

**VIII-T-1 PHARMACEUTICS –XI  
(PHARMACEUTICAL TECHNOLOGY – II)**

Design, development, formulation and evaluation of controlled release formulations. Carriers for drug delivery systems, Prodrugs.

**Microencapsulation:** Theory, methods, technology and applications.

**Transdermal Drug Delivery Systems:** Theory, formulation and evaluation.

**Targeted Drug Delivery Systems:** Concept of drug targeting, importance in therapeutics, methods in drug targeting, Nanoparticles, Liposomes, Erythrocytes etc.

**Implants and Inserts:** Types, design and evaluation, Osmotic pump.

**Packaging of Pharmaceutical Products and Cosmetics:** Packaging components, types, specifications and methods of evaluation, stability aspects of packaging, packaging equipment, factors influencing choice of containers, legal and other official requirements for containers, Packaging testing.

**VIII-P-1 PHARMACEUTICS-XI PRACTICALS  
(PHARMACEUTICAL TECHNOLOGY II)**

Formulations, evaluations and stability testing of preparations concerning dosage forms mentioned in theory.

## VIII-T-2 PHARMACEUTICS XII (BIOPHARMACEUTICS AND PHARMACOKINETICS)

Introduction to biopharmaceutics and pharmacokinetics development and their role in drug formulation.

### **Biopharmaceutics**

Definition, passage of drugs across biological barrier, Physiochemical, Biological and Pharmaceutical factors influencing biopharmaceutical performance of drugs.

1. **Gastrointestinal absorption of drugs:** Passage of drugs across biological membranes, nature of biological membranes, gastrointestinal absorption mechanisms.
2. **Factors affecting drug absorption:** Physiological factors, dietary factors, physicochemical factors, pH partition hypothesis, dosage form factors.
3. **Methods of studying gastrointestinal absorption:** *In vitro* and *in vivo* methods.
4. **Drug disposition:** Distribution in blood, cellular distribution, plasma protein binding, tissue protein binding.

Drug Excretion: Routes of drug excretion, renal excretion of drugs, factors affecting renal excretion, biliary and salivary excretion of drugs.

Drug biotransformation : Pathways of drug metabolism, drug metabolizing enzymes, factors affecting drug metabolism and drug response, inhibition and stimulation of drug metabolism.

### **Pharmacokinetics**

Absorption, distribution, metabolism and excretion of drugs, fluid compartment and circulatory system, protein binding, significance of plasma drug concentration measurement.

## **Compartment Models**

Model selection criteria, **alaika** information criterion, one-compartment and two-compartment models, Wagner-Nelson and loo Riegelman methods for estimation of absorption constants. Curve fittings, regression procedure and area under blood level curves.

## **Clinical Pharmacokinetics**

Urinary excretions, computation of pharmacokinetic parameters from urine data, haepetic clearance, biliary excretion, excretion ratio, dosage regimen adjustment in patients with and without renal failure, pharmacokinetic drug interactions and their significance in combination therapy.

## **Bioavailability and Bioequivalence**

Bioavailability and Bio-equivalence, Federal requirements, Methods of determination of bioavailability using blood level and urinary excretion data, design and evaluations, bioavailability assessment.

## **VIII-P-2-PHARMACEUTICS-XII PRACTICALS**

### **(BIOPHARMACEUTICS AND PHARMACOKINETICS)**

Experiments based on theory.

Statistical treatment of pharmaceutical data.

## **Books recommended**

- 1. Gibaldi, M. and Perrier d, Pharmacokinetics, Marcel Decker, New York.**
- 2. Notari, R.E., Biopharmaceutics and Pharmacokinetics-An Introduction, Marcel Decker, New York.**

### VIII-T-3 PHARMACEUTICAL ANALYSIS-III

Dosage forms evaluation as per monograph with special reference to I.P..

Development of new analytical methods.

Concepts in validation, validation of manufacturing and analytical equipment, validation of analytical procedures.

Documentation: Protocols, forms and maintenance of records in pharmaceutical industries, preparation of documents for new drug approval and export registration to United States, United Kingdom, Europe and Africa.

Patent processing and its applications.

Requirement of GLP, ISO 9000, WHO and U.S. F.D.A.

Basic concept of quality assurance, quality assurance system, sources and control of quality variation.

In-process quality control tests, IPQC problems in Pharmaceutical Industries, Total quality management.

Sampling plans, sampling and operating characteristics curves, Interpretation of analytical data.

Regulatory control, regulatory drug analysis.

### VIII-P-3 PHARMACEUTICAL ANALYSIS –III PRACTICALS

Evaluation of dosage formulations as per I.P. monographs.

Experiments based on theory.

#### **Books Recommended**

1. Willing, S. H., IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker Inc., New York.
2. Loftus, B. T. and Nash R., Pharmaceutical Process Validation, Marcel Dekker Inc., New York.
3. Svehla, G. Vogel's Text Book of Micro and Semi Micro Qualitative Inorganic Analysis, Orient Longman, Hyderabad.
4. Beckett, A.H. and Stenlake, J.B., Practical Pharmaceutical Chemistry, The Athlone Press of the University of London.
5. Pharmacopoeia Of India, Ministry of Health and Family Welfare, Govt. of India, New Delhi.

## **VIII-T-4 PHARMACOLOGY –IV (CLINICAL PHARMACY AND DRUG INTERACTIONS)**

Introduction to Clinical Pharmacy.

Basic Principles of cell injury and adaption-

Causes of cell injury, pathogenesis, morphology of cell injury, intra cellular alterations in lipids, proteins and carbohydrates, cellular adaption, atrophy, hypertrophy.

Basic Mechanism Involved in the Process of Inflammation and Repair-

Alterations in vascular permeability and blood flow, migration of WBC's , acute and chronic inflammation, brief outline of the process of repair.

Basic Concepts of Pharmacotherapy-

- a) Clinical Pharmacokinetics Individualization of Drug Therapy.
- b) Drug Use During Infancy and in the Elderly ( Paediatrics and Geriatrics)
- c) Drug use during Pregnancy.
- d) Drug induced disease.
- e) The Basics of Drug interactions.
- f) General principles of clinical laboratory tests.

Therapeutic Drug Monitoring

Concept of essential Drugs and Drug Use, Drug abuse.

Principles of Toxicology

- a) Detination of Poison, general principles of treatment of poisoning particular reference of barbiturates, Opioids, Organophosphorylation and Atropine poisoning.
- b) Heavy metals and heavy metal antagonists.

### **Books recommended**

1. Herfindal, E.T. and Hirschman, J.L., Clinical Pharmacy and Therapeutics, William and Wilkins.
2. Katzung, B.G., Basic and Clinical Pharmacology, Prentice Hall International.
3. Laurence, D.R. and Bennet, P.N., Clinical Pharmacology, Churchill Livingstone.

## **ELECTIVE**

### **1. PACAKAGING TECHNOLOGY**

New concepts in pharmaceutical packaging.

Package system, package design research.

Packaging materials with special reference to polymers, metals glass and plastics, control of packaging materials.

Blister and Strip packaging.

Testing of containers and closures, Pharmacopoeial tests and specifications.

Defects in Packages.

Stability of packages and packaging materials.

Ancillary materials used in packaging.

Sterlization of pacakaging materilas.

Packaging of parenterals, ophthalmics and aerosols.

Corrugated fiberboard materials, label and leaflets preparation.

Legal requirement.

### **2. FOOD TECHNOLOGY: Syllabus to be prepared.**

### **3. PERFUMES AND COLOURS**

Sources and method of extraction / preparation of essential oils, flower oils, Gums,

Oleoresins, Oleogum resins and Balsams.

**Isolation, Properties and Uses of –**

Eugenol, Pinene, Linalool, Citral and Geraniol. Deodorization of Ethanol.

**Fixatives-**

Sources, classification, chemical composition, selection and uses of fixatives.

**Flavoures –**

Sources and properties of Vanila, Rose, Pineapple, Peppermint, Mango, Raspberry, Orange and Lemon.

**Building of perfumes:** Formulation of perfumes, from synthetic substance, sources, composition and properties of Lavender, Rose, Jasmin, Violet, Orris, Cypre, Amber, Carnation, Muguet, Liliac, Acacia, cassia, Narcissus, Kewra. Incorporation of perfumes in cosmetic products like creams, lotions, powders, Hair preparations, Nail preparataions, Tooth pastes, Toilet Soaps, Baby Preparations, Lip and other preparations.

**Packaging:** Packaging of perfumes including special emphasis on aerosol products.

**Colours, Pigments, Dyes-**

Classification, uses and preparation of colours solutions/ dispersions incorporations.

Detection of colours.