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Code No: H-8077/PCI

FACULTY OF PHARMACY

M. Pharmacy I-Semester (PCI) (Pharm. Regulatory Affairs) (Backlog) Examination, December 2025

Subject: Good Regulatory Practices

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

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

1. (a) Describe EC principles of GMP (Directive 91/356/EEC). (9 Marks)
   (b) Write a note on 21 CFR Part 211. (6 Marks)

2. (a) Describe USFDA GLP Regulations. (9 Marks)
   (b) Write a note on Audit tools. (6 Marks)

3. (a) Explain the types of Audits. (8 Marks)
   (b) Describe ISO standards for Quality. (7 Marks)

4. (a) Explain Principles and requirements of GALP. (9 Marks)
   (b) Describe software evaluation checklist. (6 Marks)

5. (a) Write about legal Good Distribution Practices requirements worldwide. (8 Marks)
   (b) Write a note on good distribution practices with regard to deliveries to customers and returns. (7 Marks)

6. (a) Write about Six Sigma Concept. (8 Marks)
   (b) Describe out of specifications and change control. (7 Marks)

7. (a) Write a note on HVAC validation (Heat Ventilation and Air Conditioning). (8 Marks)
   (b) Write a note on WHO-GDP (Good distribution Practices). (7 Marks)

8. (a) Write a note on Types of validation. (8 Marks)
   (b) Write a note on general checklist for 21 CFR Part 11. (7 Marks)

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Code No: H-8079/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Semester (PCI) (Backlog) Examination, December 2025

Subject: Clinical Research Regulations

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

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

1. (a) Write a note on types of clinical studies. (6)
   (b) Write a note on Clinical Investigation of Medical Devices & IVDs. (9)

2. (a) Describe Nuremberg code and Belmont Report. (9)
   (b) Describe the role of Placebo in clinical trials. (6)

3. (a) Write a note on clinical research regulations in Europe Union (EMA). (9)
   (b) Describe Medical Devices rules 2017 of India. (6)

4. (a) Explain the ICH E6 guidelines with regard to Good Clinical Practice. (9)
   (b) Describe GHTF Study Group 5 Guidance Documents. (6)

5. (a) Write a note on CFR 21 Part 50 with regard to protection of human subjects. (9)
   (b) Explain FDA Med Watch Program. (6)

6. (a) Discuss about NDA 505(b)(2) of the FD&C Act. (6)
   (b) Discuss responsibilities of sponsor and investigator in ethical conduct of clinical research. (9)

7. (a) Write a note on Europe Union Volume 9A, Pharmacovigilance for Medicinal Products for Human Use. (10)
   (b) Write a note on Institutional review board. (5)

8. (a) Write a note on Phase 0 and Phase I clinical trials. (8)
   (b) Write a note on ICH E9 with regard to general biostatics principle applied in clinical research. (7)

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Code No: H-8078/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) I - Semester (PCI) (Backlog) Examination, Dec. 2025

Subject: Documentation and Regulatory Writing

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

Note: Answer any Five Questions. **(5x15=75 Marks)**

1. (a) Give an account on Batch Reconciliation and Batch Packaging records. (10 Marks)
   (b) Write a note on Certificate of Analysis. (5 Marks)

2. Explain the pharmaceutical product development process and write the core sections of Pharmaceutical Product Development Plan (PDP). (15 Marks)

3. (a) Discuss the ASEAN Common Technical Document (ACTD) format and its difference with CTD. (9 Marks)
   (b) Explain the Submission of eCTD. (6 Marks)

4. Explain the dossier submission procedure involved in SUGAM system. (15 Marks)

5. (a) Explain the GMP compliance Audit. (8 Marks)
   (b) Write a note on importance of internal audits. (7 Marks)

6. (a) Describe the steps involved in CAPA implementation process. (10 Marks)
   (b) Explain Establishment Inspection. (5 Marks)

7. (a) Describe the process of post approval labelling changes. (9 Marks)
   (b) Explain and differentiate FDA Warning letters Vs FDA 483s. (6 Marks)

8. Write short notes on
   (a) Report preparation and process for Pre-approval inspections (7.5 Marks)
   (b) Types of Drug Master File (DMF) (7.5 Marks)

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Code No: H-8080/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical regulatory Affairs) I-Semester (PCI) (Backlog) Examination, December 2025

Subject: Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbal, and Food & Nutraceuticals in India and Intellectual Property Rights

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

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

1. (a) Describe the regulatory requirements for clinical trial investigation. (6+9)
   (b) Write the objectives and functions of CDSCO.

2. (a) Define the terms Nutraceuticals, Magic Remedies, Narcotic drugs, IPR and Trade Marks.
   (b) Describe the registration process of Trade mark. (8+7)

3. (a) What is patent and describe the patenting process of pharmaceuticals in India.
   (b) Write a note on objectives of patent and rights of patentee. (10+5)

4. (a) What are the objectives of CPCSEA and guidelines on animal experimentation. (10+5)
   (b) Give an informative note on preclinical studies.

5. Write about (5+5+5)
   (a) Classes of prohibited advertisements according to Drugs and magic remedies act.
   (b) Construction of Bonded laboratory.
   (c) Narcotic drugs and Psychotropic substances act.

6. (a) Describe the objectives and principles of NPPA. (5+10)
   (b) Write the objectives of DPCO. Explain fixing of the ceiling prices of various formulations.

7. Write a note on (6+9)
   (a) Regulatory requirements of Bioequivalence studies.
   (b) Copy Rights.

8. (a) What are objectives of Pharmacy act. Write a note pharmaceuticals ethics. (7+8)
   (b) Describe the constitution central pharmacy council and its functions.

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Code No. G-13122/PCI

FACULTY OF PHARMACY

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

Subject: Modern Pharmaceutical Analytical Techniques

(Common to All)

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

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

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

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

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

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

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

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

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

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

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Code No. G-13167/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) I - Semester (PCI) (Main & Backlog) Examination, June 2025
Subject: Documentation and Regulatory Writing

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

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

1. (a) Give an account on Exploratory Product Development Brief (EPDB) for Drug substance and Drug product.
   (b) Describe various types of drug master file.

2. (a) Give an account on Master Formula record.
   (b) Write a detailed note on Print pack specifications.

3. Explain overview, contents and organization of common technical document (CTD). Compare paper CTD and electronic CTD.

4. (a) Explain the dossier submission procedure involved in SUGAM system. [10]
   (b) Write a note on Non eCTD electronic submissions (Nees). [5]

5. (a) Explain the strategies, preparation and conduction of regulatory audit for manufacturing facilities. [10]
   (b) Write a note in ISO 13485. [5]

6. (a) Describe quality systems requirements for national good manufacturing practice inspectorates. [10]
   (b) Explain preparation and process for Pre-approval inspections. [5]

7. (a) What are SUPAC guidelines. Explain post approval changes recommendations Provided for Manufacturing Sites Changes. [8]
   (b) Write a note on ISO risk management standard. [6]

8. Write short notes on
   (a) FDA Warning letters [7.5]
   (b) Tools and approaches used in Root cause Analysis [7.5]

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Code No: G-13166/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I – Semester (PCI) (Main & Backlog) Examination, June 2025

Subject: Good Regulatory Practices

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

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

1. (a) Write a note on US cGMP guidelines. (8 Marks)
   (b) Write a note on Global Harmonization Task Force (GHTF) guidance documents. (7 Marks)

2. (a) Explain the types of Audits and Audit tools. (10 Marks)
   (b) Write a note on GLP inspection process. (5 Marks)

3. (a) Explain the 21 CFR Part 210. (10 Marks)
   (b) Describe future of GLP regulations. (5 Marks)

4. (a) Describe relevant ISO standards for Automated Laboratory Practices. (8 Marks)
   (b) Describe principles and SOPs of GALP. (7 Marks)

5. (a) Write about Principles and Documentation in Good Distribution Practices. (8 Marks)
   (b) Write a note on USP GDP. (7 Marks)

6. (a) Describe types of Qualification. (5 Marks)
   (b) Explain Quality by Design tool for Quality Management. (10 Marks)

7. (a) Write a note on Validation Master Plan. (7 Marks)
   (b) Explain about ICH guidelines. (8 Marks)

8. (a) Describe ISO 13485. (8 Marks)
   (b) Explain about cleaning validation. (7 Marks)

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