Marwadi University
Faculty of Pharmacy

Subject code: **13PH0605**
Subject name: **Industrial Pharmacy-I**

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen, and in solving the problems raised therein.

Objective: Upon completion of this course the student should be able to:
1. Know the various pharmaceutical dosage forms and their manufacturing Techniques.
2. Know various considerations in the development of pharmaceutical dosage forms.
3. Formulate solid, liquid, and semisolid dosage forms and evaluate them for their quality.

Teaching and assessment scheme:

Teaching Scheme (Hours)			Credits	Theory/ Tutorial Marks			Practical Marks		Total Marks
Theory	Tutorial	Practical		CSE	IA (I)	ESE (E)	TW	Viva (V)	
3	1	4	6	10	15	75	15	35	150

Theory syllabus: **Teaching hours: 45 Hours**

Unit-1 — 7 Hours

Preformulation studies: Introduction to preformulation, goals and objectives, a study of physicochemical characteristics of drug substances. a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pK_a, pH, partition coefficient), polymorphism. b. Chemical Properties: Hydrolysis, oxidation, reduction, racemization, polymerization BCS classification of drugs & its significant. Application of preformulation considerations in the development of solid, liquid oral, and parenteral dosage forms and their impact on the stability of dosage forms.

Unit-2 — 10 Hours

Tablets: a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression, and processing problems. Equipment and tablet tooling. b. Tablet coating: Types of coating, coating materials, formulation of a coating composition, methods of coating, equipment employed, and defects in the coating. c. Quality control tests: In-process and finished product tests Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in the pharmacopoeia.

Unit-3 — 8 Hours

Capsules: a. Hard gelatine capsules: Introduction, Production of hard gelatine capsule shells. Size of capsules, filling, finishing, and special techniques of formulation of hard gelatine capsules, manufacturing defects. In-process and final product quality control tests for capsules. b. Soft gelatine capsules: Nature of shell and capsule content, size of capsules, the importance of base adsorption and minim/gram factors, production, in-process, and final product quality control tests. Packing, storage, and stability testing of soft gelatine capsules and their applications. Pellets: Introduction, formulation requirements, pelletization process, equipment for the manufacture of pellets.

Unit-4 10 Hours

Parenteral Products: a. Definition, types, advantages, and limitations. Preformulation factors and essential requirements, vehicles, additives, the importance of isotonicity b. Production procedure, production facilities, and controls, aseptic processing c. Formulation of injections, sterile powders, large volume parenteral, and lyophilized products. d. Containers and closures selection, filling, and sealing of ampoules, vials, and infusion fluids. Quality control tests of parenteral products. Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments, and eye lotions; methods of preparation; labelling, containers; evaluation of ophthalmic preparations.

Unit-5 10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream, and vanishing cream, toothpaste, hair dyes, and sunscreens. Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies. Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing the choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

Tutorials will be based on the above syllabus. **Teaching hours: 15 Hours**

Practical syllabus: **Teaching hours: 04 Hours/week**

1. Preformulation studies on paracetamol/aspirin/or any other drug.
2. Preparation and evaluation of Paracetamol tablets.
3. Preparation and evaluation of Aspirin tablets.
4. Coating of tablets- film coating of tables/granules.
5. Preparation and evaluation of Tetracycline capsules.
6. Preparation of Calcium Gluconate injection.
7. Preparation of Ascorbic Acid injection.
8. Quality control test of (as per IP) marketed tablets and capsules.
9. Preparation of Eye drops/ and Eye ointments.
10. Preparation of Creams (cold / vanishing cream).
11. Evaluation of Glass containers (as per IP).

Recommended References (Latest edition):

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H. A. Liberman, Leon Lachman & J. B. Schwartz.
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman.
3. Pharmaceutical dosage forms a disperse system Vol.-1 by Liberman & Lachman.
4. Modern Pharmaceutics by Gilbert S. Banker & C. T. Rhodes, 3rd Edition.
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS).
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
7. Pharmaceutics - The science of dosage form design by M. E. Aulton, Churchill Livingstone, Latest edition.
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5thedition, 2005.
9. Drug stability - Principles and practice by Cartensen & C. J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.