

(MPH 101 T)

M. PHARMACY DEGREE EXAMINATION, MAY 2024.

(Regular)

First Semester

Pharmaceutics

MODERN PHARMACEUTICAL ANALYTICAL
TECHNIQUES

Time : Three hours

Maximum : 75 marks

SECTION A — ($5 \times 5 = 25$ marks)

Answer any FIVE questions.

1. Write a note on detectors used in HPLC.
2. Describe the instrumentation and applications of spectrofluorimeter.
3. Discuss Mc Lafferty rearrangement and its significance in structural diagnosis.
4. Explain the fundamental vibrations of the molecules in IR spectrophotometry.
5. Discuss the principle and factors affecting separation of paper electrophoresis.
6. Write a note on spin-spin coupling.
7. How X-rays are generated? Briefly explain X-ray powder diffraction method.

SECTION B — ($5 \times 10 = 50$ marks)

Answer any FIVE questions.

8. Discuss principle, instrumentation and applications of AAS.
9. Explain the principle and applications of ELISA.
10. Explain briefly about detectors used in IR spectroscopy.
11. Discuss the principle and applications of bioluminescence assay.
12. Explain the various factors affecting the chemical shift in NMR spectroscopy.
13. State and explain Beer Lamberts law. Write briefly about deviations of the absorption laws.
14. (a) Explain Instrumentation of GLC. (6)
(b) How compounds are separated by callipary electrophoresis? Explain. (4)

(MPH 102 T)

M.PHARMACY DEGREE EXAMINATION,
MAY 2024.

(Regular)

First Semester

Pharmaceutics

DRUG DELIVERY SYSTEM

Time : Three hours

Maximum : 75 marks

SECTION A — (5 × 5 = 25 marks)

Answer any FIVE questions.

1. Explain the principle of mucoadhesion in buccal drug delivery system.
2. Discuss the formulation of Enzyme activated rate controlled drug delivery system.
3. Write a note on customized drug delivery system.
4. Write a note on barriers of drug permeation in ocular drug delivery system.
5. Describe physicochemical factors SR/CR formulation.
6. Write a note on Single Shot vaccines.
7. Explain permeation enhancement methods for transdermal drug delivery.

SECTION B — (5 × 10 = 50 marks)

Answer any FIVE questions.

8. Describe in detail the formulation aspects of transdermal DDS. Write a note on evaluation tests.
9. Explain about osmotic activated drug delivery system.
10. Explain (a) Telepharmacy (b) Bioelectronic medicines
11. Explain about formulation and evaluation of protein and peptide drug delivery system.
12. Write a note on gastroretentive floating drug delivery system and its advantages and limitations.
13. (a) Write about biodegradable and non-degradable polymers.
(b) Classify the polymers used to modify the drug release.
14. Discuss briefly about uptake of antigens, mucosal and transdermal delivery of vaccines.

(MPH 103 T)

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(Regular)

First Semester

Pharmaceutics

MODERN PHARMACEUTICS

Time : Three hours

Maximum : 75 marks

SECTION A — ($5 \times 5 = 25$ marks)

Answer any FIVE questions.

1. Add a note on compaction profiles and explain graphically.
2. Write a note on diffusion and dissolution parameters.
3. Explain essential components of TQM.
4. Write a note on types of validation.
5. Define inventory management and control. Explain in detail.

6. Discuss in brief solubility enhancement techniques.

7. Write a note on phases in production planning.

SECTION B — ($5 \times 10 = 50$ marks)

Answer any FIVE questions.

8. Define the term preformulation? Explain in detail physical and chemical characterization of a new drug molecule.
9. What are SMEDDs? Explain in detail composition and stability aspects of SMEDDs.
10. Discuss in detail physics of tablet compression.
11. Define dissolution. Explain factors affecting dissolution. Add a note on similarity factors- f_2 and f_1 .
12. What is optimization? Classify and explain in detail full and fractional factorial design.
13. Mention objectives of production planning. Explain elements of production control.
14. Discuss ICH and WHO guidelines for calibration and validation of equipments.

(MPH 104 T)

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(Regular)

First Semester

Pharmaceutics

REGULATORY AFFAIR

Time : Three hours

Maximum : 75 marks

SECTION A — ($5 \times 5 = 25$ marks)

Answer any FIVE questions.

1. Write about on investigator brochure.
2. Discuss the regulatory requirements of TGA.
3. Explain the activities of CRO.
4. Write a note on global submission process for non-clinical drug development as IND.
5. Explain CTD and ETC format and its usefulness in regulatory affairs.
6. Discuss the amendments of Hatch Waxman act.
7. Write a note on safety monitoring in clinical trials.

SECTION B — ($5 \times 10 = 50$ marks)

Answer any FIVE questions.

8. Discuss the developing protocols for clinical trials and explain the role of IRB.
9. Discuss the significance of BE and drug product assessment in NDA approval process.
10. Explain the regulatory requirements of EU and MHRA.
11. Write about documents of generic drug product development in pharmaceutical industry.
12. Write a note on
 - (a) IMP dossiers. (5)
 - (b) HIPAA and its significance in clinical trials. (5)
13. (a) Write a note on distribution records in pharma industry. (5)
 - (b) Specify the financial codes used in code of federal regulation. (5)
14. (a) Discuss the role of pharma Covigilance in safety monitoring
(b) Mention the parameters in chemistry manufacturing control.