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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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- 13168/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research Regulations

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

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

1.	(a)	Write a note on evaluation of medical devices.	(7)
	(b)	Write a note on Phase III and Phase IV of clinical trials.	(8)
2.	(a)	Write a note on Clinical Trial protocol.	(9)
	(b)	Write a note on Data safety monitoring boards.	(6)
3.	(a)	Describe the responsibilities of Sponsor.	(7)
	(b)	Write a note on Informed consent process and documentation.	(8)
4.	(a)	Explain NDCT 2019 rules and regulations.	(9)
	(b)	Describe FDA Good Clinical Practice guidance.	(6)
5.	(a)	Write a note on ICH E10 Choice of Control groups and related issues in Clinical trials.	(9)
	(b)	Explain ICMR Ethical Guidelines for Biomedical Research.	(6)
6.	(a)	Discuss about CFR 21 Part 812 Investigation Device Exemptions.	(9)
	(b)	write a note on FDA Safety Reporting Requirements for INDs.	(6)
7.	(a)	Write a note on Eudralex Volume 3- Scientific guidelines for medicinal products for human use.	(9)
	(b)	Write a note on ISO 14155.	(6)
8.	(a)	Write a note on Ethics of clinical research in special population.	(6)
	(b)	Write a note on ICH GCP E6 Guidelines.	(9)

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Code No: G-13125/PCI

FACULTY OF PHARMACY

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

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

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

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

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

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

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

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

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

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

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

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Code No: G-13020/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Semester (PCI) (Backlog) Examination, December 2024

Subject: Good Regulatory Practices

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

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

1. Describe US cGMP guidelines 21CFR Part 210 and 211. (15)

2. (a) Write a note on GLP inspection process. (8)
   (b) Write a note on future of GLP regulations. (7)

3. (a) What are the goals of laboratory Quality Audit. (6)
   (b) Describe WHO cGMP guidelines. (9)

4. (a) Explain 21 CFR Part 11. (9)
   (b) Describe ISO and Quality Council of India (QCI) Standards for GALP. (6)

5. (a) Write a note on USP GDP. (10)
   (b) Write a note on principles of Good Distribution Practices. (5)

6. (a) Write about Total Quality Management concepts. (10)
   (b) Describe Change control. (5)

7. (a) Write a note on types of validation and types of qualification. (6)
   (b) Describe CDSCO guidelines for Good Distribution Practices. (9)

8. (a) Write a note on SOPs of GALP. (8)
   (b) Write a note on ISO 13485. (7)

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Code No: G-13021/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) I Semester (PCI) Backlog Examination, December 2024
Subject: Documentation and Regulatory Writing

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

Note: Answer any 5 questions. All questions carry equal marks.

1. (a) Explain the goals and give the template of Exploratory Product Development Brief (EPDB) documentation. (8)
   (b) Give an account on Batch Manufacturing records and explain its calculations. (7)
2. (a) Describe purpose, scope and the contents of Site Master File (8)
   (b) Explain the rationale and sections of Product Development Report (PDR) (7)

3. (a) Write a note on Electronic Submission gateways (ESG) (5)
   (b) Explain the architecture and Submission of eCTD. (10)

4. Describe the dossier submission procedure involved in SUGAM system. (15)
5. (a) Explain the types of audits in pharmaceutical facility. (8)
   (b) Explain the purpose of Global Harmonization Task Force (GHTF) Study group 4 guiding document. (7)
6. (a) What is the purpose of CAPA? Explain the process of CAPA for Pharmaceutical industry. (8)
   (b) Describe in detail about root cause analysis. (7)

7. (a) What are SUPAC guidelines? Explain post approval changes recommendations provided for components and composition changes. (9)
   (b)Write a note on CBE 0 and CBE 30. (6)

8. Write short notes on
   (a). FDA Warning letters (7.5)
   (b). Pre-approval inspections. (7.5)

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Code No: G-13023/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) I - Semester (PCI) (Backlog) Examination, December 2024

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. All questions carry equal marks.

1. (a) What are the objectives of CPCSEA (CCSEA). Describe the guidelines in conducting the animal experimentation.
   (b) Write a note on guidelines for human participants. [10+5]

2. Define Intellectual property rights. Explain the types IPR. [15]

3. (a) Write in detail about the organization, functions and responsibilities of CDSCO. [8+7]
   (b) Describe the format of regulatory dossier for clinical trial investigation.

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

5. Write an informative note on [9+6]
   (a) Copyright
   (b) Trademarks

6. (a) Write about the BCS classification drugs. [7+8]
   (b) Write the definition and objectives patent act. Write note non patentable concepts.

7. What are Medical devices? Classify and write the regulatory guidelines for filling of medical devices. [15]

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

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Code No: G-13022/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Sem. (PCI) (Backlog) Examination, December 2024

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 Phase I and Phase III clinical trials. (8)
   (b) Write a note on clinical trial protocol. (7)

2. (a) Describe the Historical perspectives (Nuremberg Code and Thalidomide study) that resulted in following ethics in clinical research. (8)
   (b) Write a note on composition and responsibilities of Institutional Review Board. (7)

3. Write a note on NDCT 2019 rules for clinical trials. (15)

4. (a) Write a note on ICH GCP E6 guidelines. (9)
   (b) Describe ICMR ethical guidelines for biomedical research. (6)

5. (a) Write a note on 21CFR Part 812 with regard to Investigational Device Exemptions. (9)
   (b) Explain ISO 14155. (6)

6. (a) Discuss about NDA 505(b)(1) of the FD&C Act. (6)
   (b) Discuss about ICH E7 guidelines with regard to Studies in support of general population, Geriatrics. (9)

7. (a) Write a note on Europe union Eudralex volume 3 guidelines. (10)
   (b) Write a note on ICH E9 with regard to general biostatics principle applied in clinical research. (5)

8. (a) Write a note on evaluation of Medical devices. (8)
   (b) Write a note on role of Data safety monitoring boards. (7)

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Code No: F-7259/PCI

FACULTY OF PHARMACY

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

Subject: Good Regulatory Practices

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

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

1. (a) Describe GMP principles of Europe Union (directive 91/356/EEC). (8)
   (b) Write a note on WHO cGMP guidelines. (7)

2. (a) Describe USFDA GLP Regulations. (10)
   (b) Explain the types of Audits. (5)

3. (a) Explain the CFR Part 210. (5)
   (b) Describe ISO and Quality Council of India (QCI) Standards for GLP. (10)

4. (a) Describe the general check list of 21 CFR Part 11. (8)
   (b) Describe principles and SOPs of Good Automated Laboratory Practices (GALP). (7)

5. (a) Write about Documentation in Good Distribution Practices. (5)
   (b) Write about WHO GDP. (10)

6. (a) Describe concept of Quality. (5)
   (b) Explain HVAC Validation (Heat Ventilation and Air conditioning). (10)

7. (a) Write the contents of Validation Master Plan. (7)
   (b) Explain about ICH guidelines. (8)

8. (a) Describe GALP requirements and documentation. (8)
   (b) Explain about principles of GDP. (7)

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Code No: F-7261/PCI

FACULTY OF PHARMACY

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

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 clinical investigation of Medical Devices. (8)
   (b) Write a note on types of clinical studies. (7)

2. Write in detail about different phases of clinical trials. (15)

3. (a) Describe the responsibilities of Sponsor and investigator in conduct of clinical research. (9)
   (b) Write a note on Composition and role of Ethics committee. (6)

4. (a) Explain clinical research regulations in European Union (EMA). (8)
   (b) Describe FDA Guidance for Industry for Acceptance of Foreign Clinical Studies. (7)

5. (a) Explain the ICH E4 guidelines with regard to dose response information. (9)
   (b) Explain GHTF Group 5 guidance documents. (6)

6. (a) Discuss about 21 CFR Part 312, IND Application. (8)
   (b) Write a note on EU MDD with respect to clinical research. (7)

7. (a) Write a note on CFR 21 Part 50. (9)
   (b) Write a note on role of placebo in clinical trials. (6)

8. (a) Write a note on Informed consent form. (7)
   (b) Write a note ICH E10 Guidelines. (8)

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Code No: F-7262/PCI

FACULTY OF PHARMACY

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

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. All questions carry equal marks.

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

2. 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

3. (a) Define the terms Nutraceuticals, medical devices, cosmetics, advertisements and magic remedies.
   (b) Write an informative note on Geographical Indications. [8+7]

4. What are Medical Devices? Describe the regulations and guidelines for approval of Medical devices. [15]

5. Write the importance of stability studies. Describe the stability requirements as per the ICH. [15]

6. Write a note on:
   (a) Regulatory requirements for Bioequivalence studies.
   (b) Trademarks. [8+7]

7. (a) Give the definition and objectives of patent act. Discuss the patentee rights. [8+7]
   (b) Give an informative note on CPCSEA (CCSEA) guidelines on animal experimentation.

8. Define Intellectual Property Rights. Narrate the types of IPRs. [15]

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Code No: F-7260/PCI

FACULTY OF PHARMACY

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

Subject: Documentation and Regulatory Writing

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

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

1. Write a detailed note on Product development plan. Explain various sections of Pharmaceutical Product Development Report.

2. (a) Describe the batch manufacturing record and explain the calculations with example. [10]
   (b) Write a note on Certificate of analysis. [5]

3. Explain the architecture, Submission and validation of electronic Common Technical Document (eCTD).

4. (a) Describe the aim, requirement and organization of ASEAN Common Technical Dossier (ACTD). What is the difference between eCTD (ICH CTD) and ACTD? [12]
   (b) Explain Electronic Submission Gateways (ESG). [3]

5. (a) Explain the purpose of Global Harmonization Task Force (GHTF) Study group 4 guiding document. [7]
   (b) Explain in detail about various types of audits in pharmaceutical facilities. [8]

6. (a) What is the purpose of CAPA? Describe the steps involved in CAPA implementation process. [8]
   (b) Explain the benefits and tools of Root cause analysis. [7]

7. (a) Describe general requirements for post approval changes. [10]
   (b) Give an account on Establishment Inspection report (EIR). [5]

8. Write short notes on
   (a) ISO 13485 [7.5]
   (b) FDA inspection process for drug distribution channels [7.5]

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Code No: E-12441/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Semester (PCI) (Backlog) Examination, November-2023

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 Global Harmonization Task Force (GHTF) guidance documents. [8]
   (b) Write a note on WHO cGMP guidelines. [7]

2. (a) Explain the types of Audits and Audit tools. [10]
   (b) What are the goals of laboratory Quality Audit? [5]

3. (a) Explain the CFR Part 210. [5]
   (b) Describe USFDA GLP Regulations. [10]

4. (a) Describe the general check list of 21 CFR Part 11. [8]
   (b) Describe principles and SOPs of GALP. [7]

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

6. (a) Describe Six Sigma concept. [5]
   (b) Explain Quality by Design tool for Quality Management. [10]

7. (a) Write a note on Types of Validation. [7]
   (b) Explain about ICH guidelines. [8]

8. (a) Describe ISO and QCI standards for GALP. [8]
   (b) Explain about HVAC validation. [7]

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Code No: E-12444/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

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

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

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

1. a) What are Medical Devices? Describe the regulations and guidelines for approval of Medical devices.
   b) Describe the content and format for preparation of clinical trial dossier. [9+6]

2. Describe the objective of DPCO and NPPA. Explain the methods of price fixation of bulk drugs, formulations and new drugs. [15]

3. a) Define the terms Advertisement, Magic remedies, Nutraceuticals, Cosmetics and formulations.
   b) Describe the organization, functions and responsibilities of state pharmacy council. [7+8]

4. a) What is patent? Write about the objectives, rights of patentee.
   b) Define Intellectual Property Rights. Narrate the types of IPRs. [6+9]

5. What are the objectives of?
   a) Pharmacy act; b) Narcotic drugs and Psychotropic substances act;
   c) CPCSEA; d) CDSCO e) Medicinal and Toilet preparation act. [15]

6. a) Explain the constitution and functions of Pharmacy council of India. [7+8]
   b) Give an informative note on Copyrights.

7. a) Differentiate between bonded and non bonded laboratory. Describe the construction of bonded laboratory. [8+7]
   b) Give an informative note on CPCSEA guidelines on animal experimentation.

8 a) Describe the regulatory requirement for conducting BA and BE studies [8+7]
   b) Write an informative note on ICH guidelines for stability studies.

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Code No: E-12443/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Clinical Research Regulations

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

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

1. (a) Write a note on Phase I and Phase III clinical trials. [6]
   (b) Write a note on Clinical Trial protocol. [9]

2. (a) Describe the Historical perspectives that resulted in ethics to be followed in clinical research. [10]
   (b) Describe the Informed consent process. [5]

3. (a) Write a note on clinical research regulations in Europe Union (EMA) [9]
   (b) Describe guidelines for Medical Devices in India. [6]

4. (a) Explain the ICH E6 guidelines with regard to Good Clinical Practice. [9]
   (b) Describe ICMR ethical guidelines for biomedical research. [6]

5. (a) Write a note on CFR 21 Part 50 with regard to protection of human subjects. [9]
   (b) Explain ISO 14155. [6]

6. Discuss about
   (a) ANDA 505(j) of the FD&C Act. [5]
   (b) Responsibilities of sponsor, CRO and investigator in ethical conduct of clinical research. [10]

7. Write a note on
   (a) Europe union Eudralex volume 3 guidelines. [10]
   (b) ICH E9 with regard to general biostatics principle applied in clinical research. [5]

8. Write a note on
   (a) Randomized clinical trials. [8]
   (b) Instituitonal review board. [7]

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Code No: E-12442/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PCI) (Backlog) Examination, November 2023

Subject: Documentation and Regulatory Writing

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

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

1. (a) Explain the importance of EPDB for drug substance and drug products. [7]

   (b) Explain the batch formula records in detail. [8]

2. (a) Describe the contents of Site Master File. [10]

   (b) What is product development report (PDR)? Discuss the significance of PDR. [5]

3. (a) Describe the modules of ICH-CTD format with granularity. [10]

   (b) Define and compare paper CTD and electronic CTD. [5]

4. (a) Describe the aim , requirement and organization of ASEAN Common Technical Dossier (ACTD). [9]

   (b) Write a note on Electronic Submission gateways. [6]

5. (a) Discuss the internal and external Audits in detail. [8]

   (b) Explain the purpose of Global Harmonization Task Force (GHTF) study group 4 guiding document. [7]

6. (a) Write a detailed note on Pre-approval Inspections. [7.5]

   (b) Outline FDA inspection process for drug distribution channels. [7.5]

7. (a) Discuss the Post Approval Changes (SUPAC) process for an approved drug product. [10]

   (b) Write a note on Prior approval supplement. [5]

8. Write short notes on

   (a) Importance and steps involved in root cause analysis. [7.5]

   (b) CBE 30. [7.5]

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Code No: E-12317/PCI

FACULTY OF PHARMACY

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

Subject: Good Regulatory Practices

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

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

1. (a) Describe GHTF guidance documents for Medical devices. [9]
   (b) Write a note on cGMP Part 210. [6]

2. (a) Write a note on GLP inspection process. [8]
   (b) Write a note on ISO and Quality Council of India (QCI) Standards. [7]

3. (a) Explain the types of Audits. [6]
   (b) Describe USFDA GLP Regulations. [9]

4. (a) Explain 21 CFR Part 11. [9]
   (b) Describe principles and SOPs of GALP. [6]

5. (a) Write about WHO GDP. [10]
   (b) Write a note on Good Distribution principles and documentation. [5]

6. (a) Write about Total Quality Management concepts. [10]
   (b) Describe out of specifications. [5]

7. (a) Write a note on cleaning validation. [6]
   (b) Describe CDSCO guidelines for Good Distribution Practices. [9]

8. Write a note on:
   (a) ISO-GLP standards. [8]
   (b) ISO 13485. [7]

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Code No: E-12319/PCI

FACULTY OF PHARMACY

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

Subject: Clinical Research Regulations

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

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

1. (a) Write a note on clinical investigation of medical devices and IVDs. [8]
   (b) Write a note on types of clinical studies. [7]

2. Write in detail about different phases of clinical trials. [15]

3. (a) Describe the role of placebo in clinical trials. [5]
   (b) Write a note on Composition and role of Ethics committee. [10]

4. (a) Explain the regulations for clinical trials in India. [9]
   (b) Describe FDA guidance on Acceptance of foreign clinical studies. [6]

5. (a) Write a note on ICH E4 Dose response information to support drug registration guidelines. [10]
   (b) Explain GHTF Group 5 guidance documents. [5]

6. (a) Discuss about CFR 21 Part 320 Bioavailability and bioequivalence requirements. [10]
   b) Write a note on FDA Med Watch. [5]

7. Write a note on
   (a) CFR 21 Part 50. [9]
   (b) ISO 14155. [6]

8. Write a note on
   (a) Ethics of clinical research in special population. [8]
   (b) ICH E8 Guidelines. [7]

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Code No: E-12318/PCI

FACULTY OF PHARMACY

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

Subject: Documentation and Regulatory Writing

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

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

1. (a) Write a note on Certificate of Analysis. [8]

   (b) Give an account on Batch Manufacturing records and explain its calculations. [7]

2. (a) What is Drug Master File (DMF)? Discuss the types of DMFs. [8]

   (b) Explain the core sections of Pharmaceutical product Development plan (PDP). [7]

3. (a) Discuss the Non eCTD electronic submission (NeeS) format and its difference with CTD. [9]
   (b) Explain the submission of eCTD. [6]

4. Explain the dossier submission procedure involved in SUGAM system. [15]

5. (a) Explain the regulatory auditing process for manufacturing facilities. [8]

   (b) Describe Audit Analysis. [7]

6. (a) Describe the steps involved in CAPA implementation process. [10]

   (b) Explain preparation and process for Pre-approval inspections. [5]

7. (a) Describe the process of post approval labeling changes. [9]

   (b) Explain and differentiate FDA Warning letters Vs FDA 483s. [6]

8. Write short notes on

   (a) Establishment Inspection Report [7.5]

   (b) Site Master File. [7.5]

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Code No: E-12320/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical regulatory Affairs) I – Semester (PCI)
(Main & Backlog) Examination, May-2023
Subject: Regulations and Legislation for Drugs and Cosmetics, Medical Devices, Biologicals and Herbal and Food and Nutraceuticals in India and Intellectual Property Rights

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

Note: Answer any FIVE questions. All Questions carry Equal Marks.

1. Enlist the objectives of Medicinal and Toilet Preparations act, 1955. Discuss the layout and construction of bonded and non bonded laboratory [15]

2. What are the objectives of
   a) Pharmacy act; b) Narcotic drugs and Psychotropic substances act; c) CPCSEA;
   d) CDSCO e) Patent act [15]

3. Write about
   a) Drugs price control order b) Trade mark c) Geographical Indications [5+5+5]

4. Describe the Organization, functions and responsibilities of CDSCO [15]

5. a) Define Patent. Explain briefly about obtaining a patent in India. [7+8]
   b) Write CPCSEA guidelines for conducting animal experimentation and breeding of animals.

6. a) What are Medical Devices? Describe the regulations and guidelines for approval of Medical devices. [9+6]
   b) Describe the content and format for preparation of clinical trial dossier

7. Write an informative note on Industrial designs and Copyright. [15]

8 a) What are the objectives and reasons for implementation of the NPPA [6+9]
   b) Define the term API, ceiling price and formulation according to Drug price control order. Describe the fixation and calculation of ceiling price for scheduled formulation.

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Code No: E-12107/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) I - Semester (PCI) (Backlog) Examination, December 2022

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

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

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

1. a) What is patent? Describe the process of patent filling and application in India.
   b) What are gains of patentee and objective of patent act?

2. a) What is bonded and non bonded laboratory? Describe the lay out and procurement of alcohol in bonded laboratory.
   b) Define terms IPR, Nutraceuticals and Magic Remedies.

3. a) What are objectionable advertisements?
   b) Objectives and functions of Pharmacy act.
   c) Give an informative note on trademarks.

4. Write objectives, functions, responsibilities and Organization charts of CDSCO.

5. What are Medical devices and classify. Discuss the guidelines for regulatory filing of Medical devices.

6. Write the importance of stability studies. Describe the ICH guidelines in conducting stability studies.

7. Describe the objectives of DPCO and NPPA. Explain the methods of price fixation of bulk drugs, new drugs and formulations.

8. Explain the rationale for conducting animal studies. Explain the CPCSEA objective, composition and guidelines in conducting animal experiments.

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Code No: E-12105/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) (PCI) (Backlog) I Semester
Examination, December 2022
Subject: Documentation and Regulatory Writing

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

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

1. a) Describe the types of Drug Master File and write about its submission process. [8]
   b) Give an account on Batch Manufacturing records and explain its calculations. [7]

2. a) Describe the contents of Site Master File. [8]
   b) Explain the core sections of Pharmaceutical Product Development Plan (PDP) [7]

3. a) Write a note on evolution of common technical document (CTD). [5]
   b) Explain the architecture and Submission of eCTD. [10]

4. a) Explain the dossier submission procedure involved in SUGAM system. [10]
   b) Write a note on Electronic Submission gateway. [5]

5. a) Explain the regulatory auditing process for manufacturing facilities. [8]
   b) Explain the purpose of Global Harmonization Task Force (GHTF) Study group 4 guiding document. [7]

6. a) What is the purpose of CAPA? Explain the process of CAPA for pharmaceutical industry. [10]
   b) Explain preparation and process for Pre-approval inspections. [5]

7. a) What are SUPAC guidelines. Explain post approval changes recommendations provided for components and composition changes. [9]
   b) Write a note on Prior approval Supplement. [6]

8. Write short notes on
   a) FDA Warning letters [7.5]
   b) Approaches used in Root cause analysis [7.5]

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Code No: E-12104/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) I - Semester (PCI) (Backlog) Examination, December 2022

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 CFR Part 210 and Part 211. [8]
   b) Write a note on WHO cGMP guidelines. [7]

2. Describe Global Harmonization Task Force (GHTF) guidance documents for Medical Devices& IVDs. [15]

3. a) Explain the types of Audits. [6]
   b) Describe USFDA GLP Regulations. [9]

4. a) Explain 21 CFR Part 11. [9]
   b) Describe principles and SOPs of GALP. [6]

5. a) Write about USP GDP with regard to Supply Chain Integrity & Security. [10]
   b) Write a note on Good Distribution principles and documentation. [5]

6. a) Write about Total Quality Management concepts. [10]
   b) Describe out of specifications and change control. [5]

7. a) Write the contents of Validation Master Plan. [6]
   b) Explain about HVAC validation. [9]

8 a) Write a note on (a) ISO-GLP standards. [8]
   b) WHO-Good Distribution Practices. [7]

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Code No: E-12106/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) (PCI) (Backlog) I - Semester Examination, December 2022

Subject: Clinical Research Regulations

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

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

1. a) Write a note on Phase I and Phase III clinical trials. [6]
   b) Write a note on clinical investigation of medical devices and IVDs. [9]

2. a) Describe the Historical perspectives that resulted in following ethics in clinical research. [10]
   b) Describe the Informed consent process. [5]

3. Write a note on NDCT 2019 rules for clinical trials. [15]

4. a) Explain the ICH E4 guidelines with regard to dose response information. [9]
   b) Describe ICMR ethical guidelines for biomedical research. [6]

5. a) Write a note on CFR 21 Part 50 with regard to protection of human subjects. [9]
   b) Explain ISO 14155. [6]

6. Discuss about
   a) NDA 505(b)(1) of the FD&C Act. [5]
   b) ICH E6 guidelines with regard to GCP. [10]

7. Write a note on
   a) Europe union Eudralexvolume 3 guidelines. [10]
   b) ICH E9 with regard to general biostatics principle applied in clinical research. [5]

8. Write a note on
   a) Clinical trial protocol. [8]
   b) Institutional review board. [7]

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Code No: D-8281/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) I - Semester (PCI) (Main)

Examination, May 2022

Subject: Good Regulatory Practices

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

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

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

2. a) Explain the types of Audits and Audit tools. (10)
   b) What are the goals of laboratory Quality Audit. (5)

3. a) Explain the CFR Part 210. (5)
   b) Describe USFDA GLP Regulations. (10)

4. a) Describe the general check list of 21 CFR Part 11. (8)
   b) Describe principles and SOPs of GALP. (7)

5. a) Write about Good Distribution Practices. (8)
   b) Write a note on USP GDP. (7)

6. a) Describe Six Sigma concept. (5)
   b) Explain Quality by Design tool for Quality Management. (10)

7. a) Write a note on cleaning validation. (7)
   b) Explain about ICH guidelines. (8)

8. a) Describe ISO and QCI standards for GALP. (8)
   b) Describe CDSCO guidelines for Good Distribution Practices. (7)

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Code No: D-8284/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) I-Semester (PCI) (Main) Examination, May 2022

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

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

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

1. What are Medical devices and classify. Discuss the guidelines for regulatory filing of Medical devices.

2. a) Discuss the regulatory requirement s to conduct Bioequivalence studies.
   b) Give an informative note on Geographical Indications.

3. a) What is patent? Describe the process of patent filling and application in India.
   b) What are gains of patentee and objective of patent act?

4. Write the importance of stability studies. Describe the ICH guidelines in conducting stability studies.

5. Write about
   a) Objectives and functions of Pharmacy council of India.
   b) Objective of Drugs and Magic Remedies act, 1955.
   b) Functions, responsibilities and organization of state Licensing Authority.

6. Write objectives, functions, responsibilities and Organization charts of CDSCO.

7. Explain the rationale for conducting animal studies. Explain the CPCSEA objective, composition and guidelines in conducting animal experiments.

8. Describe the objective of DPCO and NPPA. Explain the methods of price fixation of bulk drugs, formulations and new drugs.

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Code No: D-8283/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) (PCI) (Main) I - Semester

Examination, May 2022

Subject: Clinical Research Regulations

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

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

1. a) Write a note on clinical trial protocol.
   b) Write a note on types of clinical studies.

2. Write in detail about different phases of clinical trials.

3. a) Describe the Belmont report and the declaration of Helsinki.
   b) Write a note on Composition and role of Ethics committee.

4. a) Explain the regulations for clinical trials in India.
   b) Differentiate 505 (b) (1), 505 (b) (2) and 505 (j).

5. a) Write a note on ICH GCP E6 guidelines.
   b) Explain GHTF Group 5 guidance documents.

6. a) Discuss about Europe union scientific guidelines for medicinal products for human use Volume 3.
   b) Write a note on FDA Med Watch.

7. Write a note on
   a) CFR 21 Part 50.
   b) Sponsor responsibilities in clinical research.

8. Write a note on
   a) Informed consent form.
   b) ICH E7 Guidelines.

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Code No: D-8282/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmaceutical Regulatory Affairs) (PCI) (Main) I - Semester Examination, May 2022

Subject: Documentation and Regulatory Writing

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

Note: Answer any 5 questions. All questions carry equal marks.

1. a) What are various types of Documents in pharmaceutical industry? Give an account on Distribution records. (9)
   b) Write a note on Certificate of Analysis. (6)

2. a) Describe the contents of Master formula record. (10)
   b) Explain various sections of Pharmaceutical Product Development Report. (5)

3. a) Describe the electronic common technical document submission and the validation process. (10)
   b) Compare Paper CTD and electronic CTD. (5)

4. a) Describe the aim, requirement and organization of ASEAN Common Technical Dossier(ACTD). (7)
   b) Explain dossier submission procedure involved in SUGAM system. (8)

5. a) What are the benefits from Audits? Explain various types of Audits in detail. (8)
   b) Describe Audit analysis. (7)

6. a) Outline FDA inspection process for drug distribution channels. (5)
   b) Explain the importance of root cause analysis. (3)
   c) Describe the steps involved in CAPA implementation process. (7)

7. a) Describe general requirements for post approval changes. (10)
   b) Explain and differentiate FDA Warning letters Vs FDA 483s. (5)

8. Write short notes on
   a) Establishment Inspection Report (7.5)
   b) Pre-approval Inspections (7.5)

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