CODE NO: H8240/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) (Phram. Quality Assurance) II Semester (Backlog) Examination, June 2026

Subject: Hazards and Safety Management

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

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

1. Write a detail note about the following resources
   i) Forest resources
   ii) ii) Water resources
   iii) iii) Mineral resources
2. a) Write a brief note on various types of Fire extinguisher.
   b) Write a note on effects of radioactive isotopes pollution and control measures of it.
3. a) Write a note on maintenance of air circulation in pharma industry for sterile and non- sterile areas.
   b) Write a brief note on preliminary hazard analysis and critical hazard management system.
4. Write a note on various sources of chemical hazards. Explain in detail about regulations and control measures for chemical based hazards.
5. Write a note on preventive and protective management from fires and explosion.
6. a) Write a note on critical training for risk management and process of hazard management.
   b) Write a note on ICH guidelines on risk assessment and risk management methods and tools.
7. a) Write a note on self-protective measures against workplace hazards.
   b) Write a note on accident prevention, elements of safety program and safety management as per factory act.
8. a) Write a note on physicochemical measurements of effluents, BOD, COD.
   b) Write a note on effluent treatment procedure.

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Code No.: H-8243/PCI

FACULTY OF PHARMACY
M. Pharmacy (PCI) II Semester (Pharm. Quality Assurance) (Backlog)
Examination, June 2026

Subject: Pharmaceutical Manufacturing Technology

Time: 3 Hours **Max. Marks: 75**
Note: Answer any five questions. **(5 x 15 = 75)**

1. a) Discuss the key factors influencing plant location and layout selection for the API and formulation industry.
   b) Detail the legal requirements and licensing process involved in establishing a pharmaceutical manufacturing facility.

2. Explain the fundamental principles of Production Planning and Control (PPC). Elaborate on the steps involved in routing, loading, scheduling, and dispatching of records in a manufacturing plant.

3. a) Provide a detailed manufacturing flowchart and process description for Large Volume Parenterals (LVPs).
   b) Outline the essential in-process quality control (IPQC) tests required for sterile emulsions and suspensions.

4. Discuss the concept of Process Automation in sterile manufacturing with specific reference to: (a) Cleaning-in-Place (CIP) and Sterilization-in-Place (SIP) systems.
   (b) Form-Fill-Seal (FFS) technology.

5. (a) Describe the principle and multi-step process of Lyophilization technology used for sterile products.
   (b) Diagrammatically explain the layout requirements and environmental control measures for an aseptic change room.

6. Explain the manufacturing process and common production problems encountered during the compression and coating of tablets. Highlight the role of Rapid Mixing Granulators (RMG) in modern tablet production.

7. (a) Discuss the types of plastics used in pharmaceutical packaging and elaborate on drug-plastic interactions.
   (b) Explain the quality control evaluations and stability testing parameters required for pharmaceutical glass containers.

8. Describe the elements and terminology of Quality by Design (QbD). Define and correlate Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), and Critical Process Parameters (CPPs) using a suitable example.

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Code No.: H-8242/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II Semester (Ph. Quality Assurance) (Backlog)
Examination June/July 2026

Subject: Audits and Regulatory Compliance

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

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

1. Explain the steps involved in management of external audit and elaborate the specific responsibilities of multi-functional team.

2. Compare and contrast the roles and responsibilities of quality control and quality assurance in drug industries.

3. Elaborate concepts of OOS, CAPA and checklist in auditing process.

4. Describe the steps involved in vendor auditing process during vendor qualification of bulk pharmaceutical chemicals and packaging materials.

5. Write the salient feature of microbial testing of water and mention process in involved in prevention of contamination.

6. Write the salient features of good warehousing practices and explain the procedures to prevent out of stock and material expiry.

7. Explain procedures and control measures in preparation and evaluation of water for injection.

8. Explain solid waste treatment process and the elaborate the check lists for effective disposal and recycle.

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Code No.: H-8241/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) (Pharmaceutical Quality Assurance) II - Semester (Backlog) Examination, June 2026

Subject: Pharmaceutical Validation

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

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

1. Explain the different stages of qualification of Tablet Compression machine and Capsule filling machine.

2. Write a brief note on
   (i) Qualification of Autoclave.
   (ii) Qualification of Friability test apparatus.

3. (i) Write a note on qualification of UV-Visible Spectrophotometer.
   (ii) Calibration of FTIR.

4. (i) Describe validation procedure for HVAC system.
   (ii) Write about validation of compressed air and nitrogen.

5. Explain the process validation of coated tablets and Capsules.

6. Describe the method validation parameters for a new analytical method as per ICH guidelines.

7. Write a note on
   (i) Electronic records
   (ii) GAMP

8. Write a note on
   (i) Mechanism for protection of Intellectual Property.
   (ii) Significance of Transfer of Technology (TOT).

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Code No: H-8111/PCI

FACULTY OF PHARMACY

M.Pharmacy- II Semester (PCI) (Pharmaceutical Quality Assurance) (Main & Backlog) Examination, December 2025

Subject: Hazards and Safety Management

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

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

1.Explain in detail about Mineral resources.

2.Explain in detail about Regulation of Chemical Based Hazards.

3.Write a brief note on Preliminary Hazard analysis and critical hazard management system.

4.Write a note on Air circulation maintenance in industry for sterile and non-sterile area.

5.Explain in detail about Control measures for chemical hazards.

6.Explain in detail about Mechanical & Chemical explosion.

7.Explain in detail about Self-protective measures against workplace hazards.

8.(a) Give a brief note on various types of fire extinguishers.

(b) Add a note on Effluent treatment procedure.

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Code No: H-8114/PCI

FACULTY OF PHARMACY

M.Pharmacy- II Semester (PCI) (Ph. Quality Assurance) (Main & Backlog) Examination, December 2025

Subject: Pharmaceutical Manufacturing Technology

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

Note: Answer any five questions. **(5X15=75 Marks)**

1. Discuss the factors influencing plant layout and special provisions of plant layout.
2. Describe about process automation in pharmaceutical industry.
3. Enumerate in process quality control tests for sterile products, suspensions & dry powder solution.
4. Discuss about advanced sterile product manufacturing technology.
5. Discuss about in process Quality control tests for tablets and Capsule.
6. Discuss about coating technology.
7. Explain about stability aspects and evaluation of packaging material.
8. Elaborate Process analytical technology.

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Code No: H-8113/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) (Pharma Quality Assurance) II - Semester (Main & Backlog) Examination, December 2025

Subject: Audits and Regulatory Compliance

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

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

1. (i) Write the objectives and different types of audit. [7]
   (ii) Discuss the functions of Management audit and planning process. [8]

2. (i) Describe cGMP regulations related to management responsibilities. [9]
   (ii) Write a brief note on “quality systems approach”. [6]

3. (i) Discuss cGMP regulations related to resources and manufacturing operations. [8]
   (ii) How do you address nonconformities during quality control activities. [7]

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

5. (i) Give an overview of auditing procedure of a vendor of API. [8]
   (ii) Explain auditing of granulation process in tablet manufacturing. [7]
6. (i) Write a note on the quality assurance in manufacturing of Water for Injection in sterile Production. [8]
   (ii) Write a note on the quality audit of building of a microbiological laboratory. [7]

7. (i) Explain the procedure for auditing water quality in a pharmaceutical production [8]
   (ii) Explain on the audit of pharmaceutical packaging materials. [7]

8. (i) What are the checklist items in a GMP audit of a finished product manufacturing facility. [9]
   (ii) Give a brief note on audit checklist of effluent treatment process. [7]

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Code No. H-8112/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma Quality Assurance) (PCI) II - Semester (Main & Backlog) Examination, December 2025

Subject: Pharmaceutical Validation

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

Note: Answer any Five questions. **(5X15=75 Marks)**

1. What is the Difference between Calibration and Validation. Explain different phases of qualification process of analytical equipment. [15]

2. Write a brief note on
   (i) Qualification of tray dryer [5]
   (ii) Validation Master Plan [5]
   (iii) Factory Acceptance Test [5]

3. Write a note on
   (i) Write a note on qualification of UV-Visible Spectrophotometer. [7]
   (ii) Qualification of HPLC [8]

4. (i) Write a brief note on qualification of friability test apparatus. [7]
   (ii) Write about pharmaceutical water system validation. [8]

5. (i) Define process validation. Explain the different steps in process validation. [10]
   (ii) Write a brief note on documentation of Process Validation. [5]

6. Write a note on
   (i) Steps in calibration of GC [8]
   (ii) Cleaning of facilities [7]

7. Write brief note on following
   (i) Validation of facilities in sterile plant [8]
   (ii) Digital signature 21 CFR part 11. [7]

8. Write a note on
   (i) Patents, Copyright, Trademark [9]
   (ii) Role of IP in pharmaceutical industry [6]

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Code No. H-8099/PCI

FACULTY OF PHARMACY

M. Pharmacy (Phar. Analysis) II - Semester (Main & Backlog)

Examination, December 2025

Subject: Modern Bio analytical techniques

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

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

1. a) Summarize the general principle and procedure involved in protein precipitation sample treatment methods.
   b) Explain the Bioanalytical method validation as per USFDA guidelines.

2. a) Describe the compendial methods of dissolution testing.
   b) Explain different experimental methods for solubility determination.

3. a) Discuss about Cytochrome P450 based drug interactions.
   b) Explain about different Pharmacokinetic and Pharmacodynamic drug interactions with examples.

4. a) Write about different cell culture media.
   b) Discuss different techniques for the characterization of cells along with their applications.

5. a) Write about the clinical significance of Bioequivalence studies.
   b) Explain different methods for assessment of the bioavailability of new drug products.

6. a) Write about basic equipment used in cell culture lab.
   b) Discuss about Biopharmaceutical factors affecting drug bioavailability.

7. a) Explain about in-vivo and in- vitro methods for checking cellular permeability of new drug products.
   b) Explain about principles, instrumentation and applications of flow cytometry.

8. a) Write about Rat liver microsomes and Human Liver microsomes.
   b) Discuss about different approaches for quantification of metabolites.

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Code No: G-13177/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Quality Assurance) (Backlog) Examination, June 2025

Subject: Hazards & Safety Management

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

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

1. Write a note on Air circulation maintenance industry for sterile and non-sterile area.
2. Explain in detail about Control measures for chemical hazards.
3. Add a note on Effluent treatment procedure.
4. Explain in detail about Forest Resources, water Resources and mineral Resources.
5. Discuss in detail about Critical Hazard Management System for fire & chemical Hazards.
6. Give a brief note on Air based and Water based hazards.
7. Explain in brief about Fundamentals of Accident prevention.
8. Add a note on ICH Guidelines on risk assessment and risk management methods and tools.

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Code No: G-13180/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Quality Assurance) (Backlog) Examination, June 2025

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 plant location.
2. Describe about production planning in pharmaceutical industry.
3. Discuss about advanced non sterile product manufacturing technology.
4. Discuss about different granulators.
5. Discuss about in process quality control tests for tablets.
6. Describe about coating technology and problems encountered in coating technology.
7. Explain about stability and evaluation of packaging material.
8. Discuss about different aspects of Quality by Design and its limitations.

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Code No. G-13178/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) II - Semester (PCI) (Main & Backlog) Examination, June 2025

Subject: Pharmaceutical Validation

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

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

1. (a) Define Calibration, qualification and validation. [6]
   (b) Explain different phases of qualification process of analytical equipment. [9]

2. Give a brief note on:
   (a) Types of Validation [6]
   (b) Qualification of autoclave [9]

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

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

5. Write a short note on:
   (a) Steps in calibration of GC [8]
   (b) Electronic records [7]

6. Define process validation. Explain the process validation of liquid orals. [15]

7. Write brief note on following:
   (a) Validation of analytical method used in cleaning with example [8]
   (b) Validation of facilities in sterile plant [7]

8. Write short note on:
   (a) Mechanism for protection of Intellectual Property [8]
   (b) Significance of Transfer of Technology [7]

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Code No: G-13179/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Quality Assurance) (Backlog) Examination, June 2025

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. Write a short note on
   (a) Responsibilities of Auditee and Auditors (7)
   (b) Types of audits (8)

2. Write about management responsibilities and evaluation activities in transitioning to quality system approach. (15)

3. Write a short note on
   (a) Auditing of warehouse and weighing in pharmaceutical industries (7)
   (b) Quality systems approach (8)

4. What are the key considerations in auditing vendors of bulk pharmaceutical chemicals and packaging materials? (15)

5. Write a short note on
   (a) Auditing of water systems in pharmaceutical industries (7)
   (b) Auditing of ETP in pharmaceutical industries (8)

6. Explain the critical systems that is to be audited within a pharmaceutical facility's HVAC system. (15)

7. Write a short note on
   (a) WHO cGMP Requirements (7)
   (b) Auditing of Sterile production area (8)

8. Write a short note on
   (a) Auditing of capsule production area (7)
   (b) Auditing of Maintenance department (8)

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Code No. G-13049/PCI

FACULTY OF PHARMACY

M. Pharmacy II - Semester (PCI) (Pharmacy Practice) (Main & Backlog) Examination, December 2024

Subject: Principles of Quality use of Medicines

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

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

1. Describe the following (8+7)
   a) Strategies to promote QUM
   b) QUM in a hospital setting

2. a) Define essential medicines list. What are the criteria for inclusion and deletion of a medicine in NLEM in India? (10)
   b) Write notes on National essential drug policy (5)

3. a) What are the strategies to promote Rational use of medicines (7)
   b) Describe QUM in pregnancy and lactation prescribing. (8)

4. a) Define and enumerate the goals of QUM service. write the importance of communication in QUM? (7)
   b) Explain the five step EBM model. (8)

5. Explain the role of pharmacist in the following (5+5+5)
   a) Promoting the quality use of medicine
   b) Pharmacovigilance
   c) Management of medication errors

6. Discuss the regulatory aspects of QUM for the OTC medications and complementary medicines in India. (15)

7. Define and classify medication errors. Explain the methods of detection of medication errors. (15)

8. a) Define Pharmacovigilance. Explain the process of spontaneous reporting of adverse drug reactions in India. (7)
   b) Explain the Naranjo's algorithm for assessment of ADRs. (8)

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Code No: G-13051/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharmacy Practice) (Main & Backlog) Examination, December 2024

Subject: Clinical Pharmacokinetics & Therapeutic Drug Monitoring

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

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

1. (a) Discuss compartment modelling approach and different categories of compartment models with their advantages and disadvantages. (8)
   (b) Define and explain renal clearance. Explain the factors effecting renal clearance. (7)

2. (a) Discuss various Methods for conversion from intravenous infusion to oral dosing. (8)
   (b) Discuss nomograms used in designing dosage regimen with one example. (7)

3. (a) Discuss different pharmacokinetic drug interactions with suitable examples. (10)
   (b) Discuss genetic polymorphism in drug transporters. (5)

4. Discuss the following
   (a) Concept of Bayesian theory (7)
   (b) Pharmacogenetics and PK/PD considerations (8)

5. (a) What are the different methods of Analysis of Population Pharmacokinetic data. (7)
   (b) Discuss the following (8)
      (i) Modeling random effects
      (ii) Simulation of dosage regimens

6. Discuss the pharmacokinetic alterations and different methods for drug dosing in pediatric patients. Add a note on peritoneal dialysis. (10+5)

7. (a) Explain general approaches for dose adjustment in renal impairment. (8)
   (b) Explain the effect of hepatic disease on pharmacokinetics. (7)

8. Give a detailed account of the following
   (a) Protocol for TDM (5)
   (b) TDM of Phenytoin and Cyclosporine (10)

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Code No: G-13050/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharmacy Practice) (Main & Backlog) Examination, December 2024

Subject: Pharmacotherapeutics - II

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

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

1. (a) Explain the selection of antiepileptic drugs based on seizure type. Add a note on complications of antiepileptics. (10)
   (b) Briefly describe pharmacological management of neuropathic pain. (5)

2. (a) Discuss the pathophysiology and explain the treatment of cognitive and behavioural symptoms of Alzheimer's disease. (9)
   (b) Write a brief note on migraine triggers and medications for prophylaxis of migraine. (6)

3. Briefly explain the following
   (a) Therapy of obstructive sleep apnea. (7)
   (b) Drug induced psychiatric disorders (8)

4. (a) Discuss the classification, assessment, and complications of CKD in detail. (8)
   (b) Explain the management of anemia of CKD. (7)

5. Explain the etiology and empirical therapy of the following infections
   (a) Dengue fever (5)
   (b) H1N1 (5)
   (c) Malaria (5)

6. (a) Explain the etiology and management of Meningitis. (10)
   (b) Briefly describe the therapy of any one upper respiratory tract infection. (5)

7. Briefly discuss the following
   (a) General principles of cancer chemotherapy (7)
   (b) Pharmacotherapy of head and neck cancer (8)

8. (a) Explain the pharmacotherapy of chronic myeloid leukemia. (7)
   (b) Explain the principle, complications, advantages and disadvantages of hemodialysis. (8)

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Code No: G-13052/PCI

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharmacy Practice) (Main & Backlog) Examination, December 2024

Subject: Pharmacoepidemiology & Pharmacoeconomics

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

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

1. (a) Write the role of diagnosis and therapy surveys in pharmacoepidemiology. (6)
   (b) Describe about the defined daily doses and prescribed daily doses. (9)

2. (a) Write the importance of post marketing surveillance in pharmacoepidemiology. (7)
   (b) Write a note on retrospective and prospective cohort studies. (8)

3. (a) Explain the resources of cost estimation in pharmacoeconomics. (7)
   (b) Write a note on incremental cost effective ratio and average cost effective ratio. (8)

4. (a) Describe the advantages of cost of illness. (5)
   (b) Write a note on cost utility analysis and cost consequences analysis. (10)

5. (a) Write the applications of pharmacoeconomics. (7)
   (b) Write a note on decision analysis and decision tree. (8)

6. (a) Explain the software used in pharmacoeconomic analysis. (8)
   (b) Write the concept time trade off and discounting. (7)

7. (a) Describe the importance of record linkage systems in pharmacoepidemiology. (8)
   (b) Write a note on odds ratio and prescription event monitoring. (7)

8. (a) Explain about the need and aims of pharmacoepidemiology. (8)
   (b) Write a note on direct cost and intangible cost. (7)

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Code No: F-7232/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II-Semester (PCI) (Backlog) Examination, June 2024

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

2. Give a brief note on
   (a) Difference between Calibration and Validation. [5]
   (b) Validation Master Plan. [5]
   (c) Qualification of autoclave [5]

3. (a) How do you qualify UV-Visible Spectrophotometer? [8]
   (b) Write about Cleaning of equipment [7]

4. (a) Write about validation of compressed air and nitrogen. [8]
   (b) Write about pharmaceutical water system validation [7]

5. Write a short note on
   (a) Steps in calibration of GC [8]
   (b) Electronic records. [7]

6. Define process validation. Explain the process validation of coated tablets. [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) Intellectual Property Rights. [8]
   (b) Patent application forms and guidelines. [7]

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Code No: F-7231/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II-Semester (PCI) (Backlog) Examination, June 2024

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. Write in detail about Water and Land resources.
2. Add a detail note on Hazards based on Radioisotopes.
3. Add a note on Critical Hazard Management System.
4. Explain in detail about Regulation of Chemical Based Hazards.
5. Explain in detail about Mechanical & Chemical explosion.
6. Add a note on ICH Guidelines on risk assessment and risk management methods and tools.
7. Explain in detail about Self-protective measures against workplace hazards.
8. Give a note on Effluent Treatment Procedure.

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Code No: F-7234/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharm Quality Assurance) II-Semester (PCI) (Backlog) Examination, June 2024

Subject: Pharmaceutical Manufacturing Technology

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

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

1. Elaborate legal requirements and licenses for API and formulation industry.
2. Describe about production planning in pharmaceutical industry.
3. Discuss about coating technology.
4. Discuss about advanced sterile product manufacturing technology.
5. Discuss about in process Quality control tests for Capsules.
6. Describe about coating technology and problems encountered in coating technology.
7. Explain about stability aspects and evaluation of packaging material.
8. Discuss about Quality by Design.

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Code No: F-7233/PCI

FACULTY OF PHARMACY

M. Pharmacy II-Semester (PCI) (Pharm. Quality Assurance) (Backlog) Examination, June 2024

Subject: Audits & Regulatory Compliance

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

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

1. (a) What is audit planning and give a brief note on objectives of audits
   (b) Discuss the functions of auditor

2. (a) Explain various categories of deficiencies that may be identified during the external audit of the pharma companies?
   (b) What do you mean by "quality systems approach".

3. (a) With the help of a suitable example, describe corrective & preventive actions (CA & PA) in pharma GMP.
   (b) “Conduct of internal audits is essential in pharma industry”. Justify the statement

4. (a) Describe the importance and procedure of audit of API vendor.
   (b) Explain the audit procedure in the production department of tableting and Coating.

5. (a) Write a note on the quality audit of building of a microbiological laboratory.
   (b) Write a short note on the audits of active and inactive raw material control.

6. (a) Write about auditing of HVAC components.
   (b) Discuss the unique features of auditing the pareneral manufacturing.

7. (a) Explain the procedure for auditing water quality in a pharma production facility.
   (b) Give a brief note on audit point of view of effluent treatment process

8. Explain the auditing procedure of control of drug product containers and closures.

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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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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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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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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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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-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 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-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 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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