Code No. G-13123/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, June 2025
Subject: Drug Delivery System

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Explain the basic concepts of novel drug delivery system. With pictorial representation mention the differences between controlled and sustained drug delivery systems. [7]
   (b) Mention the advantages and disadvantages of CDDS. Describe physicochemical approaches of the same. [8]
2. Classify polymers. Explain pharmaceutical applications of polymers with respect to novel drug delivery systems. [15]
3. What are customized drug delivery systems? Write a note on telepharmacy and 3D printing. [15]
4. (a) What are rate controlled drug delivery systems and classify? [5]
   (b) Describe any 3 activation-controlled drug delivery systems. [10]
5. (a) Explain GI transit time and methods to extend GI transit. What are the advantages and disadvantages of same. [5]
   (b) Describe different types of gastro-retentive drug delivery system. [10]
6. (a) Describe barriers of ocular drug delivery system and mention the methods to overcome the same.
   (b) Write a note on permeation enhancers.
7. Describe various types of transdermal drug delivery systems. Mention its advantages and disadvantages. [15]
8. (a) Explain the barriers of protein drug delivery system.
   (b) Write a note on single shot vaccines.

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Code No. G-13124/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) I - Semester (Main & Backlog) Examination, June 2025

Subject: Modern Pharmaceutics

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Explain the concepts of screening and optimization designs. (9 Marks)
   (b) Describe the applications of response surface method (6 Marks)
2. (a) Describe the zero and first order kinetics of Drug stability (6 Marks)
   (b) Explain the procedure involved in stability testing and expiration dating. (9 Marks)
3. Write in details about prospective, retrospective and concurrent validation and mention their significance. (15 Marks)
4. Describe URS, DQ, IQ, OQ and PQ of equipment & facilities and mention their importance. (15 Marks)
5. (a) Explain ten cGMP critical procedures and polices. (10 Marks)
   (b) Describe the crucial elements of TQM. (5 Marks)
6. (a) Write in detail about the budget planning and cost control. (8 Marks)
   (b) Explain various levels of production organization. (7 Marks)
7. (a) Write the procedures of solubility enhancement. (6 Marks)
   (b) Explain the different forces distributed during compaction and mention the Measurement techniques. (9 Marks)
8. (a) Write the procedures applicable to determine similarity and dissimilarity factors. (8 Marks)
   (b) Explain the role of Heckel plots in compaction. (7 Marks)

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Code No: G-13125/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I – Semester (Main & Backlog) Examination, June 2025
Subject: Regulatory Affairs

Time : 3 Hours **Max. Marks: 75**

Note: Answer Any Five Questions. All Questions Carry Equal Marks

1. (a) Describe Scale Up Post Approval Changes (SUPAC). (9 Marks)
   (b) Write a note on in-vitro drug product performance. (6 Marks)

2. (a) Describe documentation in pharmaceutical industry. (10 Marks)
   (b) Write a note on CFR (Code of Federal Register). (5 Marks)

3. (a) Explain regulatory requirements for approval of API. (8 Marks)
   (b) Describe the process for registration of foreign drugs in US. (7 Marks)

4. (a) Explain the regulations for Medical devices. (6 Marks)
   (b) Describe ICH guidelines for Quality. (9 Marks)

5. (a) Write a note on CTD and eCTD. (8 Marks)
   (b) Write a note on regulatory requirements of EU. (7 Marks)

6. a) Write a note on Global submission of NDA. (8 Marks)
   b) Write a note on Investigation Medicinal Products Dossier. (7 Marks)

7. (a) Write a note on HIPAA. (8 Marks)
   (b) Discuss about Institutional Review Board. (7 Marks)

8. (a) Write a note on Pharmacovigilance safety monitoring. (8 Marks)
   (b) Write a note on clinical trial protocol. (7 Marks)

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Code No. G-13122/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) I – Semester (Main & Backlog) Examination, June 2025
Subject: Modern Pharmaceutical Analytical Techniques
(Common to All)

Time: 3 Hours **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. (a) Write Beer –Lambert's law and explain the deviations to it. (7 Marks)
   (b) Explain the instrumentation of FTIR. (8 Marks)

2. (a) Write principle involved in proton NMR spectroscopy. Discuss on chemical shift (7 Marks)
   (b) Explain the instrumentation of NMR with labelled schematic diagram. (8 Marks)

3. (a) Discuss about different ionization techniques of mass spectroscopy. (7 Marks)
   (b) Brief out the fragmentation patterns and rules of different organic compounds. (8 Marks)

4. (a) Write instrumentation details of HPLC with labelled schematic diagram. (10 Marks)
   (b) Differentiate between HPTLC and HPLC. (5 Marks)

5. (a) Explain about gel electrophoresis. (8 Marks)
   (b) What is X-ray crystallography? Write Brag's law. (7 Marks)

6. Write notes on
   (a) Sampling in IR spectroscopy
   (b) FT-NMR. (2 x 7.5 = 15 Marks)

7. Give informative note on
   (a) Flame emission spectroscopy
   (b) Gas chromatography (2 x 7.5 = 15 Marks)

8. (a) Explain the instrumentation of UV-Visible spectrophotometer. (10 Marks)
   (b) Write about any one X-ray crystallographic method. (5 Marks)

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