of Pharmacy (Lateral Entry) when they have undergone the prescribed course of study for a period of not less than three years in an institution approved by the University and have passed the prescribed examinations in all subjects.

The maximum period to complete the course successfully should not exceed a period of six years.

11. **MARKS QUALIFYING FOR A PASS:**

50% of marks in the University Theory examination.
50% of marks in the University Practical examination.
50% of marks in aggregate in Theory, Practical, Viva-voce examination and Internal assessment taken together.

12. **DECLARATION OF CLASS:**

- A successful candidate obtaining 75% and more marks in the grand total aggregate in the first attempt shall be declared to have passed with **Distinction**.
- A successful candidate obtaining 60% and more but less than 75% of marks in the grand total aggregate shall be declared to have passed with **First Class**.
- A successful candidate obtaining 50% and more but less than 60% of marks in the grand total aggregate shall be declared to have passed with **Second Class**.
- Ranks shall be declared on the basis of the aggregate marks obtained by a candidate in the University Examination subjects of the course. Only those candidates who have passed all the subjects in all examination in the first attempt shall be eligible for the award of **Rank**.
### III. SCHEME OF EXAMINATION

Examination Duration : 3 Hours

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<td>4.8.3 Pharmaceutical Chemistry – VIII ( Medicinal Chemistry – III ) (Theory)</td>
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<td>4.8.4 Pharmacognosy – VI (Theory)</td>
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<td>4.8.5 Pharmacology – IV ( Clinical Pharmacy &amp; Drug Interactions ) (Theory)</td>
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IV.
COURSE OF STUDY

B.PHARM. (LATERAL ENTRY)
(from III Semester to VIII Semester)

SEMESTER -III

MATHEMATICS & BIOSTATISTICS

2.3.1. Theory 4 hrs / week

1. **Algebra**: Introductions
   - Equations reducible to quadratics,
     - Simultaneous equations:
       - Linear Quadratic
     - Determinants,
     - Properties of solution of simultaneous equations by Cramer’s rule,
     - Matrices,
     - Definition of special kinds of matrices,
     - Arithmetic operations on matrices,
     - Inverse of a matrix,
   - Solution of simultaneous equations by matrices,
   - Pharmaceutical applications of:
     - Determinants
     - Matrices.
   - Evaluation of:
     - En1, En2, En3, mensuration

2. **Calculus**: Introduction

   **Differential**: Introduction
   - Limits and functions,
   - Definition of differential coefficient,
   - Differentiation of standard functions,
   - Including function of a function (Chain rule).
   - Differentiation of implicit functions,
   - Logarithmic differentiation
   - Parametric differentiation,
   - Successive differentiation.

   **Integral**: Integration as inverse of differentiation,
   - Indefinite integrals of standard forms,
   - Integration by parts,
   - Substitution
   - Partial fractions,
   - Formal evaluation of definite integrals.
1. **Biometrics**: Significant digits and rounding of numbers, Data collection, Random sampling methods Non-random sampling methods, Sample size, Data organization, Diagrammatic representation of data: 1 – Dimensional Diagram 2 – Dimensional Diagram 3 – Dimensional Diagram Measures of central tendency: Introduction Mean Median Mode

Measures of dispersion: Introduction Types of studying dispersions Standard Deviation Standard error of means, Coefficient of variation, Confidence (fiducially) limits, Probability and events, Bayes’ theorem, Probability theorems, Probability distributions, Elements of binomial distribution Poisson distribution distribution Normal distribution Normal curve and properties, Fitting of Distribution Kurtosis Skewness, Correlation analysis Regression analysis, Difference between Correlation and Regression Method of least squares, Statistical inference, Student’s t – test Student’s t- test: Difference of Mean Student’s t – test for Single Mean Paired t-test, F-test Chi test Applications of statistical concepts in Pharmaceutical Sciences
2.3.2. Theory: 4 Hours/Week

The subject of organic chemistry will be treated in its modern perspective keeping for the sake of convenience, the usual classification of organic compounds:

1. **Structure and Properties:**
   - Atomic structure, Atomic orbital,
   - Molecular orbital theory,
   - Wave equation, Molecular orbital,
   - Bonding and Antibonding orbital
   - Covalent bond, Hybrid orbital, Intermolecular forces,
   - Bond dissociation energy, Polarity of bonds, Polarity of molecules,
   - Structure and physical properties,
   - Intermolecular forces,
   - Acids
   - Bases
   - Buffers

2. **Stereochemistry:**
   - Isomerism
   - Nomenclature
   - Associated physiochemical properties,
   - Optical activity, stereoisomerism,
   - Specification of configuration, Reactions involving stereo isomers,
   - Chirality, chiral reagents conformations

3. **Structure, Nomenclature, Preparation and Reactions of:**
   - Alkanes
     - Nomenclature
     - Physical Properties
     - Chemical Properties
   - Alkenes,
     - Nomenclature
     - Physical Properties
     - Chemical Properties
   - Cycloalkanes,
   - Dienes,
     - Nomenclature
     - Physical Properties
     - Chemical Properties
   - Benzene,
     - Nomenclature
     - Physical Properties
     - Chemical Properties
Polynuclear aromatic compounds,
  Nomenclature
  Physical Properties
  Chemical Properties
Arenes,
  Nomenclature
  Physical Properties
  Chemical Properties

Alkyl halides,
  Nomenclature
  Physical & Chemical Properties
Alcohols
  Nomenclature
  Physical Properties
  Chemical Properties
Ethers,
  Nomenclature
  Physical & Chemical Properties
Epoxides,
Amines,
  Nomenclature
  Physical Properties
  Chemical Properties
Phenols,
  Nomenclature
  Physical Properties
  Chemical Properties
Aldehydes and ketones,
  Nomenclature
  Physical Properties
  Chemical Properties
Carboxylic acids, Functional derivatives of carboxylic acids,
  Nomenclature
  Physical Properties
  Chemical Properties
Reactive intermediates:–
  Carbocations,
  Carbanions,
  Carbenes,
  Nitrene and nitrenium ions
SEMESTER – III

PHARMACEUTICAL CHEMISTRY – IV
(Organic Chemistry - II)

2.3.3. Theory: 3 Hours/Week

1. **Nucleophilic aromatic substitutions:**
   - Introduction and chemistry
   - Mechanism
   - Mechanism and application
   - Alpha, Beta – unsaturated carbonyl compounds:
     - Introduction and Preparations
     - Properties and Uses
   - Conservation of orbital symmetry and rules
     - Introduction and chemistry
     - Types of reactions
   - Electrocylic, Cycloaddition
   - Sigmatropic reactions:
     - Introduction and General accepts
     - Examples and reactions
   - Neighbouring group effects;
   - Catalysis by transition metal complexes,
   - Stereoselective and stereospecific reactions;
     - Introduction and Mechanism
     - Stereoselective reactions
     - Stereospecific reactions with examples
   - New organic reagents used in drug synthesis.
     - Reagents and Application
     - Synthetic reactions

2. **Heterocyclic Compounds:**
   - Chemistry, preparations and properties of some important heterocyclics containing 3, atoms with one or two heteroatoms like O, N, S:-
     - Introduction and nomenclature
     - 3 membered heterocyclic rings preparation and properties
   - Chemistry, preparations and properties of some important heterocyclics containing 4, atoms with one or two heteroatoms like O, N, S.
   - Chemistry, preparations and properties of some important heterocyclics containing 5, atoms with one or two heteroatoms like O, N, S.
     - Chemistry preparations and properties of Pyrrole and Pyrazola
     - Furan and Thiophen
     - Imidazoles
     - Oxazoles and Thiazoles
Chemistry, preparations and properties of some important heterocyclics containing 6, atoms with one or two heteroatoms like O, N, S.

Pyridine
Pyridazine and Pyrimidine
Thiazine and oxazine
Pyran and Piperazine and others

Chemistry, preparations and properties of some important heterocyclics containing 7, atoms with one or two heteroatoms like O, N, S.

Azepines and Indoles
Benzimidazoles and Purines

3. Chemistry of lipids,
   Introduction, Properties and Identification test
   Synthesis of Lipids
   Other Chemistry of Lipids
Carbohydrates,
   Introduction, Classification, Identification
   Monosaccharides and Disaccharides
   Polysaccharides
   Synthesis
Proteins
   Introduction, Classification, and Identification
   Chemistry of Proteins
Nucleic acids
   Properties and Chemistry
   Synthesis

2.3.3 Practicals: 4 hrs/week

At least five exercises in synthesis involving various heterocyclic ring systems
An exercise involving stereoselective synthesis of a compound.
Resolution of racemic DL-alanine or any other example.
Workshop on molecular modeling of primary, secondary and tertiary structures of proteins, molecular modeling on double helical structure of nucleic acid showing hydrogen bonding.
PHARMACEUTICAL ANALYSIS - I

2.3.4. Theory 3 hrs/week

Introduction

1. **Significance of quantitative analysis in quality control**
   - Different techniques of analysis
   - Preliminaries and definitions
   - Significant figures
   - Rules for retaining significant digits
   - Types of errors
   - Mean deviation, standard deviation statistical treatment of small data sets
   - Selection of sample, precision and accuracy,
   - Fundamentals of volumetric analysis
   - Methods of expressing concentration
   - Primary and secondary standards.

2. **Acids Base Titrations:**
   - Acid base concepts
   - Role of solvent relative strengths of acids and bases
   - Ionization, law of mass action, common – ion effect.
   - Ionic product of water,
   - pH, Hydrolysis of salts,
   - Henderson- Hesselbach equation, Buffer solutions,
   - Neutralization curves, Acid-base indicators,
   - Theory of indicators, choice of indicators,
   - Mixed indicators,
   - Polyprotic system, polyamine and amino acid systems, amino Acid titration, applications in assay of H$_3$PO$_4$, Na OH, Ca C0$_3$ etc.

3. **Oxidation Reduction Titrations:**
   - Concepts of oxidation and reduction, redox reactions,
   - Strengths and equivalent weights of oxidizing and reducing agents,
   - Theory of redox titrations
   - Redox indicators,
   - Cell representations measurement of electrode potential,
   - Oxidation- reduction curves, Iodimetry and Iodometry,
   - Titrations involving:
     - Ceric sulphate, potassium iodate,
     - Potassium bromate potassium permanganate
     - Titanous chloride and sodium 2, 6-dichlorophenol indophenols
4. **Precipitation Titrations**:  
Precipitation reactions,  
Solubility products  
Effect of acids, temperature  
Solvent upon the solubility of a precipitate,  
Argentometric titrations  
Titrations involving:  
Ammonium or potassium thio cyanate,  
Mercuric nitrate, and barium sulphate,  
Indicators, Gay-Lussac method Mohr’s method,  
Volhard’s method and Fajan’s method.

5. **Gravimetric Analysis**:  
Precipitation techniques, solubility products;  
The colloidal state,  
Super saturation co-precipitation, post –precipitation,  
Digestional washing of the precipitate,  
Filtration, filter papers and crucibles, ignition.  
Thermo gravimetric curves:  
Specific examples like barium sulphate,  
Aluminum as aluminum oxide, calcium as calcium oxalate  
Magnesium as magnesium pyrophosphate, organic precipitants.
Theoretical considerations and application in drug analysis and quality control of the following analytical techniques:

1. **Non-aqueous titrations**:
   - Theoretical considerations
   - Applications in drug analysis
   - Quality control

2. **Complexometric titrations**:
   - Theoretical considerations
   - Applications in drug analysis
   - Quality control

3. **Miscellaneous Methods of Analysis**:
   - Diazotization titrations:
     - Introduction
     - Applications
   - Kjeldhal method of nitrogen estimation
     - Introduction & Theoretical consideration
     - Application in drug analysis
   - Karl-Fischer titration,
     - Introduction & Theoretical consideration
     - Application in drug analysis
   - Oxygen flask combustion,
     - Introduction & Theoretical consideration
     - Application in drug analysis
   - Gasometry.
     - Introduction & Theoretical consideration
     - Application in drug analysis

4. **Extraction procedures including separation of drugs from excipients**
   - Introduction & Theoretical consideration
   - Different extraction procedures
   - Separation of drugs from excipients

5. **Chromatography**:
   - The following techniques will be discussed with relevant examples of Pharmacopoeial products.
   - TLC,
     - Introduction & Principle
     - Instrumentation
     - Applications
HPLC,
  Introduction & Principle
  Instrumentation
  Applications

GLC,
  Introduction & Principle
  Instrumentation
  Applications

HPTLC,
  Paper Chromatography
    Introduction & Principle
    Instrumentation
    Applications

  Column Chromatography
    Introduction & Principle
    Instrumentation
    Applications

6. Potentiometry.
   Introduction & Instrumentation
   Applications

7. Conductometry.
   Introduction & Instrumentation
   Applications

8. Coulometry.
   Introduction & Instrumentation
   Applications

   Introduction & Instrumentation
   Applications

10. Amperometry.
    Introduction & Instrumentation
    Applications
2.3.5. Practicals:  

1. **Non-aqueous Titrations**: Preparation and standardization of perchloric acid and sodium/potassium/lithium methoxides solutions; Estimations of some pharmacopeial products.

2. **Complexometric Titrations**: Preparations and standardization of EDTA solution, some exercises related to pharmacopeial assays by complexometric titrations.

3. **Miscellaneous Determinations**: Exercises involving diazotisation, Kjeldhal, Karl-Fischer, Oxygen flask combustion and gasometry methods. Determination of alcohol content in liquid galenicals, procedure(BPC) shall be covered.

4. Experiments involving separation of drugs from excipients.

5. Chromatographic analysis of some pharmaceutical products.


7. Exercises involving polarimetry.

8. Exercises involving conductometric and polarographic techniques.
2.4.1. Theory

Matter, Properties of Matter:
State of matter, change in the state latent heats and vapour pressure,
Sublimation-critical point,
Eutectic mixture,
Gases, aerosols-inhalers, relative humidity,
Liquid complexes, liquid crystals
Glassy state, solids- crystalline, amorphous and Polymorphism

MICROMERETIC AND POWER RHEOLOGY:
Particle size and distribution, particle Size, number and weight distribution,
Particle number and weight distribution, particle number,
Methods determining particle volume, optical microscopy, sieving,
Sedimentation, measurement, particle shape, specific surface, methods for
Determining surface area,
Permeability, adsorption, derived properties of powers,
Porosity, packing arrangement, densities, bulkiness and flow properties

SURFACE AND INTERFACIAL PHENOMENON:
Liquid interface, surface and interfacial tensions,
Surface free energy , measurement of surface and interfacial tensions,
Spreading coefficient, adsorption at liquid interfaces,
Surface active agents, HLB classification,
Solubilization, detergency, adsorption at solid interfaces,
Solid gas and solid-liquid interfaces,
Complex films, electrical properties of interface

Viscosity and rheology:
Newtonian systems, Law of flow, Kintemaetic viscosity,
Effect of temperature,
Non-Newtonian systems,
Pseudo plastic, dilatants,
Plastics, thixotropy, thixotropy in formulation,
Determining of viscosity, capillary, falling ball, rotational viscometers.

Dispersion systems:
Colloidal dispersions: Definition, types, properties of colloids,
Protective colloids, applications of colloids in pharmacy;
Suspensions and emulsions: Interfacial properties of suspended particles,
Settling suspensions,
Theory of sedimentation, effect of Brownian movement,
Sedimentation of flocculated particles, Sedimentation parameters,
Wetting of particles,
Controlled flocculation, flocculation in structured vehicles,
Rheological considerations;
Emulsions-types, theories, physical stability
Complexation:
Classification of complexes,
Methods of preparation
Analysis,
Applications

Kinetics and drug stability:
General considerations and concepts,
Half-life determination,
Influence of temperature, light, solvent,
Catalytic species and other factors,
Accelerated stability study, expiration dating.

Buffer:
Buffer equations and buffer capacity in general,
Buffers in pharmaceutical systems,
Preparation, stability, buffered isotonic solutions,
Measurements of tonicity,
Calculations and methods of adjusting isotonicity

2.4.1. Practicals 4 hrs / week

Determination of latent heat, vapour pressure, critical point.
Studies on polymorphs, their identification and properties.
Determining of particle size, particle size distribution and surface area using various methods of particle size analysis.
Determination of derived properties of powders like density, porosity, compressibility, angle of repose etc.
Determination of surface interfacial tension, HLB value and critical micellar concentration of surfactants.
Study of rheological properties of various types of systems using different viscometers.
Studies of different types of colloids and their properties.
Preparation of various types of suspensions and determination of their sedimentation parameters.
Preparation and stability studies of emulsions.
Studies on different types of complexes and determination of their stability constants.

Determination of half-life, rate constant and order of reaction.
To study the influence of various factors on the rate of reaction.

Accelerated stability testing, shelf-life determination and expiration dating of pharmaceuticals.

Preparation of pharmaceutical buffers and determination of buffer capacity.

Experiments involving tonicity adjustments.
2.4.2. Theory 3 hrs / week

**Stoichiometry:**
Unit processes material and energy balances, molecular units
mole fraction, tie substance
Gas laws, mole volume, primary and secondary quantities
Equilibrium state, rate process, steady and unsteady states
Dimensionless equations, dimensionless formulae, dimensionless groups
Different types of graphic representation, mathematical problems

**Heat transfer:**
Source of heat, heart transfer
Steam and electricity as heating media
Determination of requirement of amount of steam electrical energy
Steam pressure
Boiler capacity
Mathematical problems on heat transfer

**Evaporation:**
Basic concept of phase equilibria
Factor affecting evaporation
Evaporators, film evaporators
Single effect and multiple effect evaporators
Mathematical problems on evaporation

**Distillation:**
Rault,s law, phase diagrams, volatility
Simple steam
Flash distillations.
Principles of rectification
Mc. Cabe thiele method for calculations of number of theoretical plates
Azeotropic and extractive distillation
Mathematical problems on drying

**Drying:**
Moisture content and mechanism of drying, rate of drying
Time of drying calculations
Classification and types of dryers
Dryers used in pharmaceutical industries and special drying methods
Mathematical problems on drying

**Size reduction and size separation:**
Definition, objectives of size reduction,
Factors affecting size reduction,
Laws governing energy and power requirements of mills
Including ball mill, hammer mill,
Fluid energy mill etc

**Mixing:**
Theory of mixing,
Solid-solid,
Solid-liquid
Liquid-liquid mixing equipments

**Automated process control systems:**
Process variables, temperature, pressure, flow, and level
Vacuum and their measurements
Elements of automatic process control
Introduction to automatic process control systems
Elements of computer aided manufacturing (CAM)

**Reactors:**
Fundamentals of reactors
Design for chemical reactions.

**2.4.2. Practicals**

4 hrs / week

Determination of overall heat transfer coefficient.
Determination of rate of evaporation.
Experiments based on stema, extractive and azeotropic distillations.
Determination of rate of drying, free moisture content and bound moisture content.
Experiments to illustrate the influence of various parameters on the rate of drying.
Experiments to illustrate principles of size reduction, laws governing energy and power requirements of size reduction.
Experiments to illustrate solid-solid mixing, determination of mixing efficiency using different types of mixers.
SEMESTER –IV

PHARMACEUTICAL MICROBIOLOGY

2.4.3. Theory 3 hrs / week

1. Introduction to the scope of microbiology.
   a). Historical aspects Common terms and measurements used in Microbiology
   b). Scope of Microbiology – significance of microbiology in pharmaceutical studies

2. Structure of bacterial cell.

3. Classification of microbes and their taxonomy
   Classification of Bacteria
   Classification of Viruses
   Classification of Fungi
   Classification of Parasites

4. Identification of microbes :
   Microscopy
   Staining techniques – Types , Gram’s stain
   Staining techniques – Z,N stain, Albert’s stain
   LPCB mount, Leishman stain etc
   Morphology, Biochemical characters, serological characters etc

   Nutrition and cultivation of Fungi
   Nutrition and cultivation of Virus

6. Microbial genetics and variation.
   Basic principles and characters of microbial genome
   Genetic variations and mechanisms transmission of genetic material
   Genetic mechanisms of drug resistance and genetic Engineering

7. Control of microbes by physical and chemical methods.
   a. Disinfection, factors influencing disinfectants, dynamics of disinfection,
      Agents used for disinfectants and antiseptics
      Evaluation of disinfectants and antiseptics
b. Sterilization - different methods, a) Dry heat sterilization
   b) Moist heat sterilization
   Validation of sterilization methods
   Sterilization equipments
   Importance and application of sterilization principles in pharmacy

8. Sterility testing as per IP requirement
   Sterility testing of antisera, vaccines, IV fluids, etc
   Sterility testing of oral and topical medicines
   Sterility testing of other invasive and non invasive pharmacy products
   Pyrogen testing

9. Infection, sources of infection, methods of transmission
   Acquired Immunity definition and classification
   Immune response, primary, secondary
   Defense mechanisms of body - innate acquired immunity, interferon
   Microbial resistance and pathogenicity

10. Antibiotic sensitivity tests and their importance
    Dilution and diffusion tests for antibiogram
    Antibiotic assays of body fluids
    Microbial assays of vitamins
    Microbial assays of amino acids

2.4.3. Practicals 4 hrs / week

Experiments devised to prepare various types of culture Media
Sub-culturing of common aerobic and anaerobic bacteria, fungi.
Various staining methods,
Various methods of isolation and identification of microbes,
Sterilization techniques and their validation of sterilizing techniques,
Evaluation of antiseptics and disinfectants, testing the sterility of
Pharmaceutical products as per I.P. requirements,
Microbial assay of antibiotics and vitamins etc.
2.4.4. Theory

1. Study of the biological sources, cultivation, and collection, commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following groups of drugs containing glycosides:

   Introduction

   i). **Saponins:**
   - Liquorice,
   - Ginseng, dioscorea,
   - Sarsaparilla, and senega

   ii). **Cardioactive sterols:**
   - Digitalis,
   - Squill,
   - Strophanthus and Thevetia

   iii). **Anthraquinone cathartics:**
   - Aloe,
   - Senna,
   - Rhubarb and Cascara

   iv). **Others:**
   - Psoralea, Ammi majus,
   - Ammi visnaga, Gentian,
   - Saffron
   - Chirata, Quassia

2. Studies of traditional drugs, common vernacular names, botanical sources, morphology, chemical nature of chief constituents, pharmacology, categories and common uses and marketed formulations of following indigenous drugs:

   Introduction:
   - Amla
   - Kanthkari
   - Satavari and Tylophora
   - Bhilawa and kalijiri
   - Bach and Rasna
   - Punarnava
   - Chitrack and Apamarg
   - Gokhru
   - Shankhapushpi
   - Brahmi
   - Adusa
   - Arjuna
   - Ashoka
   - Methi
   - Lahsun and palash
   - Guggal
   - Gymnema
   - Shilajit
   - Nagarmotha
   - Neem
3. The Holistic concept of drug administration in traditional systems of medicine
   Introduction to Ayurvedic preparations like,
   Arishtas
   Asvas
   Gutikas
   Tailas
   Churnas
   Lehyas
   Bhasmas

   Preparation
   Evaluation

2.4.4. Practicals 4 hrs / week

1. Identification of crude drugs listed in theory

2. Microscopic study of some important glycoside containing crude drugs as outlined above. Study of powdered drugs

3. Standardization of some traditional drug formulations
2.4.5. Theory

1. Basic principles of cell injury and adaptation:
   Causes of cellular injury
   Reversible
   Irreversible
   Pathogenesis
   Morphology of cell injury
   Intercellular alterations in lipids
   Proteins and carbohydrates
   Cellular adaptation
   Atrophy, hypertrophy

2. Basic mechanisms involved in the process of inflammation and repair:
   Alterations in vascular permeability
   Blood flow,
   Migration of WBC’S
   Acute inflammation
   Chronic inflammation
   Mediators of inflammation
   Brief outline of the process of repair
   Cell cycle
   Vascularisation
   New growth

3. Pathophysiology of common diseases:
   Rheumatoid arthritis, gout
   Epilepsy
   Psychosis
   Depression
   Mania
   Hypertension
   Angina
   Congestive heart failure
   Atherosclerosis
   Myocardial infarction
   Diabetes
   Peptic ulcer
   Asthma
   Ulcerative colitis
   Hepatic disorders
   Acute/Chronic renal failure
   Tuberculosis
   Urinary tract infections
   Sexually transmitted diseases
   Anemias
   Common types of neoplasms
SEMESTER – V

PHARMACEUTICAL CHEMISTRY – V
(Biochemistry)

3.5.1. Theory: 3 Hours/Week

1. Biochemical organization of the cell and transport processes across cell membrane.

2. The concept of free energy, determination of change in free energy from equilibrium constant
Reduction potential, bioenergetics, Production of ATP
and its biological significance.

3. Enzymes:
  Nomenclature, enzyme kinetics and its mechanism of action, mechanism of inhibition,
  Enzymes and iso-enzymes in clinical diagnosis

4. Co-enzymes:
  Vitamins as co-enzymes and their significance
  Metals as co-enzymes and their significance

5. Carbohydrate Metabolism:
  Conversion of polysaccharide to glucose –1- phosphate,
  Glycolysis and fermentation and their regulation
  Gluconeogenesis and glycogenolysis,
  Metabolism of galactose and galactosemia,
  Role of sugar nucleotides in biosynthesis,
  and Pentosephosphate pathway.

6. The Citric Acid Cycle:
  Significance, reactions and energetic of the cycle,
  Amphibolic role of the cycle, and Glyoxalic acid cycle

7. Lipids Metabolism:
  Oxidation of fatty acids, Beta oxidation and its energetics
  Alpha oxidation, Omega oxidation
  Biosynthesis of ketone bodies and their utilization,
  Biosynthesis of saturated and unsaturated fatty acids,
  Control of lipid metabolism,
  Essential fatty acids and eicosanoids prostaglandins
  Thromboxanes and leukotrienes
  Phospholipids and sphingolipids

8. Biological Oxidation:
  Redox-Potential, enzymes and co-enzymes involved in
  Oxidation reduction and its control
  The respiratory chain, its role in energy capture and its control,
Energetics of oxidative phosphorylation,
Inhibitors of respiratory chain and oxidative phosphorylation,
Mechanism of oxidative phosphorylation

9. **Nitrogen and Sulphur Cycle**:
Nitrogen fixation, ammonia assimilation, nitrification and
Nitrate assimilation
Sulphate activation, sulphate reduction. Incorporation of
sulphur in organic compounds, Release of sulphur from
Organic compounds

10. **Metabolism of Ammonia and Nitrogen Containing Monomers**:
Nitrogen balance, Biosynthesis of amino acids,
Catabolism of amino acids, Conversion of amino acids to
specialized products,
Assimilation of ammonia, Urea cycle,
Metabolic disorders of urea cycle,
Metabolism of sulphur containing amino acids
Porphyrin biosynthesis
Purine nucleotide interconversion
Pyrimidine biosynthesis
Formation of deoxyribonucleotides

**Biosynthesis of Nucleic Acids**:
Brief introduction of genetic organization of the mammalian genome
Alteration and rearrangements of genetic material,
Biosynthesis of DNA and Replication of DNA
Mutation, Physical and Chemical mutagenesis
Carcinogenesis,
DNA repair mechanism,
Biosynthesis of RNA.

11. **Genetic Code and Protein Synthesis**:
Genetic code,
Components of protein synthesis
Inhibition of Protein synthesis
Brief account of genetic engineering
Polymerase chain reaction.

12. Regulation of gene expression.
3.5.1 **Practicals:**

1. Preparation of standard buffers (citrate, phosphate and carbonate) and measurement of pH.
2. Titration curve for amino acids.
3. Separation of amino acids by two dimensional paper chromatography and gel electrophoresis.
4. The separation of lipids by TLC.
5. Separation of serum proteins by electrophoresis on cellulose acetate.
8. The identification of c-terminal amino acids of a protein.
9. The identification of glucose by means of the enzyme glucose oxidase.
10. The isolation and assay of glycogen from the liver and skeletal muscle of rats.
11. Enzymatic hydrolysis of glycogen by alpha and beta amylases.
12. The isolation and determination of RNA and DNA.
SEMESTER - V
PHARMACEUTIS - V
(PHARMACEUTICAL TECHNOLOGY – I)

3.5.2. Theory 3 hrs / week

Liquid dosages forms:
Introduction, types of additives used in formulations
Vehicles, stabilizers, preservatives
Suspending agents, emulsifying agents
Solubilizers, colors, flavours and others
Manufacturing packaging and evaluation of clear liquids
Suspensions and emulsions official in pharmacopoeia

Semisolid dosage forms:
Definitions, types, mechanisms of drug penetration factors influencing penetration
Semisolid bases and their selection
General formulation of semisolids
Clear gels manufacturing procedure
Evaluation and packaging

Suppositories:
Ideal requirements, bases
Manufacturing procedure
Packaging and Evaluation

Extraction and galenical products:
Principle and
Method of extraction
Preparation of infusion
Tinctures, dry and soft liquid extracts

Blood products and plasma substitutes:
Collection, processing and storage of whole human blood
Concentrated human RBC’S
Dried human plasma
Human fibrinogen
Human thrombin
Human normal immunoglobulin
Human fibrin
Foam plasma substitutes
Ideal requirements, PVP, dextran etc. for control of blood pressure as per I.P.
Pharmaceutical aerosols:
Definition, propellants
General formulation
Manufacturing and
Packaging methods
Pharmaceutical applications

Ophthalmic preparations:
Requirements
Formulation
Methods of preparation
Containers
Evaluation

Cosmeticology and cosmetic preparations:
Fundamentals of cosmetic science,
Structure and functions of skin and hair
Formulation, preparation and packaging of cosmetics for skin, hair
Dentifrice and
Manicure preparations like nail polish,
Lipsticks,
Eye lashes, baby care products etc.

3.5.2. Practical  
4 hrs / week

Preparation, evaluation and packaging of liquid orals like lotions, suspensions and emulsions, ointments, suppositories, aerosols, eye drops, eye ointments etc.

Preparation of pharmacopoeial extracts and galenical products utilizing various methods of extraction.

Collection, processing, storage and fractionation of blood.

Formulation of various types of cosmetics for skin, hair, dentifrices and manicure preparations.
3.5.3 Theory: 3 hrs/ week

1. **General Pharmacology**:
   - Introduction to Pharmacology, Sources of drugs,
   - Dosage forms and routes of administration
   - Mechanism of action
   - Combined effect of drugs
   - Factors modifying Drug action
   - Tolerance and dependence
   - Pharmacogenetics
   - Absorption
   - Distribution
   - Metabolism
   - Excretion of drugs, Principles of Basic and Clinical pharmacokinetics
   - Adverse Drug Reactions
   - Treatment of poisoning
   - ADME drug interactions,
   - Bioassay of Drugs
   - Biological Standardization
   - Discovery of drugs
   - Development of new drugs

2. **Pharmacology of Peripheral Nervous System**:
   a. Neurohumoral transmission (Autonomic and Somatic)
   b. Parasympathomimetics
      - Parasympatholytics
      - Sympathomimetics
      - Adrenergic Receptor and neuron blocking agents
      - Ganglionic stimulants and blocking agents
   c. Neuromuscular blocking agents
   d. Local anesthetic agents

3. **Pharmacology of Central Nervous System**:
   a. Neurohumoral transmission in the C.N.S.
   b. General Anesthetics.
      - Stages
      - Drugs
   c. Alcohols and disulfiram.
   d. Sedatives, hypnotics,
      - Anti-anxiety agents
      - Centrally acting muscle relaxants.
   e. Psychopharmacological agents anti-psychotics
      - anti-depressants, anti-maniacs and hallucinogens.
   f. Anti-epileptics drugs.
      - Types
      - Drugs
g. Anti-Parkinsonism Drugs.
h. Analgesics, Antipyretics, Anti-inflammatory
   Anti-gout drugs.
i. Narcotic analgesics
   Antagonists.
j. C.N.S. stimulants.
k. Drug Addiction and Drug abuse.

3.5.3 Practicals: 4 hrs / week

1. **Introduction to Experimental Pharmacology:**
   Preparation of different solutions for experiments.
   Drug dilutions, use of molar and w/v solutions in experimental pharmacology.

   Common laboratory animals and anesthetics used in animal studies. Commonly used instruments in experimental pharmacology.

   Some common and standard techniques.
   Bleeding and intravenous injection, intragastric administration.

   Procedures for rendering animals unconscious – stunning of rodents, pithing of frogs, chemical euthanasia.

2. **Experiments on intact preparations:**
   Study of different routes of administration of drugs in mice/rats.

   To study the effect of hepatic microsomal enzyme inhibitors and induction on the pentobarbitone sleeping time in mice.

3. **Experiments on Central Nervous System:**
   Recording of spontaneous motor activity, stereotypy, analgesia, anticonvulsant activity, anti-inflammatory activity, and muscle relaxant activity of drugs using simple experiments.

4. Effects of autonomic drugs on rabbit’s eye.
5. Effects of various agonists and antagonists and their characterization
6. using isolated preparations like frog’s rectus abdominal muscle and
7. Isolated ileum preparations of rat, guinea pig and rabbit.
SEMESTER-V

PHARMACOGNOSY- IV

3.5.4. Theory  

1. Systematic study of source, cultivation, collection, processing, commercial varieties, chemical constituents, substitutes, adulterants, uses diagnostic macroscopic and microscopic features and specific chemical tests of following alkaloid containing drugs:

a). **Pyridine – piperidine:**
   Tobacco,
   Areca and lobelia

b). **Tropane:**
   Belladonna
   Hyoscyamus
   Datura
   Duboisia
   Coca
   Withania

c). **Quinoline and isoquinoline:**
   Cinchona
   Ipecac
   Opium

d). **Indole:**
   Ergot
   Rauwolfia
   Catharanthus
   Nux-vomica and physostigma

e). **Imidazole:** Pilocarpus
f). **Steroidal:** Veratrum and Kurchi

g). **Alkaloidal amine:**
   Ephedra
   Colchicum

h). **Glycoalkaloid:** Solanum

i). **Purines:**
   Coffee
   Tea and cola
2. **Role of**
   Medicinal plants in national economy
   Aromatic plants in national economy

3. **Biological sources, preparation, identification tests and uses of the following enzymes:**
   - Diastase
   - Papain
   - Pepsin
   - Trypsin
   - Pancreatin

4. **General techniques of biosynthetic studies**
   - Basic metabolic pathways
   - Shikimic acid pathways
   - Brief introduction to biogenesis of secondary metabolites of Pharmaceutical importance
   - Biosynthesis of Glycosides
   - Biosynthesis of Alkaloids
   - Biosynthesis of isoprenoid compounds

5. **Plant bitters**
   - Sweeteners

6. **Introduction and classification**
   - Study of different chromatographic methods:
     - Paper
     - TLC
     - HPLC
     - GC, HPTLC
     - Electrophoresis
   - Applications in evaluation of herbal drugs

3.5.4. **Practicals**  
4 hrs / week

1. Identification of crude drugs listed above

2. Microscopic study of characters of eight- selected drugs given in theory in entire and powdered form.

3. Chemical Evaluation of powdered drugs, and enzymes

4. Chromatographic studies of some herbal constituents
1. Organization and structure:
   Organization of a hospital and hospital pharmacy
   Responsibilities of a hospital pharmacist
   Pharmacy and therapeutic committee
   Budget preparation and Implementation

2. Hospital formulary:
   Contents,
   Preparation
   Revision of hospital formulary

3. Drug store management and inventory control:
   a. Organization of drug store,
      Types of materials stocked, and Storage conditions
   b. Purchase and inventory control principles
      Purchase procedures
      Purchase order
      Procurement and stocking

4. Drug distribution systems in hospitals:
   b. Dispensing of drugs:
      Inpatients
      Types of drug distribution systems
      Charging policy, labeling.
   c. Dispensing of drugs to ambulatory patients.
   d. Dispensing of controlled drugs.

5. Central sterile supply unit and their management:
   Types of materials for sterilization,
   Packing of materials prior to sterilization,
   Sterilization equipments,
   Supply of sterile materials

6. Manufacture of sterile and non sterile products:
   Policy making of manufacturability items
   Demand and costing
   Personnel requirements
   Manufacturing practice
   Master formula card
   Production control, manufacturing records
7. **Drug information services:**
   Sources of information on drugs, Disease, treatment schedules,
   Procurement of information,
   Computerized services (e.g., MEDLINE),
   Retrieval of information,
   Medication error

8. **Records and reports:**
   Prescription filling, drug profile,
   Patient medication profile,
   Cases on drug interaction
   Adverse reactions, idiosyncratic cases etc.

9. **Nuclear Pharmacy:**
   Introduction to Radio Pharmaceuticals,
   Radio-active half life, Units of radio-activity
   Production of radio-pharmaceuticals,
   Methods of isotopic tagging,
   Preparation of radio-isotopes in the laboratory using radiation
   dosimeter, radio-isotope generators, Permissible radiation dose level.
   Radiation hazards and their prevention,
   Specifications for radio-active laboratory.

3.5.5. **Practicals**  
4 hrs / week

1. Experiments based on Sterilization of various types of materials used in Hospitals.

2. Practicals designed on the use of computers in Drug Information Centre, prescription filling, documentation of information on drug interaction.

3. Experiments to illustrate handling of radiopharmaceutical products, measurement of radioactivity.
1. Basic Principles of Medicinal Chemistry:
Physio-chemical aspects (Optical, geometric and bioisosterism) of Drug
molecules and Biological action, Optical

Geometrical
Bio isosterism
Protein Binding

Solubility and Partition coefficient
Ionisation
Hydrogen
bonding and Biological action

Chelation
Oxidation reduction potential and surface activity
Ferguson principles

Drug – receptor interaction including transduction mechanisms.

Introduction and Isosterism
Forces involved in drug receptor inter reactions

2. Principles of Drug Design (Theoretical Aspects):
Traditional analog (QSAR) and mechanism based approaches
Introduction to graph theory:

Introduction,
Factors governing drug design
Rational approach to drug design
Mechanism

Applications of quantum mechanics, Computer aided

Drug designing (CADD) Molecular modeling.
Mechanical approach and molecular orbital indices
Examples of molecular orbital SAR studies
Molecular orbital approach
Theoretical methods based upon model systems
Quantum mechanism

Synthetic procedures of selected drugs, mode of action, uses, structure
activity relationship including physiochemical properties of the following
classes of drugs:
Drugs acting at Synaptic and neuro-effector junction sites:

i. Cholinergics and Anticholinesterases  
   Introduction, classification, mode of action,  
   Physiochemical properties  
   Synthesis of Cholinergics  
   SAR and synthesis of Anticholinesterases

ii. Adrenergic drugs  
    Adrenaline and non adrenaline and others  
    Alpha Blockers  
    Beta Blockers

iii. Antispasmodic and anti ulcer drugs  
    Introduction, classification, Properties, mode of action  
    SAR  
    Synthesis

iv. Neuromuscular blocking agents.  
    Non depolarizing drugs  
    Depolarizing

B. Autocoids

i. Antihistamines  
   Classification, mode of action, properties  
   and chemistry  
   SAR and synthesis  
   Synthesis

ii. Eicosanoids  
    Introduction chemistry  
    SAR mode of action and synthesis

iii. Analgesic- antipyretics, anti-inflammatory  
     (non-steroidal) agents.  
     Introduction, mode of action  
     SAR  
     Synthesis

C. Drugs affecting uterine motility:

Oxytocics (including oxytocin, ergot alkaloids and prostaglandins).  
Biochemical approaches in drug designing wherever applicable should be discussed.

    Oxytocin  
    Ergot alkaloids  
    Prostaglandins
3.6.1. Practicals

2. Syntheses of selected drugs from the course content.
3. Spectral analysis of the drugs synthesized.
4. Establishing the pharmacopoeial standards of the drug synthesized.
   Determination of partition coefficient, dissociation constant and molar refractivity of compounds for QSAR analysis.
3.6.2. Theory

1. Introduction to biopharmaceutics
   Pharmacokinetics
   Role in formulation development and clinical setting

2. Biopharmaceutics:
   a. Passage of drugs across biological barrier
      Passive diffusion
      Active transport
      Facilitated diffusion
      Pinocytosis).
   b. Factors influencing absorption
      Physicochemical,
      Physiological
      Pharmaceutical
   c. Drug distribution in the body,
      Plasma protein binding

3. Pharmacokinetics:
   a. Significance of plasma drug concentration measurement.
   b. Compartment model- definition and scope.
   c. Pharmacokinetics of drug absorption – zero order first order absorption
      rate constant using Wagner – Nelson and Loo- Reigelman method
   d. Volume of distribution and distribution coefficient.
      Compartment kinetics – one compartment and two Compartment models

Determination of pharmacokinetic parameters from plasma and
   Urine data after drug administration by intravascular and oral route
   Curve fitting (method of Residuals), regression procedures.
   e. Clearance concept,
      Mechanism of renal clearance,
      Clearance ratio,
      Determination of renal clearance
   f. Extraction ratio,
      Hepatic clearance,
      Biliary excretion
      Extrahepatic circulation
g. Non-linear pharmacokinetics with special reference to one
Compartment model after I.V. drug administration,
Michael Menten Equation
Detection of non-linearity (Saturation mechanism)

4. Clinical pharmacokinetics:
a. Definition and scope
b. Dosage adjustment in patients with renal failure
   Without renal failure
   With Hepatic failure
c. Design of single dose bio-equivalence study
   Relevant statistics
d. Pharmacokinetic drug interactions &
   their significance combination therapy

5. Bioavailability and bioequivalence:
a. Measures of bioavailability, $c_{max}$, $t_{max}$ and area under
   the curve (AUC)
b. Design of single dose bioequivalence study
   Relevant statistics
c. Review of regulatory requirements for conduction of bioequivalent
   studies

3.6.2 Practicals  

Experiments designed for the estimation of various pharmacokinetics
parameters with given data. - 12 hrs

1. Analysis of biological specifications for drug content and
   estimation of the pharmacokinetic parameters.
   In vitro evaluation of different dosage forms for drug release
   Absorption studies – in vitro and in situ.
2. Statistical treatment of pharmaceutical data.
3.6.3 Theory: 4 hrs/week

1. Pharmacology of Cardiovascular System:
   Introduction
   a. Digitalis
      Cardiac glycosides
   b. Antihypertensive drugs:
      Classification
      Mechanism
      Adverse effect
   c. Antianginal
      Vasodilator drugs
      Calcium channel blockers
      Beta adrenergic antagonist
   d. Antiarrythmic drugs:
      Classification
      Mechanism
      Adverse effect
   e. Antihyperlipidemic drugs.
      Classification
      Mechanism
      Adverse effect
   f. Drugs used in the therapy of shock.

2. Drugs Acting on the Hemopoietic System:
   a. Hematinics.
   b. Anticoagulants, Vitamin K
      Hemostatic agents
   c. Fibrinolytic
      Anti-platelet drugs
   d. Blood and plasma volume expanders.
      Introduction
      Advantage and Disadvantage

3. Drugs acting on urinary system:
   Fluid and electrolyte balance
   a. Diuretics:
      Loop diuretics
      Thiazide diuretics

4. Autocoids:
   a. Histamine
      5-HT antagonists
      Histamine antagonists
b. Prostaglandins
   Thromboxanes
   Leukotrienes.

c. Pentagastrin,
   Cholecystokinin
   Angiotensin
   Bradykinin
   Substance P

5. Drugs Acting on the Respiratory System:

   a. Anti-asthmatic drugs
      Bronchodilators
   b. Anti-tussives
      Expectorants
   c. Respiratory stimulants.
      Cortical
      Medullary

3.6.3. Practicals:  

1. Experiments on Isolated Preparations:

   a. To record the concentration response curve (CRC) acetylcholine using rectus abdominis muscle preparation of frog.
   b. To study the effects of physostigmine and d-tubocurarine on the CRC of acetylcholine using rectus abdominis muscle preparation of the frog.
   c. To record the CRC of 5-HT on rat fundus preparation.
   d. To record the CRC of histamine on guinea pig ileum preparation.
   e. To record the CRC of noradrenaline on rat anococcygeus muscle preparation.
   f. To record the CRC of oxytocin using rat uterus preparation.

2. Pharmacology of Cardiovascular System:

   a. To study the ionotropic and chronotropic effects of drugs on isolated frog heart.
   b. To study the effects of drugs on normal and hypodynamic frog heart.

3. Blood Pressure of anaesthetized Dog/Cat/Rat:

   a. To demonstrate the effects of various drugs on the B.P. and respiration including the Vasomotor Reversal of Dale and nicotinic action of acetylcholine.
1. Chemical approaches to simple molecules of natural origin.
   Spectral approaches to simple molecules of natural origin
   UV – Visible
   IR
   NMR
   Mass and X-ray diffraction
   Others

2. Concept of stereoisomerism
   Geometrical Isomerism
   Optical Isomerism
   Examples of Isomerism from natural products

3. Chemistry, biogenesis and pharmacological activity of medicinal important:
   Nomenclature of Terpenes
   Monoterpenes,
   Sesquiterpenes,
   Diterpenes,
   Triterpenoids.

4. Carotenoids:
   Introduction, Characteristic and Functions
   \( \alpha \) - carotenoids
   \( \beta \) - carotenes
   Vitamin A
   Xanthophylls of medicinal importance

5. Glycosides: Chemistry and biosynthesis of
   Digitoxin,
   Digoxin
   Hecogenin
   Sennosides
   Diosgenin
   Sarasapogenin

6. Alkaloids:
   Chemistry and Biogenesis
   Atropine and related compounds
   Quinine
   Reserpine
Morphine and Papaverine
Ephedrine
Ergot
Vinca alkaloids
Pharmacological activity of
Atropine and related compounds, Quinine, Reserpine
Morphine and Papaverine, Ephedrine, Ergot, Vinca alkaloids

7. Chemistry and biogenesis of medicinally important
lignans
Quassanoids
Flavonoids

8. Chemistry of
Penicillin
Streptomycin
Tetracyclines

*Therapeutic activity of*
Penicillin
Streptomycin
Tetracyclines

3.6.4. Practicals 4 hrs/week

1. Laboratory experiments on isolation, separation, purification of various
groups of chemical constituents of pharmaceutical significance.

2. Exercises on paper and thin layer chromatographic evaluations
of herbal drug constituents
SEMESTER- VI

COMPUTER APPLICATIONS IN PHARMACY

3.6.5. Theory 3 hrs / week

1. Introduction to Computers.
2. Computer applications in pharmaceutical and clinical studies
3. Computer Classification
   Mainframe, Mini and Micro Computers,
   Comparison of Analog and Digital Computers
   Hardware and Software, Calculator and Computer
4. Operating Systems
   Introduction, Types of operating systems, MS – DOS, LYNX
   and WINDOWS XP
5. Introduction to Data Structure
   Like Queues, List, trees, Binary trees algorithms, Flow Chart,
   Structured Systems, Analysis, Development, Ingress-SQL,
   Statistics and Methodologies
6. Type of Languages
   Conventional languages, their advantages, limitations
   C, Visual Basic and Programming of these languages
7. Computer Graphics
8. Introduction to Computer Networks
   Architecture of seven layers of communications
9. Introduction to Internet
10. Basic Electronics
    Semiconductors, p-n function diode, LED, photodiode and its
    uses. Rectifiers (half wave, full wave / with filters),
    Transistors configurations, Transistor amplifiers. Introduction
    to Integrated circuits, photocells and photomultiplier tubes

3.6.5. Practicals 4 Hours/week

Exercises based on the following are to be dealt:

1. Computer operating systems like MS-DOS, WINDOWS XP and LYNX
2. Simple programs in C and VISUAL BASIC
3. Study of soft-ware packages like Chem Draw, Tinker and WinMopac
4. Microsoft Package (Document, Spreadsheet, Presentations and Storage)
1. Immunology and Immunological preparations:
   Principles,
   Antigens and haptens,
   Immune system
   Cellular humoral immunity,
   Immunological tolerance,
   Antigen-antibody reactions
   Applications
   Hypersensitivity,
   Active
   Passive immunization;
   Vaccines- their preparation,
   Standardization and storage

2. Genetic recombination:
   Transformation,
   Conjugation,
   Transduction,
   Protoplast fusion
   Gene cloning
   Application
   Development of hybridoma for monoclonal antibodies
   Study of drugs produced by biotechnology such as Activase,
   Humulin
   Humatrope
   HB etc

3. Antibiotics:
   Historical development of antibiotics
   Antimicrobial spectrum and methods used for their standardization
   Screening of soil for organisms producing antibiotics fermenter,
   Its design, control of different parameter
   Isolation of mutants
   Factors influencing rate of mutation
   Design of fermentation process
   Isolation of fermentation products with special reference to penicilins
   Streptomycins,
   Tetracyclines
   Vitamin B12
4. **Microbial transformation:**
   - Introduction
   - Types of reactions mediated by microorganisms
   - Design of biotransformation processes
   - Selection of organisms
   - Biotransformation process
   - Its improvements with special reference
   - Steroids

5. **Enzyme Immobilization:**
   - Techniques of immobilization of enzymes
   - Factors affecting enzyme kinetics
   - Study of enzymes such as hyaluronidase
     - Penicillinase,
     - Streptokinase
     - Streptodornase,
     - Amylases
     - Proteases etc
   - Immobilization of bacteria
   - Plant cells
1. **Capsules:**
   Advantages and disadvantages of capsule dosage form,
   Material for production of hard gelatin capsules, size of capsules
   Method of capsule filling, soft gelatin
   Capsule shell and capsule content
   Importance of base absorption and minimum /gm factors in
   Soft capsules
   Quality control, stability testing
   Storage of capsule dosage forms.

2. **Micro-encapsulation:**
   Types of microcapsules, importance of micro encapsulation
   in pharmacy
   Micro encapsulation by phase separation, co-acervation,
   Multi orifice, spray drying,
   Spray congealing,
   Polymerization complex emulsion,
   Air suspension technique, coating pan and other techniques,
   Evaluation of micro capsules.

3. **Tablets:**
   a. Formulation of different types of tablets, granulation
      technology on large-scale by various techniques
      Physics of tablets making
      Different types of tablet compression machinery
      Equipments employed evaluation of tablets
   b. Coating of tablets :
      Types of coating, film forming materials
      Formulation of coating solution
      Equipments for coating, coating process
      Evaluation of coated tablets
   c. Stability kinetics
      Quality assurance

4. **Parenteral Products:**
   a. Pre formulation factors, routes of administration,
      water for injection
      Pyrogenicity, non aqueous vehicles, isotonicity and
      Methods of its adjustment
   b. Formulation details, containers and closures and selection.
   c. Pre filling treatment, washing of containers and closures,
Preparation of solution and suspensions,
Filing and closing of ampoules, vials, infusion fluids, lyophilization
Preparation of sterile powders, equipment for large scale manufacture
Evaluation of parenteral products

d. Aseptic techniques – sources of contamination and methods of prevention
   Design of aseptic area, laminar flow bench services and maintenance

e. Sterility testing of pharmaceuticals.

5. Sterility products:
   Definition, primary wound dressing,
   Absorbents, surgical cotton, surgical gauzes etc.,
   Bandages, adhesive tape, protective cellulosic hemostatics,
   official dressings,
   Absorbable and non absorbable sutures, ligatures and catguts.
   Medical prosthetics
   Organ replacement materials

6. Packaging of pharmaceutical products:
   Packaging components,
   Types, specifications and methods of evaluation, stability aspects of packaging.
   Packaging equipments,
   Factors influencing choice of containers,
   Legal and other official requirements for containers,
   package testing.

4.7.2. Practicals 4 hrs/week

1. Experiments to illustrate preparation, stabilization, physical and biological evaluation of pharmaceutical products like powders, capsules, tablets, parenterals, microcapsules, surgical dressing etc.

2. Evaluation of materials used in pharmaceutical packaging.
PHARMACEUTICAL INDUSTRIAL MANAGEMENT

4.7.3. Theory 4 hrs / week

1. Concept of Management:
   Administrative Management
   Planning
   Organizing
   Staffing, Directing
   Controlling
   Entrepreneurship development

   Operative Management
   Personnel, Materials
   Production, Financial
   Marketing, Time/Space, Margin/Morale

   Principles of Management
   Co-ordination, Communication, Motivation, Decision-making
   Leadership
   Innovation, Creativity
   Delegation of Authority
   Responsibility, Record Keeping

   Identification of key points to give maximum thrust for
devolution and perfection.

2. Accountancy:
   Principles of Accountancy,
   Ledger posting and book entries,
   Preparation of trial balance,
   Columns of a cash book,
   Bank reconciliation statement,
   Rectification of errors,
   Profits and loss account,
   Balance sheet, purchase,
   Pricing of stocks, Cheques,
   Bills of exchange,
   Promissory notes hundies,
   Documentary bills.

3. Economics:
   Principles of economics with special laws of
   Demand and supply,
   Demand schedule, demand curves,
   Labor welfare,
   General Principles of insurance inland and foreign trade,
   Procedure of exporting
   Procedure of Importing goods.
4. **Pharmaceutical Marketing:**
   Functions, buying, selling, transportation, storage,
   Finance, feedback, information
   Channels of distribution,
   Wholesale, retail, departmental store,
   Multiple shop and mail order business.

5. **Salesmanship:**
   Principles of sales promotion
   Advertising,
   Ethics of sales, merchandising,
   literature, detailing,
   Recruitment, training,
   evaluation, compensation to the pharmacist.

6. **Market Research:**
   a. Measuring & Forecasting Market Demands
   b. Major concept in demand measurement,
   c. Estimating current demand, Geo-demographic analysis,
   e. Market Segmentation
   f. Market Targeting.

7. **Materials Management:**
   A brief exposure or basic principles of materials management
   Major areas, scope, purchase,
   stores, inventory control
   Evaluation of materials management.

8. **Production Management:**
   A brief exposure of the different aspects of
   Production Management
   Visible and Invisible inputs,
   Methodology of Activities,
   Performance Evaluation Technique
1. Drugs Acting on the Gastrointestinal Tract:
   a). Antacids, Anti Secretory and Anti-ulcer drugs.
   b). Lacatives and antidiarrhoeal drugs.
   c). Appetite Stimulants and Suppressants.
   d). Emetics and anti-emetics.
   e). Miscellaneous – Carminatives, demulcents, protectives, adsorbents, astringents, digestants, enzymes and mucolytics.

2. Pharmacology of Endocrine System:
   a). Hypothalamic and pituitary hormones
   b). Thyroid hormones and anti thyroid drugs, parathormone, calcitonin and Vitamin D.
   c). Insulin, oral hypoglycaemic agents & glucagons.
   d). ACTH and corticosteroids.
   e). Androgens and anabolic steroids.
   f). Estrogens, progesterone and oral contraceptives.
   g). Drugs acting on the uterus.

3. Chemotherapy:
   a). General Principles of Chemotherapy.
   b). Sulfonamides and cotrimoxazole.
   c). Antibiotics–Penicillins, Cephalosporins, Chloramphenicol Erythromycin, Quinolones and Miscellaneous Antibiotics.
   d). Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, urinary tract infections and sexually transmitted diseases.
   e). Chemotherapy of malignancy and Immunosuppressive Agents.

4. Principles of Toxicology:
   a). Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates, opioids, organophosphorous and atropine poisoning.
   b). Heavy metals and heavy metal antagonists.
1. Experiments on Isolated Preparations:

   a). To calculate the pA$_2$ Value of atropine using acetylcholine as an agonist on rat ileum preparation.
   b). To calculate the pA$_2$ Value of mepyramine or chlorpheniramine using histamine as agonist on guinea pig ileum.
   c). To estimate the strength of the test sample of agonist / drug (e.g. Acetylcholine, Histamine, 5-HT, Oxytocin, etc) using a suitable isolated muscle preparation employing matching bioassay,Bracketing assay, Three point assay and four point bioassay.

2. Pharmacology of the Gastrointestinal Tract:

   To study the Anti-secretary and anti-ulcer activity using pylorus ligated rats.

3. Clinical pharmacology:

   To determine the effects of certain clinically useful drugs on human volunteers like:
   a). Antihistaminics
   b). Anti-anxiety and sedative drugs
   c). Analgesics
   d). Beta blockers.
SEMESTER – VII

PHARMACEUTICAL CHEMISTRY – VII
(Medicinal Chemistry – II)

4.7.5. Theory: 3 Hours/Week

Synthetic procedures of selected drugs, mode of action, uses, structure activity relationship including Physio-Chemical properties of the following classes of drugs:

1. **Steroids and related drugs:**
   Steroidal nomenclature
   Stereochemistry,
   - Introduction stereochemistry of Androgens and Anabolic agents
   - Stereochemistry of Estrogens, Progesterones and adrenocorticoids
   Synthesis Androgens and Anabolic agents,
   Synthesis and SAR Estrogens
   Synthesis and SAR progestational agents
   Synthesis and SAR of adrenocorticoids.

2. **Drugs acting on the Central Nervous System:**
   General Anesthetics,
   - Introduction, Classification, mode of action and Properties
   - Chemistry and Synthesis
   Local Anesthetics,
   - Introduction, Classification, mode of action and Properties
   - SAR
   - Chemistry and Synthesis
   Hypnotics and Sedatives,
   - Classification, mode of action, properties
   - SAR
   - Synthesis
   Opioid analgesics,
   - Introduction, Classification, mode of action and Properties
   - SAR
   - Chemistry and Synthesis
   - Synthesis
   Antitussives,
   - Chemistry and SAR
   - Synthesis
   Anti convulsants,
   - Chemistry and SAR
   - Synthesis
Antiparkinsonism drugs,
CNS stimulants,
Chemistry and SAR
Synthesis
Psychopharmacological agents
(neuroleptics, antidepressants, anxiolytics).
Introduction, mode of action, properties
SAR and chemistry
SAR
Synthesis

3. Diuretics,
Classification, mode of action, properties and other chemistry
SAR
Synthesis
Cardiovascular drugs,
Introduction, mode of action, properties chemistry
SAR
Anti anginian drugs and Vasodilators
Anti arrhythmic drugs
Anti hypertension and Anti hyper lipidemic agents
Anticoagulant
Chemistry and SAR
Synthesis
Antiplatelet drugs.
Chemistry and SAR
Synthesis

Biochemical approaches in drug designing wherever applicable should be discussed.

4.7.5. Practicals 4 hrs / week

1. Workshop on stereomodel use of some selected drugs.

2. Synthesis of selected drugs from the course content involving two or more steps and their spectral analysis.

3. Establishing the Pharmacopoeial standards of the drugs synthesized.
1. Preformulation studies:

   a. Study of physical properties of drug like physical form
      Particle size, shape, density,
      Wetting dielectric constant.
      Solubility, dissolution
      Organoleptic property
      Stability and bioavailability.

   b. Study of chemical properties of drugs like
      Hydrolysis,
      Oxidation,
      Reduction,
      Racemization,
      Polymerization
      Formulation
      Stability of products.

   c. Study of pro-drugs in solving problems related to
      Stability,
      Bioavailability
      Elegancy of formulations.

2. Design,
   Development
   Process validation methods
   Pharmaceutical operations involved in the production
   Pharmaceutical products with special reference to Tablets,
   Suspensions.

3. Stabilization and stability testing protocol for various
   Pharmaceutical products.
   Liquid Oral Preparations
   Solid Dosage forms
   Parental Preparations
   Cosmetic Preparations
   Biological Products
4. Performance evaluation methods:

   a. In vitro dissolution studies for solid dosage forms
      Tablets, Capsules, Powders
      Sustained release dosage forms
      Interpretation of dissolution data.
      Tablets, Capsules, Powders
      Sustained release dosage forms

   b. Bioavailability studies
      Bioavailability testing protocol
      Bioavailability testing procedures.

   c. In vivo methods of
      Evaluation
      Statistical treatment.

5. GMP Quality assurance, Quality-audit.

6. Controlled released formulations.
   Design,
   Development,
   Production
   Evaluation

4.8.1. Practicals 3 hrs/week

1. Preformulation studies including drug-excipient compatibility
   studies, effect of stabilizers, preservatives etc. in dosage
   form design.

2. Experiments demonstrating improvement in bioavailability
   through prodrug concept.

3. Stability evaluation of various dosage forms and their expiration
   dating.

4. Dissolution testing and data evaluation for oral solid dosage forms.

5. Evaluation of Bioequivalence of some marketed products.

6. In vivo bioavailability evaluation from plasma drug concentration
   and urinary excretion curves.

7. Design, development and evaluation of controlled release
   formulations.
SEMESTER-VIII

PHARMACEUTICAL ANALYSIS - III

4.8.3. Theory

3 hrs / week

Introduction

A. Quality Assurance:

1. GLP
   ISO 9000
   TQM
   Quality Review & Quality Documentation

2. Regulatory control
   Introduction
   Regulatory drug analysis
   Interpretation of analytical data

3. Validation, quality audit:
   Quality of equipment
   Validation of equipment
   Validation of analytical procedures

B. The theoretical aspects, basic instrumentation, elements of
   Interpretation of spectra, and applications of the following
   Analytical techniques should be discussed:

1. Ultraviolet and visible spectrophotometry
   Theoretical aspects
   Instrumentations
   Interpretation of spectra
   Applications

2. Fluorimetry
   Theoretical aspects
   Instrumentations
   Interpretation & Applications

3. Infrared spectrophotometry
   Theoretical aspects
   Instrumentations
   Interpretation & Applications
4. Nuclear Magnetic resonance spectroscopy including $^{13}$c NMR
   Theoretical aspects
   Instrumentations
   Interpretation of spectra & Applications

5. Mass Spectrometry
   Theoretical aspects
   Instrumentations
   Interpretation of spectra
   Applications

6. Flame Photometry
   Theoretical aspects
   Instrumentations
   Interpretation & Applications

7. Emission Spectroscopy
   Theoretical aspects
   Instrumentations
   Interpretation & Applications

8. Atomic Absorption Spectroscopy
   Theoretical aspects
   Instrumentations
   Interpretation & Applications

9. X-ray Diffraction
   Theoretical aspects
   Instrumentations
   Interpretation & Applications

10. Radio immunoassay
    Theoretical aspects
    Instrumentations
    Interpretation & Applications

4.8.2. Practicals 4 hrs/week

1. Quantitative estimation of at least ten formulations containing
   single drug or more than one drug, using instrumental techniques

2. Estimation of Na, K, Ca ions using flame photometry

3. IR of samples with different functional groups ( -COOH , -COOR,
   -CONHR; -NH$_2$ , -NHR, -OH , etc

4. Workshop to interpret the structure of simple organic compounds
   using UR, IR, NMR and MS
1. Drug metabolism and Concepts of Pro drugs.
   Pathways of metabolism, Microsomal reactions
   Non microsomal oxidation
   Drug conjugation
   Stereochemical aspects of drug metabolism, Pro drug

2. Synthetic procedures of selected drugs, mode of action, uses, structure activity relationship (including physiochemical aspects) of the following classes of drugs. (Biochemical approaches in drug designing wherever applicable should be discussed).

   a. Antimetabolites (including sulfonamides).
      Antifolates
      Amino acids Antagonists, phenyl Alanine metabolites
      Glutamic acids Antimetabolites Vitamin Antagonists
      Gaba transaminase inhibitor and Beta lactamasa, ACEI

   b. Chemotherapeutic agents used in Protozoal, Parasitic and other infection.
      Introduction, classification, physiochemical Properties,
      Mode of action of Protozoal drugs
      SAR
      Synthesis
      Anti amoebic drugs
      Leishmaniasis drugs
      Drugs used in Trichomoniasis
      Anti malarials

   c. Antineoplastic agents.
      Introduction, classification, properties and mode of action
      SAR
      Synthesis

   d. Anti-viral including anti-HIV agents.
      Introduction, classification, properties and mode of action
      SAR
      Synthesis
e. Immunosuppressive and immuno stimulants.
   Introduction, classification, properties and mode of action
   SAR
   Synthesis
   Synthesis

3. Amino acids, peptide, nucleotides and related drugs.

i) Thyroid and Anti thyroid drugs.
   Introduction, classification, properties and mode of action
   SAR
   Synthesis
   Synthesis

ii) Insulin and oral hypoglycemic agents.
   Introduction, classification, properties and mode of action
   SAR
   Synthesis
   Synthesis

iii) Peptidomimetics and nucleotidomimetics
   Introduction, classification, properties and mode of action
   SAR
   Synthesis

f. Diagnostic agents.
   Introduction, classification, properties and mode of action
   SAR
   Synthesis

g. Pharmaceutical Aids.
   Anti – Oxidants
   Preservatives
   Coloring agents
   Filtering aids , diluents , expients
   Suspending agents , adsorbents and others
4.8.3. Practicals 3 hrs / week

1. Experiments designed on drug metabolism:
   a. Preparation of S9 and microsomes from tissue homogenates and standardization of protein.
   b. Effect of Phenytoin pretreatment on microsomal cytochrome p450, cytochrome b5, and NADPH-Cytochrome C-reductase and comparison of microsomes from control.
   c. Determination of microsomal aminopyrine demethylase and p-nitroanisole o-demethylase activities.
   d. Determination of microsomal azo- and nitroreductase activities.

2. Synthesis of selected drugs.

3. Establishing the pharmacopoeal standards and spectral studies.
1. World-wide trade in medicinal plants
   Derived products with special reference to diosgenin (disocorea), taxol (Taxus sps), digitalis
   Tropane alkaloid containing plants
   Papain, Cinchona, Ipecac, Liquorice, Ginseng, Aloe, Valerian, Rauwolfia
   Plants containing laxatives

2. A brief account of plant based industries
   Institutions involved in work on medicinal and aromatic plants in India
   Utilization and production of phytoconstituents such as quinine, calcium sennosides
   Podophyllotoxin, diosgenin, Solasodine and tropane alkaloids

3. Utilization of aromatic plants
   Derived products
   Special reference to sandalwood oil, mentha oil
   Lemon grass oil, vetiver oil
   Geranium oil and eucalyptus oil

4. Historical development of plant tissue culture
   Types of cultures
   Nutritional requirements
   Growth and their maintenance
   Applications of plant tissue culture in pharmacognosy

5. Chemotaxonomy of medicinal plants
   Introduction
   Characters studied in chemotaxonomy
   Application of chemotaxonomy

6. Marine Pharmacognosy
   Introduction
   Cardiovascular active substance
   Cytotoxic compounds
   Antimicrobial compounds
   Antibiotic compounds
   Anti-Inflammatory and Antispasmodic Agents
   Marine toxins
   Miscellaneous compounds
Novel medicinal agents from marine sources

7. Natural allergens
   Photosensitizing agents
   Fungal toxins

8. Herbs as health foods
   Nutraceuticals
   Antioxidants, PUFA, Probiotics, Prebiotics
   Dietary fibres, Omega-3 Fatty acids
   Spirulina, Royal jelly, Soya, Garlic

9. Herbal cosmetics
   Cosmeceuticals
   Phyto-Cosmeuticals
   Sources, Chemical constituents and Therapeutic benefit
   Retinoic acid, Alpha-hydroxy acids, Boswellic acids
   Vitamin C and Vitamin E, Co-enzyme and Miscellaneous

4.8.4. Practicals

1. Isolation of some selected phytoconstituents studied in theory
2. Extraction of volatile oils and their chromatographic profiles
3. Some experiments in plant tissue culture
SEMESTER – VIII

PHARMACOLOGY – IV
(Clinical Pharmacy and Drug Interactions)

4.8.5 Theory: 4 hrs/week

1. Introduction to Clinical Pharmacy.
   Concept of Clinical Pharmacy

2. Basic Concepts of Pharmacotherapy.
   a. Clinical Pharmacokinetics
      Individualization of Drug Therapy
   b. Drug Delivery Systems
      Biopharmaceutic
      Therapeutic Considerations
   c. Drug Use during:
      Infancy
      Elderly
   d. Drug use during pregnancy.
      First trimester
      Second trimester
      Third trimester
   e. Drug induced diseases.
   f. The Basics of Drug Interactions.
      Pharmacokinetics
      Pharmacodynamic
      Protein Binding
      Displacement
   g. General Principles of Clinical Toxicology.
      Introduction
      Types of toxic reaction
   h. Interpretation of Clinical Laboratory Tests.
      Medical Statistics
      Students t-test

3. Important Disorders of Organ Systems and their Management:

   a. Cardiovascsular Disorders:
      Hypertension,
      Congestive Heart Failure,
      Angina,
      Acute Myocardial Infarction,
      Cardiac arrhythmias

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b. CNS Disorders:
   Epilepsy,
   Parkinsonism,
   Schizophrenia,
   Depression

c. Respiratory Disease:
   Asthma

d. Gastrointestinal Disorders:
   Peptic ulcer,
   Ulcerative colitis,
   Hepatitis, Cirrhosis

e. Endocrine Disorders:
   Diabetes mellitus
   Thyroid Disorders

f. Infectious Diseases:
   Tuberculosis,
   Urinary Tract Infection,
   Enteric Infections,
   Upper Respiratory Infections

g. Hematopoietic Disorders:
   Anemias
   Drugs used

h. Joint and Connective Tissue Disorders:
   Rheumatic diseases,
   Gout
   Hyperuricemia.

i. Neoplastic Diseases:
   Acute Leukaemias,
   Hodgkin’s disease

4. Therapeutic Drug Monitoring.
   Removal of samples
   Estimation
   Validation

   Prophylactic
   Therapeutic
   Emergency
4.8.6. List of Elective Subjects

1. Pharmaceutical Marketing
2. Medicinal Plant biotechnology.
3. Quality assurance.
4. Drug design and lead identification.
6. Cosmeticology.
7. Packaging technology.
8. Any other emerging area availing the local expertise.

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