Code No: E-12473/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II-Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Pharmaceutical Validation

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

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

1. Define qualification. Explain different phases of qualification process of analytical equipment. [15]

2. Write a short note on
   (a) Factory Acceptance Test [8]
   (b) Qualification of Friability test apparatus. [7]

3. Write a short note on
   (a) Advantages of Validation [5]
   (b) Validation master plan [5]
   (c) Calibration of FTIR [5]

4. (a) What are the different parameters in HVAC to be examined? [7]
   (b) Write about validation of compressed air and nitrogen. [8]

5. Describe the method validation parameters for a new analytical method as per ICH guidelines. [15]

6. Define process validation. Explain the process validation of capsules. [15]

7. Write a short note on
   (a) GAMP [8]
   (b) Cleaning of facilities. [7]

8. Write a short note on
   (a) Rights and responsibilities of patentee. [8]
   (b) Significance of Transfer of Technology. [7]

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OU - 1704 OU - 1704

Code No: E-12474/PCI

FACULTY OF PHARMACY

M. Pharmacy II Semester (PCI) (Pharm. Quality Assurance) (Main & Backlog) Examination, November 2023

Subject: Audits & Regulatory Compliance

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

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

1. (a) Describe different types of audit and explain the responsibilities of auditor. [10]
   (b) What do you mean by management of Audit? [5]

2. (a) Explain various categories of deficiencies that may be identified during the external audit of the pharma companies? [10]
   (b) Give a brief note on "quality systems approach". [5]

3. (a) Discuss cGMP regulations related to resources and manufacturing operations. [10]
   (b) How do you address nonconformities during quality control activities? [5]

4. (a) Give an overview of auditing procedure of a vendor of API. [7]
   (b) Explain how granulation procedures are audited in tablet manufacturing. [8]

5. (a) Write a note on the quality assurance in manufacturing of Water for Injection. [8]
   (b) Write a note on the quality audit of building of a microbiological laborator. [7]

6. (a) “Conduct of internal audits is essential in pharma industry”. Justify the Statement. [7]
   (b) Give a brief note on the auditing of HVAC components. [8]

7. (a) Give a brief note on audit checklist of effluent treatment process. [7]
   (b) Explain on the audit of pharmaceutical packaging material. [8]

8. What are the checklist items in a GMP audit of a finished product manufacturing Facility? [15]

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OU - 1704 OU - 1, 04

Code No: E-12475/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II-Semester (PCI) (Main & Backlog) Examination, November 2023

Subject: Pharmaceutical Manufacturing Technology

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

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

1. Describe the factors influencing plant layout and special provisions of plant layout.
2. Discuss about area planning & environmental control, wall and floor treatment, utilities in advanced sterile product manufacturing.
3. Discuss about in process quality control tests of ointments and suspensions.
4. Discuss about in process Quality control tests for Tablets.
5. Describe process automation in small volume parenteral and large volume parenteral.
6. Describe about quality control tests for packaging materials and filling equipment.
7. Elaborate Process analytical technology.
8. Discuss about different types of closures and closure liners.

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OU - 17

Code No: E-12472/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II Semester (PCI) (Main & Backlog) Examination, October 2023

Subject: Hazards and Safety Management

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

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

1. Explain in detail about Mineral resources.
2. Explain in detail of classification of chemical hazards.
3. Explain in detail on effects of Radioactive pollution and control measures of it.
4. Write a note on Air circulation maintenance industry for sterile and non-sterile area.
5. Explain in detail about Control measures for chemical hazards.
6. Write a note on Regulation of Chemical hazards.
7. Explain in brief about Fundamentals of Accident prevention.
8. Add a note on Effluent treatment procedure.

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OU - 1704 OU - 1704

Code No: E-12256/PCI

FACULTY OF PHARMACY

M. Pharmacy (Quality Assurance) II Semester (PCI) (Backlog) Examination, April / May 2023

Subject: Hazards and Safety Management

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

Note: Answer any FIVE questions. All Questions carry Equal Marks. (5 x 15 = 75 Marks)

1. Explain in detail about Forest Resources, water Resources and glineral Resources
2. Add a detail note on Hazards based on Radioisotopes, Air and water.
3. Write a brief note on Preliminary Hazard Analysis and critical Hazard Management system.
4. Explain in detail about Regulation of Chemical Based Hazards.
5. Explain in detail Preventive and Protective management from fires and explosion.
6. Add a note on ICH Guidelines on risk assessment and risk management methods and tools.
7. a) Give a brief note on various types of Fire extinguisher.
   b) Write a note on effluent treatment procedure.
8. Write in detail Air circulation maintenance in industry for sterile and non sterile area.

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Code N: E-12258 /PCI

FACULTY OF PHARMACY

M. Pharm. (Pharm. Quality Assurance) II-Semester (PCI) (Backlog) Examination, May 2023

Subject: Audits & Regulatory Compliance

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

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

(5 x 15 = 75 Marks)

1. (a) What are the objectives and different types of audit [7]
   (b) Discuss the functions of Management audit and planning process [8]
2. (a) What do you mean by "quality systems approach". [5]
   (b) Describe cGMP Regulations Related to management responsibilities [10]
3. (a) Discuss cGMP regulations related to resources and manufacturing operations. [10]
   (b) How do you address nonconformities during quality control activities [5]
4. (a) Give an overview of auditing procedure of a vendor of API [7]
   (b) Explain how granulation procedures are audited in tablet manufacturing. [8]
5. (a) Write a note on the maintenance audit of HVAC in pharma industries [7]
   (b) Write a note on auditing ETP's by pollution control authorities [8]
6. (a) How do you audit a capsule manufacturing facility [7]
   (b) Give a brief note on the auditing procedures for an aseptic area in parenteral manufacturing [8]
7. (a) Explain the procedure for auditing water quality in a pharmaceutical production Facility. [8]
   (b) How do you audit pharmaceutical packaging materials [7]
8. What are the checklist items in a systematic GMP audit of a finished product manufacturing facility.

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Code No: E-12257/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II Semester (PCI) (Backlog) Examination, April / May 2023

Subject: Pharmaceutical Validation

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

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

(5 x 15 = 75 Marks)

1. Define Calibration. Explain different phases of qualification process of analytical equipment. [15]
2. Write a short note on qualification of
   (a) Tray dryer. [8]
   (b) Friability test apparatus. [7]
3. Write a short note on
   (a) Validation master plan [5]
   (b) Calibration of FTIR [5]
   (c) Factory acceptance test [5]
4. (a) What are the different parameters in HVAC to be examined? [7]
   (b) Write about pharmaceutical water system validation. [8]
5. Describe the method validation parameters for a new analytical method as per ICH guidelines. [15]
6. Define process validation. Explain the different steps in process validation. [15]
7. Write a short note on
   (a) Electronic records. [8]
   (b) Cleaning of equipment. [7]
8. Write a short note on
   (a) Rights and responsibilities of patentee. [8]
   (b) Significance of Transfer of Technology. [7]

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Code No: E-12259/PCI

FACULTY OF PHARMACY

M. Pharmacy (Quality Assurance) II – Semester (PCI) (Backlog) Examination, May 2023

Subject: Pharmaceutical Manufacturing Technology

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

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

(5 x 15 = 75 Marks)

1. Discuss about legal requirements and licenses for API and formulation industry.
2. Discuss about area planning & environmental control, wall and floor treatment, utilities in advanced sterile product manufacturing.
3. Elaborate process automation in small volume parenteral and large volume parenteral.
4. Discuss about in process Quality control tests for tablets.
5. Describe about coating technology and problems encountered in coating technology.
6. Discuss about different types of closures and closure liners.
7. Explain about stability aspects and evaluation of packaging material.
8. Discuss about Quality by Design.

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Code No: E-12111/PCI

FACULTY OF PHARMACY

M. Pharmacy (Quality Assurance) II – Semester (PCI) (Main) Examination, December 2022

Subject: Hazards and Safety Management

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

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

1. Write a detail about Energy and Land resources.
2. What do you mean by Biotic and Abiotic components? Explain in detail functions & components of Ecosystem.
3. Give a brief note on Air based and Water based hazards.
4. Discuss in detail about Critical Hazard Management System. For fire & chemical Hazards.
5. Explain in detail about Control measures for chemical hazards.
6. Write in detail about ICH guidelines for risk assessment & risk management
7. Explain in detail about Self – protective measures against workplace hazards.
8. Give a note on Effluent Treatment Procedure.

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Code N: E-12113/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) II Semester (PCI) (Main) Examination, December 2022

Subject: Audits & Regulatory Compliance

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

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

1. (a) Why are audits essential in assuring pharmaceutical quality? [7]
   (b) Discuss the functions of Management audit and planning process. [8]
2. (a) Discuss cGMP regulations related to corrective & preventive actions (CA & PA). [7]
   (b) Discuss cGMP regulations related to conduct of internal audits. [8]
3. (a) Give an over view of auditing procedure of a vendor of API. [7]
   (b) Explain how granulation procedures are audited in tablet manufacturing. [8]
4. (a) What do you mean by "Quality Systems Approach"? [5]
   (b) Write a short note on the audits of active and inactive raw material control. [10]
5. (a) Write a note on the maintenance audit of HVAC in pharma industries. [7]
   (b) Write a note on auditing ETP's by pollution control authorities. [8]
6. (a) How do you audit a capsule manufacturing facility? [7]
   (b) Give a brief note on the auditing procedures for parenteral manufacturing. [8]
7. (a) Explain the procedure for auditing water quality in pharma industry. [10]
   (b) Give a brief note on transitioning to quality system approach. [5]
8. Explain the auditing procedure of control of drug product containers and closures. [15]

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OU - 1704 OU - 1704

Code No: E-12112/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II - Semester (PCI) (Main) Examination, December 2022

Subject: Pharmaceutical Validation

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

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

1. Define qualification. Explain different phases of qualification process of analytical equipment. [15]
2. Give a brief note on
   (a) Advantages of Validation. [5]
   (b) Validation Master Plan. [5]
   (c) Qualification of tray dryer [5]
3. (a) How do you qualify UV-Visible Spectrophotometer? [8]
   (b) Write about Cleaning in place [7]
4. (a) Describe validation procedure for HVAC system. [8]
   (b) Write about pharmaceutical water system validation [7]
5. Write a short note on
   (a) Steps in calibration of HPLC [8]
   (b) Electronic records. [7]
6. Define process validation. Explain the different steps in process validation. [15]
7. Write brief note on following
   (a) Digital signature 21 CFR part 11 [8]
   (b) Validation of facilities in sterile plant [7]
8. Write a short note on
   (a) Mechanism for protection of Intellectual Property. [8]
   (b) Significance of Transfer of Technology. [7]

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OU - 1704 OU - 1704

Code No: E-12114/PCI

FACULTY OF PHARMACY

M. Pharmacy (Quality Assurance) II – Semester (PCI) (Main) Examination, December 2022

Subject: Pharmaceutical Manufacturing Technology

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

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

1. Discuss the factors influencing plant layout and special provisions of plant layout.
2. Describe about production planning in pharmaceutical industry.
3. Enumerate in process quality control tests of ointments and suspensions.
4. Discuss about advanced sterile product manufacturing technology.
5. Discuss about in process Quality control tests for Capsule.
6. Discuss about coating technology.
7. Describe about quality control tests for packaging materials and filling equipment.
8. Elaborate Process analytical technology.

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