BP 502 T. Industrial Pharmacy I (Theory)

UNIT-I

Preformulation Studies: Introduction to preformulation, goals and objectives, study of

physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow

properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. 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

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients,

Formulation of tablets, granulation methods, compression and processing problems.

Equipments and tablet tooling.

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

UNIT-III

Capsules:

- a. *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.

b. *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

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential

requirements, vehicles, additives, importance of isotonicity

- b. Production procedure, production facilities and controls, aseptic processing
- c. Formulation of injections, sterile powders, large volume parenterals 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; labeling, containers;

evaluation of ophthalmic preparations

UNIT-V

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.

BP 506 P. Industrial Pharmacy I (Practical)

- 1. Preformulation studies on paracetamol/asparin/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)