14. **PACKING & PACKAGING:** Influence of Packaging materials, Stability, Packaging Lines, Packaging Area, Packaging Equipment.

STUDY TOUR: A visit to the pharmaceutical industries will be an integral part of the syllabi and will prepare and submit a report about operations in Pharmaceutical industry that will be evaluated in practical examination.

PHARMACEUTICS-IV (INDUSTRIAL PHARMACY) (Practical)

Paper 7 **Marks 100**

NOTE: Practical of the subject shall be designed from time to time on the basis of the above mentioned theoretical topics and availability of the facilities, e.g.

- Manufacture of Tablets by Wet Granulation Method, by Slugging and by Direct Compression.
- Coating of Tablets (Sugar Coating, Film coating and Enteric Coating).
- Clarification of liquids by various processes.
- Size Reduction, Homogenization.
- Ampoule filling, sealing and sterilization clarity and leakage tests in injectables.
- Capsule filling by semi automatic machines.
- Manufacture of sustained action drugs.
- Tablets Tests like Disintegration. Dissolution. Friability. Hardness and thickness tests.
- Determination of weight variation in tablets.
- Density of powder. Particle size analysis (Note: A minimum of 20 practicals will be conducted).

PHARMACEUTICS-V (BIOPHARMACEUTICS & PHARAMCOKINETICS) (Theory)

Paper 4 **Marks 100**

1. **DEFINITIONS AND TERMINOLOGY:** Biopharmaceutics, Generic Equivalence, Therapeutic Equivalents, Bioavailability, Bioequivalence, Drug Disposition, Pharmacokinetics (LADMER: Libration, absorption, distribution, metabolism, elimination and response).

2. **GASTRO-INTESTINAL ABSORPTION:** Forces which help in transmembrane movements, Anatomical and physiological factors influencing absorption of drugs. Physicochemical properties of drugs affecting absorption. Absorption of different oral dosage forms.

3. **BIOLOGICAL HALF LIFE AND VOLUME OF DISTRIBUTION:** Introduction, types, methods of determination and application**.**

4. **DRUG CLEARANCE:** Introduction, Mechanism, Models, determination and relationship of clearance with half-life.

5. **PHARMACOKINETICS:** Introduction, Linear and Non-linear Pharmacokinetics. Application of pharmacokinetics in clinical situations.

6. **BIOAVAILABILITY AND BIOEQUIVALENCE:**
    a. Introduction.
    b. Bioavailability types, parameters, significance and study protocol.
    c. Methods of Assessment of Bioavailability
    d. Bioequivalence study designs, components and application, report format

7. **CONCEPT OF COMPARTMENT(S) MODELS:**
    I. One compartment open model
        a. Intravenous Injection (Bolus)
        b. Intravenous infusion
    II. Multicompartment models
        a. Two compartment open model
        b. IV bolus, IV infusion and oral administration
    III. Non-compartmental Model
        a. Statistical Moment Theory
        b. MRT for various compartment models
        c. Physiological Pharmacokinetic model

8. **MULTIPLE DOSAGE REGIMENS:**
    a. Introduction: principles of superposition
    b. Factors: persistent, accumulation and loss factors
    c. Repetitive Intravenous injections-One Compartment Open Model
    d. Repetitive Extravascular dosing-One Compartment Open model
    e. Multiple Dose Regimen-Two Compartment Open Model

9. **ELIMINATION OF DRUGS:**
    d) Hepatic Elimination: Percent of Drug Metabolized, Drug Biotransformation reactions, (Phase-I reactions and phase-II reactions), First pass effect, Hepatic clearance of protein bound drugs and Biliary excretion of drugs.
    e) Renal Excretion of Drugs: Renal clearance, Tubular Secretion and Tubular Re-absorption.
    f) Elimination of Drugs through other organs: Pulmonary excretion, salivary excretion, Mammilary excretion, Skin excretion and Genital excretion.

10. **PROTEIN BINDING:** Introduction, types, kinetics, determination and clinical significance of drug-protein binding.

11. **PHARMACOKINETICS VARIATIONS IN DISEASE STATES:** Determination of pharmacokinetics variations in renal and hepatic diseases, general approaches for dose adjustment in renal disease and hepatic diseases.

12. **PHARMACOKINETICS OF INTRAVENOUS INFUSIONS:**

13. **BIOPHARMACEUTICAL ASPECTS IN DEVELOPING A DOSAGE FORM:** Drug considerations, drug product considerations, patient considerations, manufacturing considerations, pharmacodynamic considerations pharmacokinetic considerations.

14. **IN-VITRO-IN-VIVO CORRELATION (IVIVC):** Introduction, levels and determination of in-vitro/in-vivo correlation.

PHARMACEUTICS-V (BIOPHARMACEUTICS & PHARAMCOKINETICS) (Practical)

Paper 8 **Marks 100**

NOTE: Practical of the subject shall be designed from time to time on the basis of the above mentioned theoretical topics and availability of the facilities, e.g. Blood Sampling Techniques (In Laboratory Animals like dog, rabbits, mice etc. in human beings), In-vitro dissolution studies, Optional dose determination, Measurement of rate of Bioavailability, Determination of relative and absolute bioavailability. Plasma level-time curve (Determination of Pharmacokinetic parameters). Determination of plasma protein binding. Urinary sampling techniques. In Laboratory animals. In humans: Renal excretion of drugs or drug disposition.

PHARMACEUTICS-VI (PHARMACEUTICAL QUALITY MANAGEMENT) (Theory)

Paper 5 **Marks 100**

1. **INTRODUCTION:**
   Basic concepts and introduction of pharmaceutical industry in relevance to quality control departments, Testing, Quality Management System, Quality Assurance, Good Manufacturing Practices and Current Good Manufacturing Practices. General understanding of good laboratory practices and validation.

2. **QUALITY CONTROL OF SOLID DOSAGE FORMS** (conventional and modified release dosage forms):
   (a) Physical tests: Hardness, Thickness, Diameter, Friability, Disintegration, Weight Variation.
   (b) Chemical tests: Content uniformity, Assay of active Ingredient.
3. **QUALITY CONTROL OF SYRUPS, ELIXIRS, AND DISPERSE SYSTEM:** Viscosity, its determination and application in the Quality Control of Pharmaceuticals, Weight per ml and Assay of active Ingredient.
4. **QUALITY CONTROL OF SUPPOSITORIES:** Dissolution test, Uniformity of weight, Assay of active Ingredient, Liquefaction time test and Breaking test.
5. **QUALITY CONTROL OF STERILE PRODUCTS (PARENTERALS):** Sterility Test and Sterile section management, Leaker's test, Clarity test, Pyrogen test for Parenteral and other sterile preparations, Assay for active Ingredient.
6. **BIOLOGICAL ASSAYS:** Biological methods, Standard preparations and units of activity, Bioassay of antibiotics, Bioassay of insulin injection, Assay of prepared digitalis and Assay of Vitamin D.