NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - V)

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Course Code	**BP502T**
Course Title	**Industrial Pharmacy I -Theory**

Scope:

Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product

Objectives:

Upon completion of the course the student should be able to:

1. Understand various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their Quality

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the importance of preformulation factors influencing in the designing the dosage forms.
2. Describe formulation and evaluation of tablet and liquid oral formulation.
3. Discuss manufacturing and quality control of sterile products.
4. Explain formulation and development of hard gelatin capsule, soft gelatin capsule and pellets.
5. Practice solid, liquid orals and cosmetics, with its labelling and packaging.
6. Develop and evaluate formulation of cosmetic and aerosol formulation

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **07 Hours**

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT II **10 Hours**

Tablets:

Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems.

Equipments and tablet tooling.

Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

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 pharmacopoeia

UNIT – III 8 Hours

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

UNIT – IV 10 Hours

Parenteral Products:
Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
Production procedure, production facilities and controls, aseptic processing
Formulation of injections, sterile powders, large volume parenterals and lyophilized products.
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; labeling, containers; evaluation of ophthalmic preparations

UNIV – V 10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, 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 choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

Tutorials Teaching Hours: 15 Hours

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Banker, G. S. & Rhodes, C. T, *Modern pharmaceutics,* New York: Marcel Dekkar Inc.
2. Lieberman, H.A., Lachman, L., & Schwartz, J.B. *Pharmaceutical Dosage forms - Tablets*, volume 1 to 3. New York: Marcel Dekkar Inc.
3. Lieberman, H.A, Rieger, M.M., & Banker, G.S. *Pharmaceutical dosage forms - Disperse systems,* volume 1 to 3. New York: Marcel Dekkar Inc.
4. Lieberman, H.A, Lachman, L., & Avis, K. E.. *Pharmaceutical dosage forms - Parentral medications,* volume 1 to 3. New York: Marcel Dekkar Inc.
5. Aulton, M. E., *Pharmaceutics: The science of dosage form design.* London: Churchill livingstone,
6. Alfonso R., Gennaro, A. M., *Remington: The science and practice of pharmacy,* volume 1& 2. Newyork: Lippincott Williams & Wilkins.

L= Lecture, T= Tutorial, P= Practical, C= Credit
^ this is not an exhaustive list