Code No. H-8060/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) - Pharmaceutical Chemistry/Pharmaceutics/Pharmacology /Pharmaceutical Analysis/Ph.Quality Assurance
I - Semester (Backlog) Examination, December 2025
(Common paper for all Streams)

Subject: Modern Pharmaceutical Analytical Techniques

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

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

1. (a) State and Explain Beer- Lambert's law. Add a note on the deviations from Beer's law.
   (b) Explain the principle of flame photometry (7+8 Marks)
2. (a) Explain the sampling techniques in IR spectroscopy.
   (b) List and explain the IR detectors. (7+8 Marks)
3. (a) Define chemical shift. What are the factors affecting chemical shift?
   (b) Explain the spin-spin coupling in NMR spectroscopy with suitable example. (7+8 Marks)
4. What is the principle of MS? With a neat labelled diagram briefly explain the components of MS instrumentation. (15 Marks)
5. Explain the principle, instrumentation and application of capillary electrophoresis giving a neat labelled diagram. (15 Marks)
6. (a) Explain Bragg's equation and derive the equation.
   (b) List and explain the different **methods** used for X-ray diffraction studies. (7+8 Marks)
7. (a) What is the principles of Fluorescence? Add a note on the factors affecting fluorescence and quenchers in fluorescence.
   (b) What are the applications of AAS? (9+6 Marks)
8. (a) Explain the principle and instrumentation of HPLC.
   (b) List and explain any 3 GC detectors. (7+8 Marks)

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OU - 1702 OU - 1702

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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OU - 1702 OU - 1702

Code No. H-8064/PCI

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)

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OU - 1702 OU - 1702

Code No. H-8065/PCI

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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OU - 1702 OU - 1702

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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OU - 1702 OU - 1702

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.

OU - 1702 OU - 1702

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-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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OU - 1702 OU - 1702

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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OU - 1702 OU - 1702

Code No : G-13001/PCI

FACULTY OF PHARMACY

M. Pharmacy I-Semester (PCI) (Common to All) (Backlog) Examination, December 2024

Subject: Modern Pharmaceutical Analytical Techniques

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

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

1. (a) State and explain Beer-Lambert's law. Add a note on the deviations from Beer's law. 9
   (b) Explain the electronic transitions in UV spectroscopy. 6

2. Explain the principle, sample handling techniques and any three 3 detectors of IR spectroscopy. 2+5+8

3. Explain the principle, working of Hallow cathode lamp, any three Interferences with remedy and Applications of Atomic Absorption Spectroscopy. 2+5+5+3

4. (a) What is the significance of chemical shift? What are the factors affecting chemical shift? 8
   (b) Write a note on spin-spin coupling, coupling constant and its Importance. 7

5. (a) Write different modes of fragmentation and fragmentation rules in Mass Spectroscopy. 9
   (b) Define Base peak, molecular ion peak and metastable ion. 6

6. (a) Write the principle and instrumentation of Capillary electrophoresis. 8
   (b) Write the principle and Instrumentation of Gel Electrophoresis. 7

7. (a) Define Braggs law and its importance. 5
   (b) Write in detail about rotating crystal technique and the applications of X-ray Diffraction. 10

8. Discuss the principle, instrumentation, working and application of 8+7
   (a) Affinity Chromatography
   (b) Gel Chromatography

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OU-1702 OU-1702

Code No: G-13002/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Backlog) Examination, December 2024

Subject: Drug Delivery System

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1. (a) Explain the basic concepts of sustained and controlled drug delivery systems with suitable examples. (5)
   (b) Explain the Biological approaches for the preparation of SR/CR systems. (10)

2. (a) Classify different types of polymers. Mention the properties of different types of biodegradable polymers. (9)
   (b) Describe in detail applications of polymers in drug delivery systems. (6)

3. Write a note on following.
   (a) Customised drug delivery system. (7)
   (b) 3D printing of pharmaceuticals. (8)

4. (a) Explain in detail principles of different types of osmotic drug delivery system. (8)
   (b) Describe in detail pH and enzyme activated DDS. (7)

5. (a) Explain the theories of mucoadhesive drug delivery system. (10)
   (b) What are the advantages and disadvantages of mucoadhesive system? (5)

6. (a) What are different types of novel ocular drug delivery system? What are the barriers of it? (9)
   (b) Write a note on penetration enhancers. (6)

7. (a) Explain formulation of protein and peptide drug delivery system? (9)
   (b) Describe in detail stability of protein drug delivery system. (6)

8. What are transmucosal drug delivery system? Explain single shot vaccines. (15)

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OU - 1702 OU - 1702

Code No: G-13004/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Backlog) Examination, December 2024

Subject: Regulatory Affairs

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

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

1. (a) Write a note on DMF and distribution records. [10]
   (b) Write a note on Generic drug product development. [5]

2. (a) Explain classification of new drug and write a note on NDA approval process. [9]
   (b) Describe the objectives and methods of Post Market Surveillance of drugs. [6]

3. (a) Explain SUPAC guidelines specific to manufacturing changes. [8]
   (b) Write a brief note on regulations for medical devices. [7]

4. (a) Describe the importance and organization of CTD. Compare Paper and electronic CTD. [10]
   (b) Write a note on regulatory requirements of TGA. [5]

5. 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.

6. (a) Write a note on clinical trial protocol. [7]
   (b) Explain informed consent process and its procedures. [8]

7. (a) Give an account on ICH quality guidelines. [8]
   (b) Explain the salient features of HIPAA. [7]

8. Write short notes on
   (a) Biologics license application (BLA)
   (b) Regulatory requirements for MHRA

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OU-1702 OU-1702

Code No: G-13003/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Backlog) Examination, December 2024

Subject: Modern Pharmaceutics

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

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Write about DSC and FTIR for drug excipient compatibility studies with examples. (8)
   (b) Discuss about accelerated stability studies. (7)

2. (a) Discuss calibration and validation equipment according to ICH guidelines. (7)
   (b) Write about budget planning and sales forecast in industries. (8)

3. (a) Write a note on total quality management. (9)
   (b) Write a note on inventory management control. (6)

4. Discuss the aqueous solubility enhancement techniques for poorly soluble drugs. (15)

5. (a) Discuss about model dependent kinetics. (8)
   (b) Write about student t-test. (7)

6. (a) Write a note on various types of qualifications in validation process. (7)
   (b) Describe the factorial design and its application in formulation optimization. (8)

7. (a) Write about compaction profile. (7)
   (b) Write a note on preparation and evaluation of emulsion dispersion systems. (8)

8. Write a note on (a) ANOVA (b) Standard Deviation. (8+7)

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OU - 1702 OU - 1702

Code No: F-7239/PCI

FACULTY OF PHARMACY

M. Pharmacy I - Semester (PCI) (Common to All) (Main & Backlog) Examination, June 2024

Subject: Modern Pharmaceutical Analytical Techniques

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

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

1. (a) Explain different methods of single component and Multicomponent analysis of Pharmaceutical formulation by UV-Visible Spectroscopy. [9]
   (b) Explain the electronic transitions in UV spectroscopy. [6]

2. (a) Explain the molecular vibrations in IR. [8]
   (b) Write the sampling methods in IR spectroscopy. [7]

3. (a) Explain the principle of fluorescence. Add a note on quenching effect.
   (b) With a diagram explain the instrumentation for AAS. [8+7]

4. (a) Explain the principle and Instrumentation of NMR Spectroscopy. [8]
   (b) Write a note on spin-spin coupling and Applications of NMR [7]

5. (a) Classify the ionization techniques in MS. Explain any three methods in detail. [9]
   (b) Define Base peak, molecular ion peak and metastable ion. [6]

6. (a) Write the principle and instrumentation of flame photometry. [7]
   (b) Write notes on any two GC detectors with a neat labeled diagram. [8]

7. (a) Briefly explain the source of AA. [8]
   (b) List and explain the interferences. [7]

8. Discuss the principle, instrumentation working and application of [7+8]
   (a) Paper electrophoresis
   (b) Gel electrophoresis

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OU - 1702 OU - 1702

Code No: F-7242/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, June 2024

Subject: Regulatory Affairs

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

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

1. (a) Describe various parts of master formula record and write its importance. [8]
   (b) Explain the contents of Hatch-Waxman Act and discuss the requirements of ANDA. [7]

2. (a) Explain CFR with respect to pharmaceutical product development. [9]
   (b) What is the impact of outsourcing Bioavailability and Bioequivalence studies to Contact Research Organisations. [6]

3. Explain SUPAC guidelines for immediate release dosage form.

4. (a) Explain the objectives of CMC considerations during drug development. [10]
   (b) Write a note on CTD. [5]

5. Describe the objectives of harmonization guidelines. Enlist ICH quality and safety guidelines.

6. (a) Explain regulatory requirements for ROW Countries. [10]
   (b) Write a note on Regulatory requirements for Biological product approval. [5]

7. Write a note on investigation of medicinal products dossier (IMPD) and Investigator brochure.

8. Write short notes on
   (a) Health Insurance Portability and Accountability Act. [7.5]
   (b) Pharmacovigilance safety monitoring in clinical trials [7.5]

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OU - 1702 OU - 1702

Code No: F-7241/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, June 2024

Subject: Modern Pharmaceutics

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

Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)

1. (a) Describe any two methods of drug excipient compatibility studies with examples? (8)
   (b) Discuss the preparation and evaluation of SMEDDS. (7)

2. (a) Discuss the details of budget planning in industries. (8)
   (b) Write a note on calibration and validation of equipment according to ICH guidelines? (7)

3. (a) Discuss the details of budget planning in industries. (8)
   (b) Write about inventory management and control. (7)

4. (a) Explain the compaction profile. (5)
   (b) Discuss the aqueous solubility enhancement techniques of drugs. (10)

5. Write a note on (a) ANOVA (b) Student t-test. (8 + 7)

6. (a) Discuss the RSM (response surface method) for pharmaceutical formulation and Optimization. (8)
   (b) Add a note on similarity and difference factors calculations. (7)

7. (a) Discuss the preparation and evaluation of suspensions. (7)
   (b) Write about the accelerated stability studies. (8)

8. (a) Discuss the Total quality management. (8)
   (b) Add a note on pharmacokinetic parameters. (7)

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OU - 1702 OU - 1702

Code No: F-7240/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, June 2024

Subject: Drug Delivery System

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1. (a) Neatly draw a graph and differentiate sustained release and controlled release systems with examples. (5)
   (b) Explain the physicochemical approaches for the formulation of SR/CR systems. (10)

2. (a) Classify different types of polymers. Mention the properties of different types of non – biodegradable polymers. (9)
   (b) Describe in detail advantages and disadvantages of biodegradable and non- biodegradable polymers in drug delivery systems. (6)

3. Write a note on following.
   (a) Bioelectronic medicines (7)
   (b) Tele pharmacy (8)

4. Explain in detail principles of different types of activation modulated drug delivery system. (15)

5. (a) Describe different types of gastro retentive drug delivery system. (10)
   (b) What are the advantages and disadvantages of mucoadhesive system? (5)

6. (a) Explain various approaches in formulation transdermal drug delivery system ? (12)
   (b) Write a note on penetration enhancers. (3)

7. (a) What are the evaluation tests for protein and peptide drug delivery system? (9)
   (b) Describe various types of novel ocular drug delivery system. (6)

8. (a) Explain in detail mucosal and transdermal delivery of vaccines? (12)
   (b) Write a note on single shot vaccines. (3)

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OU - 1702 OU - 1702

Code No: E-12421/PCI

FACULTY OF PHARMACY

M.Pharmacy I-Semester (PCI) (Common to all) (Backlog) Examination, November-2023

Subject: Modern Pharmaceutical Analytical Techniques

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

Note: Answer any Five Questions. All Questions carry Equal marks.

1. a) Explain the electronic transitions with suitable examples
   b) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. (6+9)

2. a) Explain the sampling techniques in IR spectroscopy.
   b) What are the applications of IR spectroscopy (9+6)

3. a) What is the principles of flame photometrty? Explain the instrumentation.
   b) What are the factors affecting fluorescence? (9+6)

4. a) Explain chemical shift and the factors affecting chemical shift ?
   b) Draw a schematic NMR spectrum and explain splitting α signal intensity. (10+5)

5. With a neat labelled diagram, explain MS instrumentation. Draw MS spectrum for any two compounds α explain its peaks.

6. a) Classify the ionization techniques in MS. Explain any three methods in detail.
   b) Explain the fragmentation rules in MS. (9+6)

7. a) Explain HPLC instrumentation with a labelled diagram.
   b) Explain the factors affecting resolution & peak symmetry. (8+7)

8. a) Explain the principle and applications of capillary electrophoresis
   b) Classify the types of crystals and add a note on the applications of X-ray diffraction. (8+7)

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OU - 1702 OU - 1702

Code No: E-12424/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Regulatory Affairs

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

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

1. a) Explain Hatch-Waxmann Act and its Amendments. [9]
   b) Write a note on Master formula record. [6]

2. a) Explain the regulatory requirements for approval of API. [8]
   b) What is the impact of outsourcing Bioavailability and Bioequivalence studies to Contract Research Organisations (CRO) [7]

3. a) Explain ANDA approval process. [8]
   b) Explain the regulatory requirements for approval of NDA for novel therapies. [7]

4. a) Write a note on chemistry, manufacture and control in pharmaceutical industry. [9]
   b) Write a note on Regulations for Medical devices. [6]

5. a) Explain the regulatory requirements of Europe Union. [9]
   b) Write a note on Investigation medicinal products dossier. [6]

6. a) Write a note on global submission of NDA. [8]
   b) Write a note on Investigator Brochure. [7]

7. Discuss about (a) Health Insurance Portability and Accountability Act. [9]
   b) Institutional Review Board. [6]

8. a) Write a note on Pharmacovigilance and safety monitoring in clinical trials. [9]
   b) Write a note on CTD format. [6]

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OU - 1702 OU - 1702

Code No: E-12423/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Modern Pharmaceutics

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

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

1. List out the methods used for drug- excipient interactions and discuss any three methods in detail with examples? [15]

2. (a) Discuss the ICH guidelines for calibration and validation of equipment with an example? [10]
   (b) Write about validation and it's types? [5]

3. (a) Write a note on inventory management and production control management? [10]
   (b) Describe the layout of buildings, services according to GMP? [5]

4. Discuss the methods for enhancement of aqueous solubility of drugs? [15]

5. (a) Discuss ANOVA?
   (b) Describe the comparison of dissolution profiles using f1 and f2 factors?

6. (a) Discuss about the factorial designs for optimization of formulation? [8]
   (b) Explain the terms DQ, IQ, OQ and PQ? [7]

7. (a) Explain the phases of compaction profile? [7]
   (b) Write a note on Total quality management? [8]

8. (a) Discuss about SMEDDS and their method of preparation? [8]
   (b) Write about the variance and standard deviation and their application in pharmaceutical formulations? [7]

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OU - 1702 OU - 1702

Code No. E-12422/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Drug Delivery System

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

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

1. a) What do you mean by personalised drug delivery system?
   b) Write a note on 3D printing of pharmaceuticals and telepharmacy

2. a) Describe the various principles involved in rate controlled drug delivery system.
   b) Write a note on pH & enzyme activated system.

3. a) What are the advantages and disadvantages of buccal drug delivery system. How buccal formulations are evaluated?
   b) Describe in detail any two theories of mucoadhesion.

4. a) What are the barriers and explain various methods to overcome the barriers of ocular drug delivery system.
   b) With a neat sketch draw the structure of the skin. What are the barriers of skin? What are the techniques to overcome the skin barriers?

5. a) Explain in detail mucosal delivery of vaccines.
   b) Write a note on single shot vaccines.

6. a) Explain matrix and reservoir type of transdermal drug delivery system.
   b) Explain any five evaluation methods of transdermal formulations?

7. a) Explain strategies to formulate a stable protein and peptide drug formulations.
   b) Describe physical and chemical stability of proteins.

8. a) What are biodegradable polymers? Explain various mechanism of polymer degradation from a drug delivery system.
   b) What are the applications of polymers in controlled drug delivery system.

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OU - 1702 OU - 1702

Code No: E-12297/PCI

FACULTY OF PHARMACY

M. Pharmacy I Semester (PCI) (Common to all) (Main & Backlog) Examination, May 2023

Subject: Modern Pharmaceutical Analytical Techniques

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

Note: Answer any Five Questions. All Questions carry Equal marks.

1. a) With a neat labelled diagram explain UV/Visible instrumentation.
   b) What are the criteia in the solvent selection for UV spectroscopy? Give examples for solvents. What is meant by solvent effect? (9+6)

2. a) Explain the Principle, advantages and instrumentation of FTIR with a neat labelled diagram.
   b) Explain the molecular vibrations in IR spectroscopy. (10+5)

3. a) Explain the principle of fluorescence. Add a note on quenching effect
   b) With a diagram explain the instrumentation for AAS. (8+7)

4. a) Explain the principle of proton NMR spectroscopy.
   b) Explain the spin-spin coupling in NMR spectroscopy with suitable example. (7+8)

5. a) Explain the principle of mass spectroscopy.
   b) Explain any two mass analysers used in MS in detail. (7+8)

6. a) Explain GC instrumentation with a labelled diagram.
   b) Explain the applications of XRD technique. (9+6)

7. a) Explain the instrumentation & working of HPLC. (8+7)
   b) Explain the factors affecting resolution & Peak symmetry.

8. Define and classify the electrophoretic techniques. Explain the principle and applications of gel electrophoresis. (15)

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OU-1702 OU - 1702

Code No. E-12298/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, May 2023

Subject: Drug Delivery System

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1. a) Define sustained release and controlled release drug delivery system? What are the advantages and disadvantages of sustained/controlled release formulations?
   b) Explain in detail various physiochemical approaches for controlled release formulations.

2. a) Explain the mechanism of polymer degradation.
   b) Explain in detail applications of polymers in controlled release formulations.

3. a) Define pharmacogenetics. Write a note on personalised medicines?
   b) Write in detail about bioelectronic medicines and telepharmacy.

4. a) What are rate controlled drug delivery system?
   b) Explain in detail oral and injectable osmotic drug delivery system.

5. What are the advantages of targeting the drug delivery system to GI tract. Classify and explain in gastro-retentive drug delivery system.

6 a) What are permeation enchancers, explain the mechanism of transdermal permeation enhancers with examples.
   b) Explain the permeation barriers of ocular drug delivery system

7. What do you mean by single shot vaccines? Explain stability of proteins.

8. What are the barriers of protein drug delivery system? Explain formulation and evaluation of protein drug delivery system.

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OU - 1702 OU - 1702

Code No: E-12299/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Main & Backlog) Examination, May 2023

Subject: Modern Pharmaceutics

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

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

(5 x 15 = 75 Marks)

1.	(a)	Discuss the preparation and evaluation of SMEDDS?	[9]
	(b)	Describe evaluation tests for parenteral dosage forms?	[6]
2.	(a)	Discuss the calibration and validation of equipment with an example?	[7]
	(b)	Explain the terms DQ, IQ, OQ and PQ?	[8]
3.	(a)	Write a note on inventory management?	[7]
	(b)	Write note on sale forecast and budget planning?	[8]
4.	(a)	Discuss any three methods for aqueous solubility enhancement of drugs?	[9]
	(b)	Explain the phases of compaction profile with a suitable example?	[6]
5.	(a)	Write a note on ANOVA test?	[8]
	(b)	Write about the student t-test and its application?	[7]
6.	(a)	Write a note on factorial design for optimization of formulation?	[8]
	(b)	Describe the layout of buildings, services according to GMP?	[7]
7.	(a)	Write in brief about the determination of shelf- life of formulations?	[8]
	(b)	Discuss the evaluation tests of emulsions?	[7]
8.	(a)	Write a note on total quality management.	[8]
	(b)	Discuss comparison of dissolution profiles by f1&f2?	[7]

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OU - 1702 OU - 1702

Code No: E-12300/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, May 2023

Subject: Regulatory Affairs

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

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

1. a) Write a note on Generic drug product development [8]
   b) Write a note on CFR (Code of Federal Register). [7]

2. a) Explain SUPAC for Immediate release dosage forms. [8]
   b) Write a note on DMF and distribution records. [7]

3. a) Explain regulatory requirements for approval of biologics. [8]
   b) Describe the regulatory approval process for NDA. [7]

4. a) Explain the regulations for combination products. [6]
   b) Describe ICH guidelines. [9]

5. a) Write a note on CTD and eCTD. [8]
   b) Write a note on regulatory requirements of TGA. [7]

6. a) Write a note on Global submission of IND. [8]
   b) Write a note on Investigator brochure. [7]

7. a) Write a note on clinical trial protocol. [8]
   b) Explain informed consent process and its procedures. [7]

8. a) Write a note on Pharmacovigilance safety monitoring. [8]
   b) Write a note on HIPAA. [7]

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OU - 1702 OU - 1702

Code No. E-12124/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (Main & Backlog) Examination, December 2022

Subject: Molecular Pharmaceutics (Nano Tech and Targeted DDS)

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

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

1 (a) Define drug targeting. Explain different types of drug targeting in detail.
(b) Write a note on tumor targeting.

2 (a) Describe hybridoma technology for production of monoclonal antibodies.
(b) How will you characterize monoclonal antibodies?

3 What are niosomes? Describe in detail methods of preparation and characterization of niosomes.

4 (a) Explain the cell biology and anatomy of blood brain barrier.
(b) Describe in detail invasive methods to brain targeting.

5 (a) What are aerosols? Explain various propellants used in the manufacturing of aerosols.
(b) Describe in detail evaluation methods of nasal drug delivery system.

6 (a) Explain detail about aquasomes.
(b) Give a brief account on phytosomes.

7 (a) Define gene therapy. Explain viral and non viral gene transfer methods.
(b) Explain aptamers as drugs of future.

8 Explain the methods for the preparation and evaluation of microspheres.

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OU - 1702 OU - 1702

Code No: E-12127/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, December 2022

Subject: Cosmetics and Cosmeceuticals

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

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

1. (a) Define the terms Cosmetics, Misbranded cosmetics, Spurious cosmetics. Write a note on Offences and Penalties with regard to manufacture and sale of cosmetics.
   (b) Write a note on conditions for obtaining licence for manufacture and sale of cosmetics.

2. (a) Discuss the problems relating to skin.
   (b) Discuss about the cleansing and care needs for body.

3. (a) Write a note on regulatory provisions relating to labeling of cosmetics
   (b) Write a note on structure of hair and hair growth cycle.

4. (a) Discuss about the building blocks for formulation of tooth paste.
   (b) Write a note on emollients and rheological additives.

5. (a) Describe cosmeceutical products for acne and sun-protection.
   (b) Write a note on cosmeceuticals for sensitive teeth.

6. Describe the COSMOS guidelines for herbal cosmetics.

7. (a) What are the challenges in formulating herbal cosmetics.
   (b) List the herbal ingredients used in Hair care.

8. (a) Write a note on formulation of soaps and syndet bars.
   (b) Write a note on sunscreens.

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OU-1702 OU - 1702

Code No: E-12126/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) II Semester (PCI) (Main & Backlog) Examination, December 2022

Subject: Computer Aided Drug Delivery System

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

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

1. Write about history of computers in pharmaceutical research and development.
2. Write the application of Quality-by-Design (QbD) in pharmaceutical development. Explain QbD approach for formulation development.
3. Discuss the importance and applications of statistical modeling in pharmaceutical research and development.
4. Write a note on computational modeling techniques for drug absorption, drug distribution and drug excretion.
5. Write a note on following i) P-gp transporters ii) hPEPT1 iii) BBB- Choline transporter
6. Describe briefly factorial design for optimization and screening of pharmaceutical formulation in formulation development with example.
7. Write briefly about
   i) Computer aided biopharmaceutical characterization for GI absorption simulation.
   ii) Write about *invitro* dissolution & *invitro-invivo* correlation
8. Write about application of artificial intelligence & robotics in pharmaceutical automation. Write advantages, disadvantages and challenges of robotics in pharmacy automation.

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OU-1702 OU - 1702

Code No: E-12145/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacy Practice) II Semester (PCI) (Main & Backlog) Examination, December 2022

Subject: Pharmacotherapeutics - II

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

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

1. a) Write a detailed note on etiology of Parkinson's disease. Explain the motor complications of L-Dopa. [9+6]
   b) Define an epileptic seizure and explain the classification of seizures based on clinical features.

2. a) Classify Pain and explain the pathophysiology of nociceptive pain. [9]
   b) Explain different hypotheses explaining pathophysiology of depressive disorders. [6]

3. a) Classify Acute Kidney Injury and explain the types. Add a note on non-dialysis management of AKI. [10]
   b) Give a detailed account of drug induced renal diseases. [5]

4. a) Discuss the clinical presentation of acute meningitis. Briefly explain the etiology and management of meningitis. [10]
   b) Give an outline of the management of chronic bronchitis. [5]

5. a) Explain the clinical presentation and management of diarrhea. [8]
   b) Discuss the etiology and pharmacotherapy of Urinary tract infections. [7]

6. a) Explain the Antimicrobial Prophylaxis used in Specific Surgical Procedure. [7+8]
   b) What are the common opportunistic infections in a HIV patients? Explain their management.

7. a) Give an outline of treatment strategy in Acute leukemia with the help of an algorithm. [9]
   b) Explain the Tumor lysis syndrome. [6]

8. a) Write a detailed note on hormone replacement therapy. [7]
   b) Explain the treatment of stage I and II of non-small cell lung cancer. [8]

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OU - 1702 OU - 1702

Code No. D-8261/PCI

FACULTY OF PHARMACY

M. Pharmacy I - Semester (Common to All) (PCI) (Main & Backlog) Examination, May 2022

Subject: Modern Pharmaceutical Analytical Techniques

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) State and explain Beer-Lambert's Law. Add a note on the deviations from Beer's law.
(b) Explain the concept of chromophore, auxochrome and bathochromic shift with suitable examples.

2 (a) Explain the instrumentation of FTIR with a neat labelled diagram. Add a note on the advantages of FTIR.
(b) Explain the mplecular vibrations in IR.

3 (a) What is the principle AAS? Explain the instrumentation.
(b) List the differences between AAS and flame photometry.

4 What is the significance of chemical shift? What are the factors affecting chemical shift? Name the internal standard and justify its selection as internal standard in NMR spectroscopy.

5 What is the principle of Mass Spectrometry? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base peak, molecular ion peak and metastable ion.

7 (a) Explain the principle of X-ray diffraction.
(b) Explain HPLC instrumentation with a labelled diagram.

8 (a) Explain the experimental set up required for gel electrophoresis.
(b) Describe the principle and applications of RIA.

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OU-1702-OU-1702

Code No. D-8264/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, May 2022

Subject: Regulatory Affairs

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) Write a note on documentation in pharmaceutical industry.
(b) Write a note on Hatch Waxman Act amendments.

2 Explain SUPAC for Immediate release and Modified-release dosage forms.

3 Describe the regulatory approval process for ANDA and NDA.

4 (a) Explain the regulations for medical devices.
(b) Describe Q8, Q9 and Q10 ICH Quality guidelines.

5 (a) Write a note on CTD and eCTD.
(b) Explain the ways and means of US registration for foreign drugs.

6 Discuss about
(a) Investigation of Medicinal Products Dossier (IMPD)
(b) Investigation brochure.

7 Write a note on
(a) Clinical trial protocol
(b) Regulatory requirements of MHRA

8 Write a note on
(a) Pharmacovigilance safety monitoring
(b) Institutional review board.

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OU - 1702 OU - 1702

Code No. D-8263/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, May 2022

Subject: Modern Pharmaceutics

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) Write the determination of shelf-life of formulations?
(b) Discuss the evaluation of parenteral dosage forms?

2 (a) Discuss the ICH guidelines for calibration and validation of equipment?
(b) Explain the terms DQ, IQ, OQ and PQ?

3 (a) Write a note on inventory management and production control management?
(b) Write a note on sale forecasting and budget planning in industries?

4 (a) Explain the phases of compaction profile?
(b) Discuss the solubility enhancement techniques of drugs?

5 (a) Write a note on ANOVA test?
(b) Write about the pharmacokinetic parameters?

6 (a) Write a note on response surface method for optimization of formulation?
(b) Describe f1 and f2 factors and their calculations?

7 (a) Discuss the evaluation of dispersion systems?
(b) Describe the preparation and evaluation of SMEDDS?

8 (a) Write note on Total quality management?
(b) Discuss students t-test and it's applications?

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OU - 1702 OU - 1702

Code No. D-8262/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I - Semester (PCI) (Main & Backlog) Examination, May 2022

Subject: Drug Delivery System

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

Note: Answer any five questions. **(5 x 15 = 75 Marks)**

1 (a) What are the differences between sustained release and controlled release formulations?
(b) Explain in detail various physiochemical and biological approaches for controlled release formulations.

2 (a) Classify polymers? What are biodegradable and non biodegradable polymers?
(b) Explain in detail applications of polymers in controlled release formulations.

3 (a) Define pharmacogenetics. What are personalized medicines?
(b) Write in detail about bioelectronics medicines and telepharmacy.

4 (a) What are rate controlled drug delivery system?
(b) Explain in detail osmotic drug delivery system.

5 Classify and explain in gastro-retentive drug delivery systems.

6 Explain about mucosal stransdermal delivery of vaccines.

7 (a) What are permeation enchancers, explain the mechanism of permeation enhancers with examples.
(b) Explain the permeation barriers of ocular drug delivery system.

8 (a) What are the barriers of protein drug delivery system.
(b) Explain stability of proteins.

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OU - 1702 OU - 1702

Code No. D8001/PCI

FACULTY OF PHARMACY

M. Pharmacy I Semester (PCI) (Suppl) Examination, December 2021
(COMMON TO ALL)

Subject: Modern Pharmaceutical Analytical Techniques

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.
(3 x 25 = 75 Marks)

1 (a) State and explain Beer-Lambert's law. Add a note on the deviations from Beer's law.
(b) Explain the electronic transitions in UV spectroscopy.

2 (a) Explain the principle and instrumentation of FTIR with a neat labelled diagram.
(b) Explain the named advantages of FTIR.
(c) What are the major differences between Dispersive instruments and FTIR?

3 (a) What is the principle of Fluorescence? Explain the radiative and non radiative pathways of relaxation.
(b) Add a note on the factors affecting fluorescence.

4 (a) Explain NMR instrumentation with a diagram.
(b) Briefly explain shielding and deshielding with suitable example.

5 (a) What is the principle of MS? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base Peak, molecular ion peak and metastable ion.

7 (a) Explain GC instrumentation with a labelled diagram.
(b) What are the applications of HPLC?

8 (a) Explain the experimental set up required for capillary electrophoresis.
(b) Describe the principle and application of ELISA.

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OU-1702 OU - 1702

Code No. D8002/PCI

FACULTY OF PHARMACY

M.Pharmacy (Pharmaceutics) I Semester (PCI) (Suppl) Examination, December 2021

Subject: Drug Delivery System

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.
(3 x 25 = 75 Marks)

1 (a) Define personalized medicine. Explain telepharmacy and 3D printing of pharmaceuticals.
(b) What are non-biodegradable polymers? Explain the mechanism of polymer degradation?

2 (a) Mention different types of rate controlled drug delivery system. Explain in detail rate preprogrammed drug delivery system.
(b) Describe in detail osmotic drug delivery system.

3 (a) Explain various theories of mucoadhesion.
(b) Explain in detail types of gastro retentive drug delivery system.

4 (a) What are the barriers of ocular drug delivery system?
(b) Describe in detail evaluation of ocular DDS.

5 Define vaccine. Write a note on uptake of antigens and permeation of vaccines through mucosal and transdermal route.

6 (a) Classify transdermal drug delivery system. What are the ideal properties of a drug to be formulated as TDDS?
(b) Describe in detail Iontophoretic DDS.

7 (a) What are stability issues of proteins and peptides?
(b) Explain various non-invasive routes of administration of proteins and peptides.

8 (a) Mention different types of transdermal permeations enhancers and write about its mechanism of improving permeation.
(b) Write a note on Bioelectronic medicines.

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OU-1702 OU - 1702

Code No. D8003/PCI

FACULTY OF PHARMACY

M.Pharmacy (Pharmaceutics) I Semester (PCI) (Suppl) Examination, December 2021

Subject: Modern Pharmaceutics

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.
(3 x 25 = 75 Marks)

1 (a) Discuss the preparation and evaluation of SMEDDS.
(b) List out the methods used for determination of drug-excipient interactions and discuss any three methods in detail with examples.

2 (a) Discuss the ICH guideline for calibration and validation of equipment with an example.
(b) Write a note on sale forecasting and budget planning in industries.

3 (a) Describe the layout of buildings, services in industries according to GMP.
(b) Write a note on inventory management and production control management.

4 (a) Write the Heckel equation and draw the Heckel plots for determination of Porosity of tablet during compression process.
(b) Discuss the methods for enhancement of aqueous solubility of drugs.

5 (a) Discuss about the pharmacokinetic parameters required for determination of bioavailability.
(b) Describe the comparison of dissolution profiles of dosage forms using similarity and difference factors.

6 (a) Write a note on response surface method for optimization of formulation.
(b) Explain the terms DQ, IQ, OQ and PQ.

7 (a) What is compaction profile? Explain the phases of compaction profile with a suitable examples.
(b) Write a note on Total quality management.

8 (a) Write in brief about the determination of shelf-life of formulations.
(b) Write about the variance and standard deviation and its application in pharmaceutical formulations.

OU-1702 OU - 1702

Code No. D8081/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I Semester (PCI) (Suppl) Examination, December 2021

Subject: Regulatory Affairs

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three questions. All questions carry equal marks.
(3 x 25 = 75 Marks)

1 (a) Write a note on Hatch Waxmann Act.
(b) Write a note on SUPAC guidelines.

2 Explain ANDA regulatory approval process.

3 What are the regulatory requirements for approval of API?

4 (a) Explain the objectives of CMC considerations during drug development.
(b) Enlist ICH quality guidelines.

5 Explain the regulatory requirements of Europe Union (EU).

6 Discuss about
(a) Investigation of medicinal products dossier (IMPD).
(b) Bio-equivalence studies for generic drugs assessment.

7 Write a note on
(a) HIPAA.
(b) Pharmacovigilance safety monitoring.

8 Write a note on
(a) Informed consent process and procedures.
(b) Institutional review board.

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OU - 1702 OU - 1702

Code No. 12115/PCI

FACULTY OF PHARMACY
M.Pharmacy I Semester (PCI) (Main & Backlog) Examination, July 2021
(COMMON TO ALL)

Subject: Modern Pharmaceutical Analytical Techniques

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three from the following questions. **(3 x 25 = 75 Marks)**

1 (a) With a neat labelled diagram explain UV/Visible instrumentation.
(b) Briefly explain the electronic transitions with examples.

2 (a) Explain the molecular vibrations in IR.
(b) Write the sampling methods in IR spectroscopy.

3 (a) Explain the principle of flame photometry.
(b) With a diagram explain the instrumentation for flame photometry.
(c) List some metals that can be analysed by flame photometry.

4 (a) Explain the principle of proton NMR spectroscopy.
(b) What is the significance of chemical shift? What are the factors affecting chemical shift?
(c) What is the internal standard used in NMR spectroscopy? Why it is selected as internal standard?

5 (a) List and explain the steps in MS.
(b) What are the mass analysers used in MS? Explain any two in detail.

6 (a) Explain HPLC instrumentation with a labelled diagram.
(b) List and explain any 2 GC detectors.

7 (a) Explain Bragg's equation and derive the equation.
(b) Explain the principle and the materials required for Paper electrophoresis.

8 (a) Explain the principle and types of RIA?
(b) Briefly explain Zone electrophoresis and Moving boundary electrophoresis.

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CU-1702 CU-1702

Code No. 12117/PCI

FACULTY OF PHARMACY
M.Pharmacy (Pharmaceutics) I Semester (PCI) (Main & Backlog) Examination, July 2021

Subject: Modern Pharmaceutics

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three from the following questions. **(3 x 25 = 75 Marks)**

1 (a) Discuss about the preparation and evaluation of SMEDDS.
(b) Discuss the evaluation tests for parenteral dosage forms

2 (a) Discuss the ICH guidelines for calibration and validation of equipment with an example.
(b) Explain the terms DQ, IQ, OQ and PQ.

3 (a) Write a note on inventory management and production control management.
(b) Write note on Total quality management.

4 (a) What is compaction profile? Explain the phases of compaction profile with a suitable examples.
(b) Discuss the methods for enhancement of aqueous solubility of drugs.

5 (a) Write a note on ANOVA test.
(b) Write about the variance and standard deviation and its application in pharmaceutical formulations.

6 (a) Write a note on response surface method for optimization of formulation.
(b) Describe the comparison of dissolution profiles of dosage forms using similarity and difference factors.

7 (a) Write in brief about the determination of shelf-life of formulations.
(b) Discuss the evaluation tests for both dispersion systems.

8 (a) Write a note on sale forecasting and budget planning in industries.
(b) Discuss students t-test and its applications.

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OU-1702 OU - 1702

Code No. 12116/PCI

FACULTY OF PHARMACY
M.Pharmacy (Pharmaceutics) I Semester (PCI) (Main & Backlog) Examination, July 2021

Subject: Drug Delivery System

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three from the following questions. **(3 x 25 = 75 Marks)**

1 (a) Define sustained release, delayed release and controlled release drug delivery system with examples.
(b) Define pharmacogenetics. Explain Bioelectronic medicines.

2 (a) Classify activation modulated system. Explain osmotic drug delivery system.
(b) What are rate controlled drug delivery system? Explain feedback regulated systems.

3 (a) Mention the various barriers of buccal mucoadhesive drug delivery system. Mention two exmaples of marketed mucoadhesive drug delivery system.
(b) What are the drug properties to formulate as a FDDS? Explain in detail floating drug delivery system.

4 (a) Describe formulation and evaluation of ocular drug delivery system.
(b) Write a note on ocular insitu gels.

5 (a) Explain structure of skin. What are barriers of transdermal permeation? What are the ideal properties of a drug candidate to permeate through the skin?
(b) Classify transdermal permeation enhancers. Explain the mechanism of permeation enhancers.

6 (a) Describe in detail different strategies to formulate a stable protein and peptide drug formulations.
(b) Describe physical and chemical stability of proteins and peptides.

7 (a) Explain in detail mucosal and active transdermal methods of delivering vaccines through mucosa and skin.
(b) Explain single shot vaccines.

8 (a) Explain various physicochemical and biological factors that influences the formulation of SR and CR formulations.
(b) Classify polymers. Describe properties of any two synthetic non-biodegradable polymers.

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QP-1702 OU-1702

Code No. 12118/PCI

FACULTY OF PHARMACY
M.Pharmacy (Pharmaceutics) I Semester (PCI) (Main & Backlog) Examination, August 2021

Subject: Regulatory Affairs

Time: 2 Hours **Max. Marks: 75**

Note: Answer any three of the following questions. (3 x 25 = 75 Marks)

1 (a) Explain CFR with respect to Pharmaceutical product development.
(b) Write a note on generic drugs product development.

2 (a) Explain the importance of documentation and documents to be maintained in Pharmaceutical industry.
(b) What is the impact of outsourcing Bioavailability and Bioequivalence studies to Contact Research Organisations (CRO).

3 (a) Explain SUPAC guidelines for Immediate release dosage form.
(b) Explain evaluation of drug product performance by *invitro* studies.

4 Write a note on
(a) CTD and eCTD.
(b) Regulations for combination products.

5 Explain the regulatory requirements of TGA.

6 Discuss about
(a) Health Insurance Portability and Accountability Act.
(b) Institutional review board/ independent ethics committee.

7 Write a note on investigation of medicinal products dossier (IMPD) and Investigator brochure.

8 Write a note on
(a) Pharmacovigilance and safety monitoring in clinical trials.
(b) Enlist ICH Efficacy guidelines.

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OU - 1702 OU - 1702

Code No: 6330/PCI

FACULTY OF PHARMACY

M. Pharmacy (pharmaceutics) I-semester (PCI) (Suppl.) Examination, October 2020

Subject: Drug Delivery System

Time: 2 hrs **Max Marks: 75**

Note: Answer any three questions. **(3x25=75 Marks)**

1. Explain different mechanisms of drug delivery from sustained or controlled release formulations? Add a note on application of polymers in sustained release dosage forms?

2. What do you mean by personalized medicines? Describe in detail 3D printing of pharmaceuticals and telepharmacy.

3. Explain the principles of rate-controlled drug delivery systems? Write a note on feedback regulated drug delivery systems?

4. a) Mention different types of gastro-retentive drug delivery system?
   b) Describe in detail floating drug delivery system and its evaluation?

5. a) Describe in detail formulation and evaluation of buccal drug delivery system?
   b) Explain the different factors affecting mucosal drug permeation?

6. a) Describe barriers of ocular drug delivery system and what are the methods to overcome the same?
   b) Describe ideal properties of a drug to formulate as a transdermal drug delivery system?

7. a) Describe different routes of administration of protein drug delivery and its barriers of permeation ?
   b) Explain stability of protein pharmaceuticals?

8. What do you mean by single shot vaccine delivery systems? Explain mucosal delivery of vaccines?

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OU-1702 OU - 1702

Code No: 6332/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Suppl.)

Examination, November 2020

Subject : Regulatory Affairs

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three questions. **(3 x25=75 Marks)**

1. a) Explain evaluation of drug product performance by *invitro* studies
   b) Write a note on generic drugs product development

2. Explain Hatch-Waxmann Act and its amendments.

3. Explain SUPAC guidelines for immediate release dosage form

4. Write a note on
   a) CTD and eCTD
   b) Regulations for combination products.

5. Explain the regulatory requirements of TGA

6. Discuss about
   a) ICH guidelines for quality & safety
   b) Institutional review board / independent ethics committee

7. Write a note on investigation of medicinal products dossier (IMPD) and Investigator brochure.

8 Write a note on
   a) Pharmacovigilance and safety monitoring in clinical trials.
   b) Enlist ICH Efficacy guidelines.

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OU-1702 OU - 1702

Code No: 6331/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Suppl.)

Examination, November 2020

Subject: Modern Pharmaceutics

Time: 2 Hours **Max. Marks: 75**

Note: Answer any Three questions. **(3 x25=75 Marks)**

1. Explain the about drug – Excipient interactions and methods of determination

2. Describe accelerated stability testing of solution and solid dosage forms.

3. What is validation. Discuss the validation & calibration of any two equipment

4. Discuss WHO good manufacturing practices in a pharmaceutical Industy.

5. Discuss about IQ, OQ, PQ & DQ by taking an example.

6. a) Explain the types of compaction profiles.
   b) Write the advantages and disadvantages of strain gauges.

7. a) Describe Heckle plots and its significance with necessary equations and graphs.

   b) Write Biopharmaceutics Classification System (BCS) of drugs with examples.

8. a) Explain the reasons for conducting the stability studies of drugs.
   b) Explain formulation and dosage form related factors influencing the dissolution of tablets.

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OU - 1702 OU - 1702

CODE NO: 6102/PCI

FACULTY OF PHARMACY

M. Pharmacy I – Semester (Main & Backlog) Examination, January 2020
(Common Paper for all Except Pharmacy Practice)

Subject : Modern Pharmaceutical Analytical Techniques

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

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

1. (a) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. 8
   (b) Explain solvents and the selection criteria for UV/Visible spectroscopy. 4
   (c) What is solvent shift? 3

2. (a) Explain the principle and instrumentation of FTIR with a neat labelled diagram. 8
   (b) Explain about the sampling techniques and applications of FR spectroscopy 7

3. (a) What is the principle of Fluorescence? Explain the radiative and non radiative pathways of relaxation. 7
   (b) Add a note on the factors affecting fluorescence and quenchers in fluorescence. 6
   (c) What are the criteria for a molecule to exhibit the phenomena of fluorescence 2

4. (a) Explain the principle of proton NMR spectroscopy. 5
   (b) What is the significance of chemical shift. What are the factors affecting chemical shift ? 6
   (c) Explain about spin-spin crippling and it's importance in NMR 4

5. (a) Classify the ionization techniques in MS. Explain any three methods in detail. 12
   (b) Differentiate between Base peak and molecular ion peak. 3

6. (a) Explain HPLC instrumentation. 10
   (b) What are the applications of HPLC? 5

7. (a) Explain Braggs equation and derive the equation. 8
   (b) What is the principle involved in rotating crystal technique? 7

8. Explain the principle, working and applications of
   (a) Capillary electrophoresis $7^{1/2}$
   (b) Gel electrophoresis $7^{1/2}$

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Code No: 6103/PCI

FACULTY OF PHARMACY

M.Pharmacy (pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, February 2020

Subject: Drug Delivery System

Time: 3hrs **Max Marks: 75**

Note: Answer any five questions, all questions carry equal marks.

1 Explain physiochemical and biological approaches for designing SR formulations? (15)

2 What do you mean by personalized medicines? Describe in detail bioelectronic medicines and telepharmacy. (15)

3 Explain the principles of rate controlled drug delivery systems? Write a note on osmotically controlled drug delivery systems? (15)

4 a) Mention different types of gastroretentive drug delivery system? Mention its advantages and disadvantages? (5)
b) Describe in detail buccal drug delivery system? (10)

5 Explain the principles and theories of mucoadhesion? Add a note on mechanisms of mucosal drug permeation? (15)

6 a) Describe barriers of ocular drug delivery system and what are methods to overcome the same? (8)
b) Write a note on transdermal permeation enhancers? (7)

7 What are the barriers of protein drug delivery? Explain various modified formulations of proteins and peptides to overcome the absorption barriers? (15)

8 What are the advancements in vaccine delivery systems? Explain transdermal delivery of vaccines? (15)

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OU - 1702 OU - 1702

Code No: 6105/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, January 2020

Subject: Regulatory Affairs

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

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

1 (a) Write a note on CFR (code of federal regulation). (8)
(b) Write a note on distribution records and master formula record. (7)

2 Explain NDA regulatory approval process. (15)

3 What are the regulatory requirements for approval of API? (15)

4 (a) Explain the objectives of CMC considerations during drug development. (9)
(b) Enlist ICH Quality guidelines. (6)

5 Explain the regulatory requirements of TGA (15)

6 Discuss about :
a) global submission of ANDA (9)
b) Bio-equivalence studies for generic drugs assessment. (6)

7 Write a note on:
(a) HIPAA (6)
(b) Pharmacovigilance safety monitoring (9)

8 Write a note on:
(a) Investigator brochure (8)
(b) Clinical trial protocol (7)

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OU - 1702 OU - 1702

Code No: 6104/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, January 2020

Subject: Modern Pharmaceutics

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

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

1. a) Explain about distribution of forces during tablet compression with diagrams and equations. 10M
   b) Write the applications of force displacement curves of tablet compression. 5M

2. Explain about Heckell and peppas plots 15M

3. a) Write various drug excipients interactions with necessary examples. 10M
   b) Describe the salient features of accelerated stability testing of solution dosage forms. 5M

4. Describe calibration and validation of equipment as per ICH and WHO guidelines. 15M

5. Explain the WHO good manufacturing practices. 15

6. Write the formulation considerations and evaluation of parentral dosage forms. 15M

7. Explain about Material management inventory control in pharmaceutical industry. 15M

8. a) Define factorial designs and write its applications in formulations. 5M
   b) Describe the methods of comparision of dissolution of two products. 10M

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OU -1702 OU - 1702

Code No. 13303/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common paper for all Specialization) I-Semester (PCI) (Suppl.) Examination, August 2019

Subject : Modern Pharmaceutical Analytical Techniques

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

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

1 a) Write Beer-Lambert's law and derive the expression 5

b) Mention the different methods of quantitative analysis by uv-visible spectroscopy. Explain any one method in detail. 10

2. a) Explain the interpretation procedure of IR spectra of different organic compounds in detail. With examples of schematic IR spectra.

b) What is fluorescence? Write the factors affecting fluorescence. 5

3. a) What is chemical shift? Write the factors influencing chemical shift? 8

b) Write a note on FT-NMR 7

4. a) Explain the instrumentations and working of mass spectrometer with schematic diagram. 8

b) Write the fragmentation patterns of different organic compounds observed in mass spectroscopy. With the help of schematic mass spectra of a few compounds 7

5. Describe the components and working procedure of HPLC with a neat labeled block diagram. 15

6. a) Write the principle, instrumentation and working of zone electrophoresis. 8

b) Write the principle and theory of X-ray diffraction study using Brag's law 7

7. a) Write the principle and instrumentation of flame photometry 7

b) Write notes on any two GC detectors 8

8. Explain the principle, equipment, procedure, advantages and applications of IR Spectrophotometer 15

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OU-1702 OU - 1702

Code. No: 13306/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (Suppl.) Examination, August 2019

Subject : Regulatory Affairs

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

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

1. (a) Write a note on importance and types of Drug Master file 7
   (b) Explain the contents of Hatch-Waxman Act 5
   (c) Write about the importance of Post marking surveillance 3

2. Explain the regulatory requirements for ANDA approval process in US 15

3. (a) Describe the importance, preparation and organization of CTD 10
   (b) Describe the objectives and structure of Harmonization guidelines (ICH) 5

4. Explain in brief
   a. The regulations for medical devices 8
   b. Regulatory requirements of MHRA 7

5. Give a brief note on each part of the contents of Investigational New Drug Application (IND) 15

6. (a) What is Investigational Medicinal Product dossier (IMPD)? Explain the requirements and contents of IMPD. 7
   (b) Write a note on Scale up process 8

7. Explain briefly various phases of clinical trials and design of clinical trials for the submission of data to FDA for getting NDA approval. 15

8. Give a brief note on the following:
   a. Institutional Review Board (IRB) 8
   b. Informed Consent 7

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OU - 1702 OU - 1702

Code. No: 13304/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (Suppl.) Examination,

August 2019

Subject : Drug Delivery System

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

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

1. (a) Define personalized medicine? Explain bioelectronic medicines and 3D printing of pharmaceuticals? 10
   (b) What are biodegradable polymers? Explain the mechanism of polymer degradation? 5

2. (a) Classify rate controlled drug delivery system? Explain in detail rate preprogrammed drug delivery system? 8
   (b) Explain osmotic drug delivery system? 7

3. (a) Describe in detail theories of mucoadhesion? 10
   (b) Explain in detail evaluation of gastro retentive drug delivery system? 5

4. (a) What are the barriers of ocular drug delivery system? 5
   (b) Describe in detail formulation of ocular DDS? 10

5. Define vaccine? Write a note on uptake of antigens and permeation of vaccines through mucosal & transdermal route? 15

6. Classify transdermal drug delivery system? Describe in detail active and passive methods of transdermal DDS? 15

7. (a) What are the stability issues of proteins and peptides? 7
   (b) Explain non-invasive routes of administration of protein and peptides ? 8

8. (a) Explain in trandermal permeations enhancers and write about its mechanism of improving permeation? 8
   (b) Write a note on telepharmacy? 7

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OU 1702 OU - 1702

Code. No: 13305/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Suppl.) Examination, August 2019

Subject : Modern Pharmaceutics

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

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

1. (a) Explain the procedure of drug excipient compatibility studies 8
   (b) Write a note on response surface methodology 7

2. (a) Write the approaches of process validation and mention their significance 8
   (b) Describe different steps involved in equipment qualification 7

3. Explain different elements of Total Quality Management 15

4. (a) Explain the distribution of forces and consolidation during compaction 10
   (b) Write a note on compaction profiles 5

5. (a) Explain about various diffusion parameters $7^{1/2}$
   (b) Write about the Higuchi & poppas plots $7^{1/2}$

6. (a) Discuss in detail about ICH guidelines for validation and calibration of equipment 8
   (b) Discuss management of materials and inventory control in industries 7

7. (a) Explain about various optimization techniques in formulation processing with suitable examples 8
   (b) Explain physiological and formulation considerations for parenterals 7

8. Write in brief about
   (a) Heckel plots
   (b) Solubility
   (c) Good manufacturing practices

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OU -1702 OU - 1702

CODE NO: 13147/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common Paper for all Specialization) I – Semester

(Main & Backlog) Examination, January 2019

Subject : Modern Pharmaceutical Analytical Techniques

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

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

1) a) With a neat labeled diagram explain UV/Visible instrumentation. 8

b) Briefly explain the electronic transitions with examples 8

2) a) Explain the factors affecting vibrational frequencies in IR. 8

(b) Write the sampling methods in IR spectroscopy. 7

3 (a) Briefly explain the source of AAS. 8

(b) List and explain the interferences. 5

(c) List some metals that can be analysed by AAS. 2

4 (a) Explain NMR instrumentation. 8

(b) Briefly explain spin-spin coupling with a suitable example. 7

5 (a) What is the principle of MS. With a neat labelled diagram briefly explain the components of MS instrumentation. 8

(b) Explain Quadrupole and time of flight analysers in detail. 7

6. (a) What are the column efficiency parameters? 7

(b) List and explain any 2 GC detectors. 8

7. Explain the principle and application of capillary electophoresis. Give a labelled diagram to indicate the components of the instrument.

8 (a) Discuss the principle, instrumentation working and application of

a. Paper electrophoresis

b. Gel electrophoresis 7+8

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OU - 1702 OU - 1702

Code. No: 13150/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (Main & Backlog) Examination,

February 2019

Subject : Regulatory Affairs

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

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

1. (a) Describe various parts of master formula record and write its importance. 7
   (b) Explain salient features of Hatch Waxman Act and its amendments. 8

2. Enlist different sections of NDA and Write a note on NDA approval process. 15

3. (a) Explain regulatory requirements of US registration for foreign durgs. 8
   (b) Explain SUPAC guidelines specific to manufacturing changes 7

4. (a) Describe the objectives of harmonization guidelines. Enlist ICH quality guidelines. 10
   (b) Explain the objectives of CMC considerations during drug development. 5

5. (a) Explain the regulatory requirement for biologics product approval. 8
   (b) What is the purpose of Investigator's Brochure? Give a brief note on the Information to be filled in each part of the IB. 7

6. (a) Write a note on eCTD. 7
   (b) Write different designs of BE studies for Generic drugs assessment. 8

7. (a) Give an outline of factors that must be addressed in the clinical trial protocols as per USFDA check list. 8
   (b) Give a brief note on Pharmacovigilance and safety monitoring in clinical trials. 7

8. Write brief notes on:
   a. Regulatory requirements of EU 7
   b. Health Insurance Portability and Accountability Act. 8

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OU - 1702 OU - 1702

Code. No: 13149/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main & Backlog) Examination, February 2019

Subject : Modern Pharmaceutics

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

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

1. (a) Write about stability testing of pharmaceuticals 8
   (b) What is optimization? Explain various optimization techniques used for pharmaceutical formulations 7

2. (a) Define validation. What is the importance of validation? Write a note on different types of validation 8
   (b) Explain the terms DQ, IQ, OQ, & PQ 7 7

3. (a) Discuss about Higuchi & poppas plots 10
   (b) Explain in brief about Industrial and Personnel Relationship. 5

4. (a) Describe in detail about physics of tablet compression 10
   (b) Write a note on heckle plots 5

5. (a) Explain about various parameters influencing dissolution 10
   (b) Write in brief about students T test 5

6. (a) Explain about the production planning and control with suitable examples 8
   (b) What are SMEDDS? Give a note on importance and formulation of SMEDDS 7

7. (a) Explain different drug excipient interactions with examples 7
   (b) Give an account on various approaches for inventory management and control 8

8. Write a note on
   (a) Similarity, dissimilarity factors
   (b) Total quality management
   (c) Factorial design

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OU - 1702 OU - 1702

Code. No: 13148/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI)(Main & Backlog) Examination, January 2019

Subject : Drug Delivery System

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

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

1. (a) Compare sustained release, delayed release and controlled drug delivery system with examples? 6
   (b) Define pharmacogenetics? Explain telepharmacy? 9

2. (a) What do you mean by activation modulated system? Explain osmotic drug delivery system? 8
   (b) Classify rate controlled drug delivery system? Explain feedback regulated systems 7

3. (a) What are the barriers of buccal mucoadhesive drug delivery system? Mention two examples of marketed mucoadhesive drug delivery system? 7 7
   (b) Explain in detail floating drug delivery systems? 8

4. (a) Describe formulation and evaluation of ocular drug delivery system? 10
   (b) What are ocular insitu gels? 5

5. (a) Explain structure of skin? What are barriers of transdermal permeation? What are the ideal properties of a drug candidate to permeate through the skin? 10
   (b) Classify transdermal permeation enhancers? Explain the mechanism of permeation enhancers? 5

6. (a) Explain in detail various strategies to formulate a stable protein and peptide drug formulations? 8
   (b) Describe physical and chemical stability of protein and peptides? 7

7. (a) Explain in detail mucosal and active transdermal methods of delivering vaccines through mucosa and skin? 8
   (b) Write a note on single shot vaccines? 7

8. (a) Explain various physiochemical and biological factors that influences the SR and CR formulations? 10
   (b) Classify polymers? Explain properties of any two synthetic biodegradable polymers? 5

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OU-1702 OU - 1702

Code No. 1289/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common to All) I-Semester (PCI) (Suppl.) Examination,

August 2018

Subject: Modern Pharmaceutical Analytical Techniques

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

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

1 (a) Discuss the instrumentation of double beam UV visible spectrophotometer with a neat labeled diagram. (10)
(b) What is Isobestic point? Explain with a labeled UV spectrum giving tow examples. (5)

2 (a) Compare the instrumentation and working a dispersive and foruier transform IR spectrometers. Write the advantages and disadvantages of the two techniques. (10)
(b) Draw a schematic IR spectrum for any one compound and indicate the absorption wave number regions for any four functional groups in the compound. (5)

3 (a) Explain
(i) Chemical shift and factors influencing chemical shift. (6)
(ii) Spin-spin coupling and coupling constant. (6)
(b) Draw a schematic HNMR spectrum for any one compound and explain the following:
(i) Chemical shift values (ii) Nature of protons (iii) Number of protons (3)

4 (a) Discuss the theory and principle of mass spectroscopy and explain the instrumentation and working of mass spectrometer with a neat labeled diagram. (10)
(b) What is fragmentation? Explain the following by taking a simple example
(i) Fragmentation peaks (ii) Molecular ion peak (iii) Base peak (5)

5 (a) Discuss the theory of HPLC. Describe the instrumentation and working of HPLC with a neat labelled diagram. (10)
(b) Draw a schematic HPLC chromatomgram and explain
(i) Retention time (ii) Resolution (iii) Peak Asymmetry (5)

6 (a) Discuss the theory and principle of electrophoresis. Explain the method of capillary electrophoresis and its applications with examples. (12)
(b) What is isoelectric focusing? (3)

7 (a) Discuss the theory and principle of Gas chromatography. Explain the instrumentation and working of Gas chromatography and explain various stationary and mobile phases used in GC. (11)
(b) How non voralile compounds can be analysed by GC. Explain the technique with few examples? (4)

8 Write a note on :
(a) Flame emission spectroscopy (6)
(b) Instrumentation and application of Florescence spectroscopy (9)

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FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Suppl.) Examination, August 2018

Subject: Drug Delivery Systems

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

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

1 Discuss in detail physicochemical and biological factors influencing design of SRDDS. (15)

2 (a) Classify polymers and write the applications of polymers in controlled drug delivery systems. (8)
(b) Write a note on 3D printing of pharmaceuticals. (7)

3 Write a short note on
a) Osmotic activated drug delivery systems. (8)
b) Mechanically activated drug delivery system (7)

4 What are buccal drug delivery systems? Write a detail note on merits, demerits, structure of oral mucosa and buccal absorption. (15)

5 a) Write the barriers for permeation of ocular drug delivery system? (5)
b) Write about mucosal and transdermal delivery of vaccines. (10)

6 a) Explain various essential components of transdermal drug delivery system. (5)
b) Explain in detail various evaluation methods for TDDS. (10)

7 Define protein and peptide delivery systems. Add a note on barriers for protein delivery. (15)

8 a) What are methods to enhance drug permeation through transdermal route? (7)
b) Describe in brief preparation and evaluation of gastro retentive floating tablets. (8)

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OU - 1702 OU - 1702

Code No. 1292/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Supple.) Examination, August 2018

Subject: Regulatory Affairs

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

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

1 (a) Explain the importance of documentation in pharmaceutical industry and add a note on master formula record, distribution records. (10)
(b) Write a note on Code Of Federal Regulation. (5)

2 Explain ANDA regulatory approval process. (15)

3 What are the regulatory requirements for approval of an API? (15)

4 Write a note on
(a) CTD and eCTD (9)
(b) ICH Quality guidelines (6)

5 Explain the regulatory requirements of EU (15)

6 Discuss about regulations for Combination products and Medical devices. (15)

7 Write a note on
(a) informed consent process and procedures (6)
(b) Pharmacovigilance safety monitoring (9)

8 Write a note on
(a) Investigator brochure (7)
(b) investigation of medicinal products dossier (8)

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OU - 1702 OU - 1702

Code No. 1291/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Suppl.) Examination, August 2018

Subject: Modern Pharmaceutics

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

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

1 (a) Explain the methods for testing of drug excipient compatability studies. 6
(b) Describe the preparation of SMEDDS and their evaluation tests. 6
(c) Define factorial design. Describe the applications and limitations. 3

2 (a) Discuss the ICH guidelines for calibration and validation of equipment with an example. 8
(b) Describe the validation of tableting process. 7

3 (a) Discuss the sales forecasting and budget planning in pharmaceutical industries. 8
(b) Describe the layout of buildings, services, equipment and their maintenance in industries. 7

4 (a) What is compaction profile? Explain the phases of compaction profile with a suitable examples. 5
(b) Define the term intrinsic solubility. How to determine ? it's significance? 5
(c) Explain the properties of granules effecting the compression behavior of tablets. 5

5 (a) Discuss the pharmacokinetic parameters for determination of bioavailability. 5
(b) Describe the comparison of dissolution profiles of dosage forms using similarity and difference factors. 5
(c) Explain the variance and standard deviation with it's significance. 5

6 (a) Describe the methods of evaluation of physical stability of emulsions. 5
(b) Describe the sterilization procedures for evaluation of parenterals. 5
(c) Describe the chi-square distribution. 5

7 (a) Write the methods for determination of the order of a reaction. 8
(b) Explain the photo degradation and it's testing procedure. 7

8 (a) Discuss the methods for improvement of aqueous solubilty of drugs. 8
(b) Write Heckle equation and draw Heckle plots for porosity and explain them. 7

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OU - 1702 OU - 1702

Code No. 1147/PCI

FACULTY OF PHARMACY

M. Pharmacy (Common to All) I-Semester (PCI) (Main) Examination,
February 2018

Subject: Modern Pharmaceutical Analytical Techniques.

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

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

1 (a) Derive the expression for Beer-Lambert law and explain the deviations with examples. (9)
(b) Explain the solvent effect with examples. (3)
(c) Discuss the principle and functions of monochromators in UV spectrophotometer. (3)

2 (a) Draw a schematic IR spectrum for any one compound and indicate the absorption wave numbers regions for any four functional groups in the compound. (5)
(b) Explain various kinds of IR vibrational modes and their energy levels. (5)
(c) Explain the sampling methods for liquids and solid samples for taking IR spectra. (5)

3 (a) Explain the principle and instrumentation of NMR spectroscopy. (10)
(b) Draw a schematic HNMR spectrum for any one simple compound and explain the following:
(i) Chemical shift values (ii) Nature of protons (ii Number of protons (5)

4 (a) Explain about the ionization techniques - electron impact, chemical ionization, FAB and MALDI and their advantages and disadvantages. (12)
(b) What are isotopic peaks and how are they identified? What is the importance of isotopic peaks? (3)

5 (a) Discuss the theory of HPLC. Describe the instrumentation and working of HPLC with the help of a neat labeled diagram. (10)
(b) Draw a schematic HPLC chromatogram and explain
(i) Resolution (ii) Tailing (iii) Peak (5)

6 **(a)** Discuss the theory and principle of electrophoresis. Explain the method of gel electrophoresis and its applications with examples. (12)
b) What is isoelectric focusing? (3)

7 **(a)** Discuss about various types of detectors used in gas chromatography. (11)
(b) Explain about moving boundary electrophoresis with required labeled diagram. (4)

8 Write a note on:
(a) Emission spectroscopy (6)
(b) Instrumentation and application of fluorescence spectroscopy (9)

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OU-1702 OU-1702

Code No. 1155/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main) Examination, February 2018

Subject: Modern Pharmaceutics

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

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

1	(a) Discuss the different orders of reaction and their applications?	7
	(b) Discuss the production facilities and formulations of parenterals?	8
2	(a) Discuss the ICH guidelines for calibration and validation of equipment with an example?	8
	(b) Describe the validation of tableting process?	7
3	(a) Discuss the sales forecasting and budget planning in pharmaceutical industries?	8
	(b) Describe the layout of buildings, services, equipment and their maintenance in industries?	7
4	(a) What is compaction profile? Explain the phases of compaction profile with a suitable examples?	5
	(b) Define the term intrinsic solubility ? How to determine ? it's significance?	5
	(c) Explain the properties of granules effecting the compression behavior of tablets?	5
5	(a) Discuss student t-test and it's applications?	5
	(b) Discuss the pharmacokinetic parameters for determination of bioavailability?	5
	(b) Describe the comparison of dissolution profiles of dosage forms using similarity and difference factors?	5
6	(a) Describe the influence of temperature on rate of reaction?	3
	(b) Explain the methods for testing of drug excipient compatability studies?	6
	(c) Describe the preparation of SMEDDS and their evaluation tests?	6
7	(a) Describe the preformulation of suspensions?	4
	(b) Explain the ANOVA test?	7
	(c) Describe the sterilization procedures for evaluation of parenterals?	4
8	(a) Discuss the methods for improvement of aqueous solubilty of drugs?	8
	(b) Write Heckle equation and draw Heckle plots for porosity and explain them?	7

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OU-1702 OU-1702

Code No. 1154/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main) Examination, February 2018

Subject: Drug Delivery Systems

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

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

1 a) Discuss in detail about biodegradable and natural polymers. (8)
b) Write a note on customized drug delivery system. (7)

2 Classify various types of rate preprogrammed drug delivery systems with suitable examples. (15)

3 Give detailed account of various formulation mechanisms in gastric retentive drug delivery system. (15)

4 a) Discuss in detail formulation approaches for TDDS with suitable examples. (10)
b) What are barriers of permeation for TDDS? (5)

5 a) Discuss about different approaches to overcome occular barrier. (8)
b) Explain uptake of antigen in vaccine delivery system with neat diagram. (7)

6 Write about various formulation approaches and evaluation of protein and peptide delivery systems. (15)

7 a) Explain principle involved in mucoadhesion. Describe various theories to explain mucoadhesion. (8)
b) Explain in brief mechanism of drug release from sustained release formulation. (7)

8 Write a short note on
(a) Bioresponsive drug delivery systems. (8)
(b) pH activated drug delivery system. (7)

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Code No. 1156/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutics) I-Semester (PCI) (Main) Examination, February 2018

Subject: Regulatory Affairs

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

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

1	(a) Explain Hatch-Waxmann Act, its benefits in generic approval.	(10)
	(b) Write a note on Bolar Amendment.	(5)
2	Explain NDA regulatory approval process.	(15)
3	What are the regulatory requirements for approval of biologics?	(15)
4	Write a note on	
	(a) CTD and eCTD	(9)
	(b) ICH Quality guidelines	(6)
5	Explain the regulatory requirements of TGA	(15)
6	Discuss about global submission of ANDA	(15)
7	Write a note on	
	(a) HIPAA	(6)
	(b) Pharmacovigilance safety monitoring	(9)
8	Write a note on	
	(a) Investigator brochure	(8)
	(b) Clinical trial protocol	(7)

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