Code No. [illegible]

FACULTY OF PHARMACY

M. Pharmacy (PCI) I – Semester (Main & Backlog) Examination, June 2023

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 [illegible]. (7 Marks)
   (b) Explain the instrumentation of FTIR. (8 Marks)

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

3. (a) Discuss about different ionisation techniques in mass spectroscopy. (7 Marks)
   (b) Brief out the fragmentation patterns and [illegible] different organic compounds. (8 Marks)

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

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

6. Write notes on:
   (a) [illegible] IR spectroscopy
   (b) FT-NMR (2 x 7.5 = 15 Marks)

7. Give informative notes 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)

*****

Code No. G-12N/PG

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) I - Semester (PCI) Main & Backlog Examination, June 2023
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 Plan (EPDP) 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 classification process involved in SUGAM system. [10]
   (b) Write a note on Non eCTD electronic submissions (Nees) [5]

5. (a) Explain the strategies, organizational conduction of regulatory audit for manufacturing facilities. [10]
   (b) Write a note on ICO 13485 [5]

6. (a) Detail the quality systems requirements for national good manufacturing practice inspectorates. [7.5]
   (b) Explain preparation and process for Pre-approval inspections. [7.5]

7. (a) What are ICH Q12 guidelines. Explain post approval changes recommendations Provided for Manufacturing Sites Changes. [8]
   (b) Write a note on ISO risk management standard. [7]

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

***

Code No: G-13169/PC

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Regulatory Affairs) I – Semester (PCI Scheme & Backlog) Examinations, June 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 US cGMP guidelines. (8 Marks)
   (b) Write a note on Global Harmonized e Task Force (GHTF) guidance documents. (7 Marks)

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

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

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

5. (a) Write about Principles and Documentation in Good Distribution Practices. (8 Marks)
   (b) Write a note on USP 1079. (7 Marks)

6. (a) Describe types of Qualification. (3 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)

***

Code No: P-7269/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 principles 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 GMLP requirements and documentation. (8)
   (b) Explain about principles of GDP. (7)

Code No: F-[illegible]

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Regulatory Affairs) I - Semester (PG) (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 E11 guidelines with regard to data requirement information. [9]
   (b) Explain GHTF Study 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. [8]
   (b) Write a note on role of placebo in clinical trials. [7]

8. (a) Write a note on Informed consent form. [7]
   (b) Write a note ICH E6 Guidelines. [8]

*****

Code No: F-[illegible]

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 & 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) Describe the objectives and principles of NPPA. [8+7]
   (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 patentability. [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]

****

Code No: P-2068/PCI

FACULTY OF PHARMACY

M. Pharmacy (Regulatory Affairs) I - Semester (PC) (Main & Backlog) Examinations

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 circumstances with example. [7M]
   (b) Write a note on Certificate of analysis. [8]

3. Explain files and factors, 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 (EU eCTD) and ACTD? [7]
   (b) Explain Electronic Submission Gateways (ESG). [8]

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 have of Root cause analysis. [7]

7. (a) Describe general requirements for post approval changes. [7M]
   (b) Give an account on Establishment inspection report (EIR). [8]

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

Code No: E-12441/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I-Semester (PCI) (Backlog) Examination, November-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 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. [7]
   (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 GMP. [7]

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

6. (a) Describe Six Sigma concept. [5]
   (b) Explain Cause & Effect Diagram 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 OCI standards for GALP. [8]
   (b) Explain about HVAC validation. [7]

Code no: E-12402/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 substances 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 organizational 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 recognition process for drug distribution channels. [7.5]
7. (a) Discuss the Post Approval Changes (SUPAC) process for an approved drug product. [10]
   (b) Write briefly on Prior approval supplement. [5]
8. Write short notes on:
   (a) Importance and steps involved in root cause analysis. [7.5]
   (b) CSC 30. [7.5]

Code No: R-12403(PC)

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Regulatory Affairs) I Semester (PC) (Backlog) Examination, November 2020

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 II clinical trials. [8]
   (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 European Union (EMA). [8]
   (b) Describe guidelines for Medical Devices in India. [9]

4. (a) Explain the ICH E8 guidelines with regard to Good Clinical Practice. [8]
   (b) Describe ICMR ethical guidelines for biomedical research. [9]

5. (a) Write a note on CFR 21 Part 50 with regard to protection of human subjects. [8]
   (b) Explain ISO 14155. [9]

6. Discuss about
   (a) ANDA 505(j) of the FD&C Act. [8]
   (b) Responsibilities of sponsor, CRO and investigator in ethical conduct of clinical research. [10]

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

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

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. [7+8]

2. Describe the objectives 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. [8+7]

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.
   b) Give an informative note on CPCSEA guidelines on animal experimentation. [8+7]

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