



Regulatory

Code No: H-8066/PCI

FACULTY OF PHARMACY
M. Pharmacy (PCI) (Pharmaceutics) I Semester (Backlog)
Examination, December 2025

Subject: Regulatory Affairs

Time: 3 Hours

Max. Marks: 75

Note: Answer any Five questions.

(5 x 15 = 75 Marks)

1. Explain the importance of documentation in pharmaceutical industry. Write a detailed note on Master Formula record and distribution Records. (15 Marks)
2. a) Explain the contents of Hatch-Waxman Act. (5 Marks)
b) Write a note on Generic drug product development and explain the regulatory requirements for ANDA approval process in US. (10 Marks)
3. (a) What are the regulatory requirements for approval of biologics. (9 Marks)
(b) Describe the objectives and methods of Post Market Surveillance of drugs. (6 Marks)
4. (a) Explain SUPAC guidelines specific to manufacturing changes. (8 Marks)
(b) Write a brief note on regulations for Regulation for combination products. (7 Marks)
5. (a) Give an account on ICH quality guidelines. (10 Marks)
(b) Write a note on regulatory requirements of TGA. (5 Marks)
6. Describe the salient features of the Preclinical Drug Development stage for the submission of Investigational New Drug (IND). Write a note on Global submission of IND. (15 Marks)
7. (a) Give an account on Investigator's Brochure (8 Marks)
(b) Explain the salient features of HIPAA. (7 Marks)
8. Write short notes on
(a) Clinical trial protocol (7.5 Marks)
(b) Pharmacovigilance safety monitoring in clinical trials (7.5 Marks)



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FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) (PCI) I – Semester (Backlog) Examination, December 2025

Subject: Modern Pharmaceutics

Time: 3 hours

Max. Marks: 75

Note: Answer any Five questions

(5 x 15 = 75 Marks)

1. (a) Discuss the preparation and evaluation of SMEDDS? (8 Marks)
(b) Describe the stability kinetics? (7 Marks)
2. (a) Discuss calibration of equipment according to ICH guidelines? (7 Marks)
(b) Write about budget planning and sales forecast in industries? (8 Marks)
3. Discuss the following
(a) Total quality management? (9 Marks)
(b) Inventory control and management? (6 Marks)
4. Discuss the solubility enhancement techniques for poorly water soluble drugs? (15 Marks)
5. (a) Discuss about curve fitting method kinetics? (8 Marks)
(b) Write about chi square test? (7 Marks)
6. (a) Discuss various types of qualifications in the validation process? (7 Marks)
(b) Explain about response surface methodology in formulation optimization? (8 Marks)
7. (a) Write about compaction profile? (7 Marks)
(b) Explain the drug excipient compatibility studies with any two techniques? (8 Marks)
8. Write a note on (i) student t-test (ii) standard deviation? (8+7 Marks)



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FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Backlog) Examination, Dec. 2025

Subject: Drug Delivery Systems

Time: 3 Hours

Max. Marks: 75

Note: Answer any Five from the following questions. (5x15=75)

1. a. Define sustained and controlled release drug delivery systems. (5 Marks)
b. Explain in detail biological approaches to fabricate sustained and controlled release formulations. (10 Marks)
2. a. What are biodegradable polymers. Explain with examples. What is mechanism of drug release through biodegradable polymers. (9 Marks)
b. Write a note on bioelectronic medicines. (6 Marks)
3. a. Explain feedback regulated drug delivery system. (7 Marks)
b. Write a note on osmotically controlled drug delivery system. (8 Marks)
4. a. Explain the principle of mucoadhesion. (8 Marks)
b. Explain the methods to evaluate buccal drug delivery system. (7 Marks)
5. a. What are ocular novel drug delivery system. How ocular barriers prevent the drug Permeation (5 Marks)
b. Explain the structure of skin and its barriers. How to overcome the barriers using permeation enhancers and describe the mechanism of permeation enhancers with examples. (10 Marks)
6. a. Describe evaluation of transdermal drug delivery system (10 Marks)
b. Mention the barriers of protein drug delivery systems. (5 Marks)
7. Describe the formulation and evaluation of protein drug delivery system (15 Marks)
8. a. What are vaccine drug delivery system (5 Marks)
b. Explain mucosal and transdermal delivery of vaccines. (10 Marks)



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. [5]
(b) Write a note on permeation enhancers. [5]
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. [5]
(b) Write a note on single shot vaccines. [5]



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)



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)



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)
