

BP502T. INDUSTRIAL PHARMACY I (Theory)

45 Hours

Course content:

Unit-I

07 Hours

Pre-formulation Studies: Introduction to pre-formulation, 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, racemization, polymerization. BCS classification of drugs & its significance.

Application of pre-formulation 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. Equipment's 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

08 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, palletization process, and equipment 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 parenteral 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.

Unit-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.