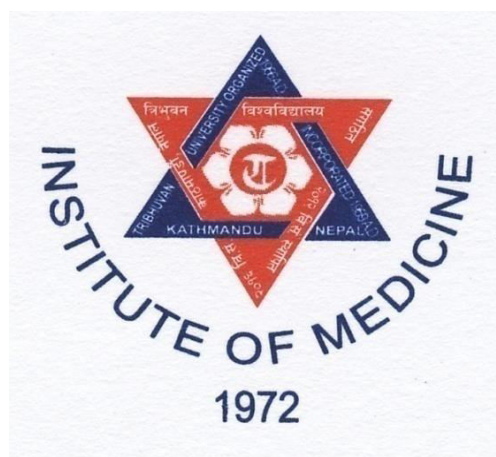


Curriculum
on
Bachelor in Pharmacy
(B. Pharm)



Published by

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INSTITUTE OF MEDICINE

NATIONAL CENTRE FOR HEALTH PROFESSIONS EDUCATION

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PHARMACEUTICS III (INDUSTRIAL PHARMACY)

Subject: Theory	Year: Fourth	Code: BP 703 A
Full Marks: 100	Total Teaching hours: 90	Credit hour: 6

Course Description: This course is designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.

General objectives:

At the end of this course, the student will be able to

- a. Describe the concept of Technology development and transfer
- b. Understand the various drug delivery systems
- c. Describe the elements of Pilot Plant Scale up Technique.
- d. Understand quality management systems and document maintenance in pharmaceutical industry

Specific objectives:

Unit 1. Pilot-plant scale up techniques:[10 Hrs]

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

- a Discuss general considerations for Pilot-plant scale up of solids, liquid orals, semi solids and relevant documentation,
- b Discuss SUPAC guidelines
- c Explain Platform technology.

Unit 2. Technology development and transfer:[10 Hrs]

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

- a Discuss WHO guidelines for Technology Transfer
- b Discuss Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning).

Unit 3. Novel Drug Delivery System

3.1. Microencapsulation: [4 Hrs]

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

- a Discuss definition, advantages and disadvantages of microspheres /microcapsules.
- b Discuss methods and applications of microencapsulation.

3.2. Mucosal Drug Delivery system: [4 Hrs]

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

- a Discuss Principles, advantages and disadvantages bioadhesion / mucoadhesion
- b Explain transmucosal permeability
- c Discuss formulation considerations of buccal delivery systems

3.3.Implantable Drug Delivery Systems: [3 Hrs]

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

- a Discuss introduction, advantages, disadvantages and concept of implants and osmotic pump

3.4.Transdermal Drug Delivery Systems (TDDS): [3 Hrs]

After the completion of the course, students will be to

- a Discuss permeation through skin
- b Explain factors affecting permeation
- c List permeation enhancers
- d Discuss basic components of TDDS
- e Discuss formulation approaches of TDDS

3.5.Gastroretentive drug delivery systems (GRDDS):[4 Hrs]

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

- a Discuss introduction, advantages, disadvantages and approaches for GRDDS
- b Discuss the applications of GRDDS
- c Mention recent developmenst in GRDDS

3.6.Nasopulmonary drug delivery system:[3 Hrs]

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

- a Discuss Nasal and Pulmonary routes of drug delivery
- b Discuss formulation of Inhalers (dry powder and metered dose)
- c Discuss about nasal sprays and nebulizers

3.7.Protein and Peptide Delivery:[3 Hrs]

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

- a Explain barriers for protein delivery.
- b Discuss formulation and Evaluation of delivery systems of proteins and other macromolecules.

3.8.Vaccine delivery systems:[3 Hrs]

After the completion of the course, students will be able to
Discuss mucosal and transdermal delivery of vaccines.

3.9.Ocular Drug Delivery Systems: [2 Hrs]

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

- a Discuss intra-ocular barriers and methods to overcome the barriers.
- b Discuss ocular formulations and ocuserts.

3.10. Intrauterine Drug Delivery Systems (IUDs): [2 Hrs]

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

- a Discuss introduction, advantages and disadvantages of IUDs

- b** Discuss development of intra uterine devices (IUDs) and applications.

Unit 4: Nanotechnology and its Concepts: [4 Hrs]

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

- a** Discuss concepts and approaches for targeted drug delivery systems
- b** Mention advantages and disadvantages of targeted drug delivery systems
- c** Describe liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications. [

Unit 5: Quality management systems and Document maintenance in pharmaceutical industry:[12 Hrs]

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

- a** Discuss Quality management: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept
- b** Discuss Good manufacturing practices (GMP), SOP, BMR, MFR,BPR, 5's' quality assurance, quality assurance and quality audit, CGMP (inherited or in-built quality) as per WHO.

Unit 6: Surgical products:[7 Hrs]

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

- a** Explain primary wound dressing, absorbent surgical cotton, surgical gauzes, bandages, adhesive tape, protective cellulosic hemostatic, official dressings, absorbable and non-absorbable sutures, catguts, medical prosthetics and organ replacement materials

Unit 7: Validation:[7 Hrs]

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

- a** Define Pharmaceutical Validation
- b** Discuss scope & merits of Validation
- c** Discuss types of validation
- d** Discuss ICH & WHO guidelines for calibration and validation of equipments,
- e** Discuss Validation of specific dosage form.
- f** Discuss Manufacturing Process Model, URS, DQ, IQ, OQ& PQ of facilities.

Unit 8: Pharmaceutical industry [9 Hrs]

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

- a** Discuss Good Warehouse practice
- b** Explain Plant location with its layout, utilities and services: (water purification, gases, compressed air).
- c** Discuss effluent treatment plant, industrial hazards and safety measures

Reference Books: [Latest Editions]

1. Martinich J. S. Production and operations management: An applied modern approach. John Wiley & Sons.
2. Subramanyam C. V. S. Pharmaceutical production and management.
3. Lachman L, Lieberman H. A, Kanig J. L. The theory and practice of industrial pharmacy. Lea & Febiger.
4. Aulton M. E. Pharmaceutics: The science of dosage form design. Churchill Livingstone.
5. Rawlins E. A. Bentley's Textbook of Pharmaceutics, University Printing House.
6. Vyas S. P, Khar R. K. Controlled drug delivery concepts and advances. Vallabh Prakashan.