

Roll No.

Total No. of Questions : 06

Total No. of Pages : 02

M.Pharmacy (Pharmaceutics) (Sem.-1)
DRUG DELIVERY SYSTEM
Subject Code: MPH-102T
M.Code: 74658

Date of Examination : 07-01-2026

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Discuss the mechanisms of drug permeation through the oral route.
b) Give a brief account of the polymers commonly used to control the rate of drug release from solid dosage forms.
2. a) What are osmotic activated drug release dosage forms? Give an account of these formulations and mention the function of each excipient used in them.
b) Enumerate the approaches employed for modulating the gastric transit time of dosage forms. Give a brief account of floating tablet formulations.
3. a) Discuss the challenges for ocular drug delivery.
b) Distinguish between a reservoir and matrix type of TDDS. Give a brief account of in vitro and in vivo evaluation of TDDS.
4. a) Give an account of various barriers of oral protein delivery and mention their remedies.
b) Explain the mechanisms for up take of antigens.
5. a) What are pH activated drug delivery systems? Give an example of such dosage forms and mention the key excipients used.
b) Give a brief account of personalized therapy.

6. Write a short notes on (Any Three) :

- a) Advantages of controlled drug release.
- b) Orally disintegrating tablets.
- c) Single shot vaccines.
- d) Drug in adhesive transdermal patches.

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M.Pharmacy (Pharmaceutics) (Sem.-1)

REGULATORY AFFAIRS

Subject Code : MPH-104T

M.Code :74660

Date of Examination: 12-01-2026

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) What are combination products? Give examples. Highlight the regulatory requirements to be fulfilled for them.
b) What is a CRO? Highlight the essential requirements for a CRO.
2. a) What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial.
b) What is meant by HIPPA? Highlight its key features aimed at protecting sensitive patient data.
3. a) What is the purpose of maintaining drug distribution records? Write a note on ICH requirements pertaining to drug distribution records.
b) Briefly discuss Master Formula Record and its importance.
4. a) Discuss the requirements for filing ANDA application.
b) What is post marketing surveillance ? Highlight its purpose and briefly discuss the methods to conduct PMS.
5. a) Write a short note on IMPD.
b) Give a note on Residual solvents in medicines.
6. a) What is meant by bioequivalence? Briefly explain the requirements for proving two products bioequivalent.
b) Write a note on ICH guidelines for quality and efficacy.

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**M.Pharmacy (Pharmaceutics)(Sem.-2)
MOLECULAR PHARMACEUTICS
(NANO TECH AND TARGETED DDS)**

Subject Code : MPH-201

M.Code : 74961

Date of Examination: 03-12-2025

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carry FIFTEEN marks.

1. Enlist the challenges involved in drug delivery to the brain. Briefly explain various approaches employed for drug targeting to the brain giving examples.
2. a) Distinguish micro capsules from micro spheres. Give an account of the polymer-polymer interaction method used for preparing microspheres.
b) Give a brief account of Niosomes and their applications.
3. a) What are aerosols and their advantages? Discuss the propellents used in aerosol formulations.
b) Briefly describe the preparation of monoclonal antibodies.
4. a) Enumerate various diseases where gene therapy can be useful. Discuss gene therapy giving suitable example for cancer treatment.
b) Highlight the pharmaceutical, anatomical and physiological challenges for successful intranasal drug delivery. Briefly discuss how these challenges can be overcome?
5. Write short notes on:
a) Non-Viral gene transfer
b) Electrosomes
c) Aptamers

6. Critically comment on:

- a) Liposome evaluation
- b) Components of aerosol containers
- c) Nanoparticles evaluation.

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