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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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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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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