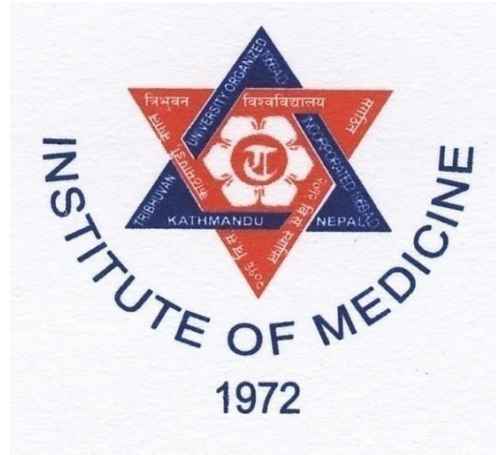


Curriculum
on
Bachelor in Pharmacy
(B. Pharm)



Published by

TRIBHUVAN UNIVERSITY

INSTITUTE OF MEDICINE

NATIONAL CENTRE FOR HEALTH PROFESSIONS EDUCATION

Maharajgunj, Kathmandu, Nepal

2020 (2076)

PHARMACEUTICS-II (DOSAGE FORMS AND FORMULATION)

Subject: Theory	Year: Third	Code: BP 602 A
Full Marks: 100	Total Teaching hours: 90	Credit hour: 6

Course Description: This 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.

General objectives:

Upon completion of the course, the student will be able to

- a. Discuss the various pharmaceutical dosage forms and their manufacturing techniques.
- b. Discuss various considerations in development of pharmaceutical dosage forms
- c. Identify the various types of cosmetic preparations and their formulation
- d. Formulate solid, liquid and semisolid dosage forms and evaluate them for their Quality
- e. Explain the basic concepts of controlled release drug delivery system

Specific objectives:

Unit 1: Introduction to dosage forms [2 Hrs]

After the completion of the course, students will be able to

- a Discuss definitions, classification and applications of different pharmaceutical dosage forms.

Unit 2: Tablets: [9 Hrs]

After the completion of the course, students will be able to

- a Define and classify tablet
- b Discuss ideal characteristics of tablets
- c Discuss Excipients used in formulation of tablets
- d Explain granulation methods
- e Explain compression and processing problems.
- f Discuss Equipments and tablet tooling.
- g Discuss tablet coating and coating materials
- h Explain formulation of coating, composition, methods of coating, equipment employed and defects in coating.
- i Discuss their-process and finished product tests of tablets

Unit 3: Liquid orals: [11 Hrs]

After the completion of the course, students will be able to

- a Distinguish Solution, Suspension and Emulsion
- b Discuss advantages and disadvantages of liquid dosage forms (Solution, Suspension and Emulsion)
- c Discuss excipients used in formulation of liquid dosage forms

- d Explain techniques of solubility enhancement
- e Discuss formulation and manufacturing considerations of syrups
- f Discuss flocculated and deflocculated suspensions, stability problems and methods to overcome
- g Discuss test for identification of types of emulsions; methods of preparation and stability problems and methods to overcome
- h Discuss formulation and manufacturing consideration of solutions, suspensions and emulsions
- i Discuss filling and packaging of solutions, suspensions and emulsions
- j Discuss the evaluation of liquid orals dosage forms in official Pharmacopoeia

Unit 4: Parenteral Products: [8 Hrs]

After the completion of the course, students will be able to

- a Discuss advantages and limitations of Parenteral dosage forms
- b Discuss preformulation factors and essential requirements.
- c Discuss formulation of injections, sterile powders, large volume parenterals and lyophilized products
- d Describe different techniques of Sterilization.
- e Discuss containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Discuss the evaluation of Parenteral products in official Pharmacopoeia

Unit 5: Semi-solid dosage forms: [5 Hrs]

After the completion of the course, students will be able to

- a Explain Semisolid dosage forms with special emphasis on types
- b Explain mechanisms of drug penetration and factors influencing penetration
- c Discuss semisolid bases and their selection
- d Explain general formulation of semisolids and clear gels
- e Discuss the manufacturing procedure and packaging
- f Discuss the advances in the formulation of semisolid dosage forms.
- g Discuss the evaluation of Semi-solid dosage forms in official Pharmacopoeia

Unit 6: Suppositories/ Pesseries: [3 Hrs]

After the completion of the course, students will be able to

- a Explain Suppositories and Pesseries including ideal requirements and bases
- b Discuss the manufacturing procedure of Suppositories.
- c Discuss packaging and evaluation
- d Mention special type of suppositories

Unit 7: Ophthalmic Preparations: [4 Hrs]

After the completion of the course, students will be able to

- a Discuss formulation considerations of different ophthalmic preparations.
- b Discuss formulation of eye drops, eye ointments and eye lotions
- c Explain methods of preparation, labeling, containers and evaluation of ophthalmic preparations

Unit 8: Preformulation Studies: [5 Hrs]

After the completion of the course, students will be able to

- a Discuss goals and objectives of preformulation
- b Explain different factors affecting preformulation study.
- c Discuss 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 9: Pharmaceutical Aerosols: [3 Hrs]

After the completion of the course, students will be able to

- a Define and characterize aerosols
- b Discuss different types and components of aerosol system
- c Discuss formulation and manufacture of aerosols
- d Discuss evaluation of aerosols
- e Explain stability studies of aerosols

Unit 10: Capsules: [5 Hrs]

10.1. Hard gelatin capsules

After the completion of the course, students will be able to

- a Define and characterize hard gelatin capsule
- b Discuss filling, finishing and special techniques of formulation of hard gelatin capsules.
- c Discuss In process and final product quality control tests for capsules.

10.2. Soft gelatin capsules

After the completion of the course, students will be able to

- a Define and characterize soft gelatin capsule
- b Discuss importance of base adsorption and minimum/gram factor
- c Discuss in process and final product quality control tests.
- d Packing, storage and stability testing of soft gelatin capsules

Unit 11: Pellets: [2 Hrs]

After the completion of the course, students will be able to

- a Define pellets and their applications
- b Discuss formulation requirements, and pelletization process
- c Discuss equipments for manufacture of pellets.

Unit 12: Controlled drug delivery systems: [7 Hrs]

After the completion of the course, students will be able to

- a Discuss terminology/definitions and rationale, advantages, disadvantage and selection of drug candidates.
- b Discuss approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles.

- c Explain physicochemical and biological properties of drugs relevant to controlled release formulations.
- d Discuss classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems

Unit 13: Cosmetology: [15 Hrs]

After the completion of the course, students will be able to

- a Discuss classification of cosmetic and cosmeceutical products
- b Mention different cosmetic excipients with their applications
- c Show the structures and functions of skin and hair.
- d Discuss regulatory requirements regarding manufacture of Cosmeticeuticals.
- e Discuss formulation and evaluation of the following cosmetic preparations: lipsticks, shampoos, manicure, cold cream and vanishing cream, moisturizers, tooth pastes, soaps, face wash, hair dyes and sunscreens (Normal and Tinted)
- f Discuss classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Unit 14: Stability studies and prodrugs. [3 Hrs]

After the completion of the course, students will be able to

- a Discuss stability protocols of pharmaceutical dosage forms as per ICH guidelines.
- b Discuss definition, types, purposes, approaches of Prodrugs design (With lipoproteins, with block copolymers and pharmacosomes).
- c Discuss Site specific prodrug approaches (By chemical modification and Targeting through antibodies).

Unit 15: Packaging Technology:[5 Hrs]

After the completion of the course, students will be able to

- a List types of packaging materials
- b Discuss factors influencing choice of packaging materials
- c Discuss legal and official requirements for containers and labels.
- d Discuss stability aspects of packaging materials
- e Describe quality control tests of packaging materials.

PHARMACEUTICS-II (DOSAGE FORMS AND FORMULATION)

Subject: Practical	Year: Third	Code: BP 602 B
Full Marks: 50	Total Teaching hours: 90	Credit hour: 2

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

1. Perform preformulation study for prepared granules
2. Perform formulation and evaluation of different types of tablets
 - a) Ordinary compressed tablets - wet granulation, direct compression and dry granulation
 - b) Soluble tablet
 - c) Chewable tablet

3. Perform coating of tablets and their evaluation
4. Perform hard gelatin capsule filling and evaluation
5. Perform manufacture and evaluation of parenterals
 - a) Ascorbic Acid Injection
 - b) Calcium Gluconate Injection
 - c) Oily Injection
 - d) Sodium Chloride Infusion
 - e) Dextrose Infusion
6. Perform evaluation of packaging materials – containers, foils and papers
7. Perform short-term stability studies of various formulations
8. Perform formulation and evaluation of liquid oral preparations
 - a) Emulsion
 - b) Suspensions
 - c) Syrup
 - d) Mouth Wash
10. Perform formulation and evaluation of semisolids
 - a) Ointment
 - b) Lotion
 - c) Gel formulation
11. Distinguish Cosmetic Preparations:
 - a) Lipsticks
 - b) Cold cream and vanishing cream
 - c) Clear liquid shampoo
 - d) Tooth paste and tooth powders.

Reference books (Latest Editions)

1. Rawlins A. Bentley's Textbook of Pharmaceutics.
2. Cooper J.W, Gunn G. Tutorial Pharmacy, Petman Books Ltd., London.
3. Lachman L. Lieberman H.A, Kanig J.L. Theory and Practice of Industrial Pharmacy.
4. Wilkinson J. B, Moore R. J. Harry's cosmeticology. Longman Scientific & Technical.
5. Thomssen E.G. Modern Cosmetics, Universal Publishing Corporation.
6. Published Journal Articles on Formulation and Evaluation of dosage forms.