B.PHARM FINAL YEAR

IV.T.1. PHARMACEUTICAL TECHNOLOGY (Dosage forms)
(Theory)[3 Hrs/Week]

1. Liquid orals:
Formulation and technology and evaluation of:
(a) Solutions, (b) Suspensions (c) Emulsions and (d) Dry syrups.

2. Parenteral preparations: Definitions, classification, formulation, vehicles, containers, filling, sealing and testing, design of aseptic filling area-quality control.

3. Solid dosage forms:
(b) Capsules-Hard and Soft: Formulation and manufacture and their quality control.


5. Semi-solid dosage forms: Classification of bases, formulation, preparation packaging, storage and quality control of ophthalmic ointments, creams and suppositories.

6. Aerosols: Classification, propellants, advantages and disadvantages, formulation and manufacture. Pressurized packaging and applications. Quality control.

7. Container Materials: Packaging of all formulations, package testing.

III.P.1. PHARMACEUTICAL TECHNOLOGY (Dosage forms)
(Practicals)[3 Hrs/Week]

Formulation and manufacture of representatives of each class of dosage forms discussed in theory.

IV.T.2. PHARMACEUTICAL BIOTECHNOLOGY
(Theory)[3hrs/Week]

I. Fermentation Technology:
1. Screening Methods for bioactive metabolites.
2. Introduction to fermenter and its accessories.
3. Anaerobic and aerobic fermentations: Surface, submerged and solid state fermentations.
4. Manufacture of the following: Study of culture, media, production conditions, extraction and purifications of:
   (i) Artibiotics-Pencilllin and Streptomycin.
   (ii) Acids-citric and lactic acids.
   (iii) Solvents-Alcohol.
   (iv) Enzymes-Fungal diastase.
   (v) Aminoacids- (L)-Glutamic acid.
   (vi)Vitamins-Vitamin B12.
   (vii)Polysaccharides-Dextran.
   (viii)Biomass-Lactobacillus sporogenes.

II. Animal, blood and immunological products.

Animal Products:
A. i) Insulin-extraction, purification and types of formulations.
B. Blood products and plasma substitutes official in I.P.(Preparation, uses and storage).
C. Immunological preparations: Manufacture, standardisation of sera, vaccines, antitoxins and diagnostic agents official in I.P.
D. Surgical ligatures and sutures of I.P. Sterilization , manufacture and standardization.

III. Testing methods:
A. Test for sterility: Sterility testing, media, sampling, neutralization of various antimicrobial substances in dosage forms. Conducting these tests for injections, surgical sutures (cat gut), cotton, infusion, tubing, bottles etc.
C. Radio immunoassay (RIA): Theoretical principles, practice and applications, and modifications of RIA viz., ELISA.
D. Pyrogens: Source, nature of pyrogens - Testing by LAL method

I. Enzymes and animal cell biotechnology:
1. Enzymes: Sources, classification, properties, general methods of preparation and purification. Application in pharmaceutical industry, therapeutics and clinical analysis.
2. Immobilization of enzymes, advantages and limitations of immobilization and brief study of a few methods of immobilization.
4. Brief account of animal cell culture and its applications.

VI. r-DNA (recombinant DNA) technology and applications.

2. Cutting and joining of DNA molecules: Cutting of DNA molecules, restriction endonucleases and their nomenclature, target sites and mechanical sheering of DNA, Joining of DNA molecules, DNA ligase, double linkers, adapters and homopolymer tailing.

3. Introduction in to host cell: Transfection with recombinant phage DNA, transformation with plasmid DNA, in \textit{vitro} DNA packaging into phase coat. Recombinant selection by genetic, immunochemical, and nucleic acid hybridization methods and Expression of cloned genes.

4. Plasmids as cloning vehicles: Basic properties of plasmids, purification of plasmid DNA. Desirable properties of plasmid cloning vehicles. Natural and artificial plasmids-PSC101 and PBR 322 as vectors.


\textbf{IV.P.2. PHARMACEUTICAL BIOTECHNOLOGY}
(Practicals) [4 Hrs/week] (3hr on the same day and 1hr in the next day morning)

1. Preparation of killed bacterial vaccine
2. Sterility testing of injections, powders
3. Preparation of antiserum from rabbit (demo)
4. Estimation of lactic acid produced by \textit{Lactobacillus sporogenes}.
5. Production of alcohol and estimation of alcohol
6. Microbiological assay of antibiotics-by agar diffusion method.
7. Microbiological assay of antibiotics-turbidimetry method.
8. Production of an antibiotic.
10. Gel electrophoresis of nucleic acid (demo).
11. Isolation of plasmid DNA from bacterial cells.
12. Transformation of \textit{E.coli}.
15. Heparin bio-assay (demo)
17. Determination of Additive/synergistic effect of combination of drugs.
18. Pyrogen testing - LAL test (demo)
19. Antigen - Antibody reaction (TT, ATS) diffusion method.
20. RIA/ESLISA test. (Demo).

\textbf{IV.T.3. BIOPHARMACEUTICS AND PHARMACOKINETICS}
(Theory) [2 Hrs/Week]
1. INTRODUCTION TO BIOPHARMACEUTICS:
   1.1 Introduction
   1.2 The Concept of Biopharmaceutics

2. ABSORPTION OF DRUGS
   ABSORPTION OF DRUGS FROM GASTROINTESTINAL TRACT
   2.1 Introduction
   2.2 Rate Limiting Step in Bioavailability
   2.3 Anatomical and Physiological Considerations of the Gastrointestinal Tract (GIT).
   2.4 Mechanisms of Drug Absorption.
   2.5 Factors Governing Gastrointestinal Drug Absorption.
      2.5.1 Physiological Factors
      2.5.2 Physicochemical Factors
      2.5.2.1 Oil/Water Partition Coefficient (Lipid solubility).
      2.5.2.2 Drug Dissociation Constant and Gastrointestinal pH.
      2.5.2.3 pH-Partition Hypothesis.
   2.6 Metabolic Factors
   2.7 Complicated Factors
   2.8 Formulation Factors

3. DISSOLUTION
   3.1 Mechanisms of Dissolution
   3.2 Factors Affecting the Rate of Dissolution
   3.3 Measurement of Dissolution Rates
      Official Methods of Dissolution.
      Unofficial Methods of Dissolution
      Control of Variables in Dissolution Testing
   3.4 In-vitro and In-vivo Correlation's
   3.5 Limitations of Dissolution Test

4. DRUG DISTRIBUTION
   4.1 Physicochemical Properties of the Drug
   4.2 Organ/Tissue Size
   4.3 Blood Flow to the Organ
   4.4 Physiological Barriers to the Diffusion of Drugs
   4.5 Drug Binding in Blood
   4.6 Drug Binding to Tissue and Other Macromolecules
   4.7 Apparent Volume of Distribution

5. DRUG ELIMINATION
   5.1 Renal Excretion
   5.2 Renal Blood Flow
5.3 Renal Clearance
5.4 Hepatic Elimination of Drugs
5.5 Drug Metabolism
  5.5.1 Phase-I Reactions
  5.5.2 Phase-II Reactions
5.6 Induction and Inhibition of Drug Metabolizing Enzymes
5.7 Hepatic Clearance
5.8 Pharmacological Activity of Metabolites
5.9 Disposition of Metabolites
5.10 First Pass Effect
5.11 Biliary Excretion
5.12 Enterohepatic Circulation
5.13 Extrahepatic Metabolism
5.14 Minor Pathways of Drug Excretion

6. INTRODUCTION TO PHARMACOKINETICS
6.1 Mathematical Model
6.2 Drug levels in blood
6.3 Introduction to Pharmacokinetic Models
6.4 Pharmacokinetic Study

7. ONE COMPARTMENT OPEN MODEL
A. INTRAVENOUS INJECTION (BOLUS)
7.1 I.V. Bolus-Unchanged Drug in Blood Plasma
  Apparent volume of distribution
  Elimination Rate Constant
  Biological Half-life
  Area under the curve (AUC)
  Clearance
7.2 I.V. Bolus-Unchanged Drug in Urine
  Calculation of Pharmacokinetic Parameters
  Excretion Rate Method
  Sigma-Minus Method
  Comparison of the two methods

IV.P.3. BIOPHARMACEUTICS AND PHARMACOKINETICS
(Practicals) [3 Hrs/Week]

Experiments based on theory.

IV.T.4. MEDICINAL CHEMISTRY - II (Synthetic)
(Theory) [3 Hrs/Week]

I. Basic considerations of Drug activity:
a) Introduction, (b) Factors affecting bioactivity (c) Theories of drug activity (d) A brief account of quantitative aspects of drug action (e) Receptor concept of drug action mechanism.

II. Mechanisms of Drug Action: (a) Introduction (b) Enzyme stimulation, (c) Enzyme inhibition, (d) Sulfonamides (e) Membrane - active drugs.

III. Drug metabolism and inactivation: (a) Introduction, (b) Biotransformations, (c) Metabolic reactions (d) Conjugation reactions.

IV. A study of the following classes of drugs including: introduction, classification, structures, mechanism of action and SAR. Synthesis of compounds specified against each class is to be studied.

A. Drugs acting on CNS:
   a) Neurotransmitters, Noradrenaline, Dopamine, Acetylcholine.
   b) Hypnotics and anxiolytics - Phenobarbital, Buspirone, Diazepam, Alprazolam.
   c) Antipsychotic drugs - Chlorpromazine, Thiothixene, Haloperidol.
   d) Antiepileptic drugs - Phenytoin, Valproic acid.
   e) Antidepressants - Imepramine - Fluoxetine,

B. Drugs affecting adrenergic mechanism:
   a) Introduction
   b) Adrenergic concepts, catabolism
   a) Indirect acting sympathomimetics: Amphetamine.

C. Drugs affecting cholinergic mechanism:
   a) Introduction- Some aspects of cholinergic system.
   b) Cholinergic drugs : Carbacol.
   c) Anticholinesterase agents : Neostigmine
   d) Antidotes for Ach inhibitors.
   e) Cholinergic blocking agents : Propantheline.
   f) Neuromuscular blocking agents : Galamine.

D. Drugs and Cardio-vascular diseases:
   a) Introduction (cardiovascular diseases)
   b) Anti-hypertensives-Methyl Dopa, Amlodipine.
   c) Anti-arrhythmics-Procainamide.
   d) Diuretics- Acetazolamide, Hydrochlorothiazide, Furosemide
   e) Anticoagulants, anti-anginals, and coronary vasodilators, Isosorbide Dinitrate, Verapamil, Diltiazem.
   g) Antihyperlipidemics (Hypocholesteremic drugs) : Clofibrate.
   h) Anti-diabetics - Phenformin, Glipizide.
   i) Drugs affecting thyroid function: Methimazole, Propylthiouracil.

E. Analgesics and non-steroidal anti-inflammatory agents:
   a) Introduction-(Types of pain & Inflammation)
b) Classification - mild analgesics and strong analgesics : Meperidine and Methadone.
b) Non-steroidal anti-inflammatory drugs Aspirin, Paracetamol, Indomethain, Piroxicam, Ibuprofen, Diclofenac, Nimesulide.

IV.P.4. MEDICINAL CHEMISTRY - II (Synthetic)
(Practicals) [3 Hrs/Week]
A. Preparation of some important medicinal compounds involving at least two steps in their synthesis.
B. Quantitative estimations of 1) halogens by Strepeno’s method, 2) hydroxy groups (alcoholic and phenolic), 3) Carboxyl groups by silver salt method and 4) methoxy groups by Zeissel’s method.
C. Assay of some pharmaceutical formulations.

IV.T.5. PHARMACOGNOSY – III
(Theory) [3 hrs/week]
I. Volatile Oils : Study of volatile oils of Mentha, Coriander, Cinnamon, Cassia, Lemon peel, Orange peel, Lemon grass, Citronella, Caraway, Dill, Clove, Fennel, Nutmeg, Eucalyptus, Cheno podium, Cardamom, Musk, Palmarosa, Gaultheria, and Sandal wood.
II. Resins : Study of drugs containing Resins and Resin Combinations like Podophyllum, Cannabis, Capsicum, Myrrh, Asafoetida, Balsam, of Tolu, Balsam of Peru, Storax, Benzoin, Turmeric, Ginger and Guggul.
III. 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:
   b) Tropane : Belladonna, Hyoscyamus, Datura, Duboisia, Coca and Withania.
   c) Quinoline and isoquinoline : Cinchona, Ipecac, Opium.
   d) Indole : Ergot, Rauwolfia, Catharanthus and Nux-vomica.
   e) Imidazole : Pilocarpus.
   f) Steroidal : Kurchi
   g) Alkaloidal amine : Ephedra and Colchicum.
   h) Glycoalkaloid : Solanum.
   i) Quinazoline : Vasaka
   j) Purines : Coffee, Tea and Cola

IV. Study of the biological sources, cultivation, collection, commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following groups of drugs containing glycosides:
   a) Saponins: Liquorice, Ginseng, and Dioscorea.
   b) Cardioactive sterols: Digitalis, Squill and Strophanthus.
   c) Anthraquinone cathartics: Aloe, Senna, Rhubarb and Cascara.
   d) Others: Psoralea, Ammi majus, Ammi visnaga, Gentian, Saffron, Chirata, Quassia.

V. Historical development of plant tissue culture; types of cultures, nutritional requirements, growth and their maintenance. Applications of plant tissue culture in production of pharmaceutically important secondary metabolites.

VI. Sources, structure, commercial significance and uses of novel biomedicinals – taxol, gymnemic acid, bucoposides, Asiaticoside, neem derivatives, artemesinin, camptothecin.

IV.P.5. PHARMACOGNOSY – III
I. Histological studies of Cinnamon, Clove, Ephedra, Fennel, Ginger, Ipecac, Linseed, Nux-vomica, Quassia and Senna.
II. Identification of powdered crude drugs and their combinations with the help of organoleptic, microscopic, micro-chemical and chemical methods, (if any).
III. Detection of alkaloids, glycosides, sterols, flavonoids and by chemical tests.
IV. Few exercises on isolation of active principles from crude drugs.
V. Establishment of thin layer chromatographic profiles of some volatile oils and extracts containing alkaloids and glycosides.
VI. Spotting of crude drugs mentioned in theory.

IV.T.6. PHARMACOLOGY - I I
(Theory) [3 Hrs./Week]

2. Drugs acting on respiratory system: Drugs affecting respiration and drugs used in disorders of respiratory function.
3. Drugs acting in atherosclerosis. Lipid lowering drugs.
5. Peptides and proteins as mediators: Regulation of peptides and peptide antagonists, proteins and peptides as drugs.

IV.P.6. PHARMACOLOGY – II
(Practicals) [3 hrs/week]

IV.T.7. HOSPITAL AND CLINICAL PHARMACY
(Theory) [2 Hrs/Week]

SECTION - A : Hospital Pharmacy

1. Introduction to hospitals and hospital pharmacy: A historical development.
2. Hospital pharmacy: Objectives and functions, organization, planning and administration of modern hospital pharmacy services, location, layout, personal, qualifications, requirements, abilities and evaluation of hospital pharmacist, workload and remuneration of hospital pharmacist.
3. i. Hospital drug policy – General considerations.
   ii. Pharmacy and therapeutic committee – Purpose, organization and functions.
   iii. Hospital formulary – Organization, formulary content, preparation and distribution. Pharmacy procedural manual preparation and publication. Hospital committees – Infection control committee, Antibiotic committee and Research and ethics committee.

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Role of hospital pharmacist in hospital committees and practice of Rational Drug Therapy. Drug exchange program.

4. **Hospital manufacturing**: Economical considerations and estimation of demands lay out, raw materials, production planning, requirements, manpower requirements and quality assurance, manufacturing of (including repacking and prepacking) sterile products (small and large volume perenterals), non-sterile products, total perenteral nutrition and intravenous additives.

5. **Drug distribution**: Outpatient and Inpatient services, unit dose drug distribution systems, floor ward stock systems, satellite pharmacy services, central sterile services and bedside pharmacy.

6. **Radiopharmaceuticals**: Radioisotope committee, role of hospital pharmacist in isotope and non-isotope pharmacy.

**SECTION - B : Clinical Pharmacy**

1. Definition, scope, history and development of clinical pharmacy.

2. **Professional activities of the clinical pharmacist**: Drug therapy monitoring (medication chart review, clinical review, TDM and pharmacist interventions), ward round participation, adverse drug reaction management, drug information and poison information, medication history review and patient counseling.

3. **Patient data analysis**: Clinical laboratory tests used in the evaluation of common disease states, interpretation of test results of liver function tests, pulmonary function tests, haemogram and renal function tests. The patient’s cases history, its structure and use in evaluation of drug therapy.

4. **Basic and general principles of drug therapy**:
   - **Monitoring of drug therapy**: Therapeutic, pharmacokinetic and pharmacodynamic monitoring of drug therapy.
   - **Adverse reactions to drugs**: Incidence, classification and surveillance methods of adverse reactions to drugs.
   - **Pharmacogenetics**: Pharmacokinetic and pharmacodynamic aspects of pharmacogenetics.
   - **Drug interactions**: Incidence, pharmacokinetic and pharmacodynamic drug interactions.
   - **Patient compliance**: Factors, which effect compliance, methods of measuring and improving drug compliance.
   - **Pharmacology of placebos**: Mode of action, uses of abuse, adverse effects and factors that influence the response of placebos.

5. General prescribing guidelines in pediatric and geriatric patients, pregnancy and lactation.

6. **Drug and poison information services**: Introduction of drug information, resources available, design of literature searches, critical evaluation of drug information and literature, preparation of written and verbal reports, development of a drug information data base and emergency treatment of poisoning.

7. **Pharmacotherapy of diseases**: Pathophysiology, drug therapy and critical analysis of rational use of drugs in the following disorders:
   - **Cardiovascular disorders**: Hypertension, congestive cardiac failure, ischaemic heart disease, arrhythmias and hyperlipidaemias.
   - **Respiratory disorders**: Asthma and chronic obstructive airways disease.
   - **Renal disorders**: Acute renal failure, chronic renal failure and drug dosing in renal impairment.
   - **Hematological disorders**: Anemia and drug induced hematological disorders.
   - **Endocrine disorders**: Diabetes, thyroid disease and hormone replacement therapy.
   - **Nervous diseases**: Epilepsy, Parkinson’s disease and headache.
Psychiatric disorders: Schizophrenia, depression, anxiety disorders and sleep disorders.
Gastrointestinal disorders: Peptic ulcer disease, inflammatory bowel diseases, hepatitis, alcoholic liver disease and drug induced liver disease.
Infectious disease: Respiratory tract infections, gastro-enteritis, pneumonia, typhoid, urinary tract infections, tuberculosis, leprosy, protozoal infections, helminthiasis, sexually transmitted disease and AIDS.

IV.P.7. PROJECT WORK
(Practicals) [3 Hrs/Week]
To be carried out under the supervision of a faculty member and report to be submitted at the end of academic year before final year annual examinations.