Code No: [illegible]

FACULTY OF PHARMACY

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

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 [illegible] area.
2. Explain in detail about Control measures for chemical hazards.
3. Add a note on Effluent treatment procedures.
4. Explain in detail about Fire Prevention, [illegible]
5. Discuss in detail about Critical Hazard Management System for fire & chemical hazards.
6. Give a brief note on [illegible] hazards.
7. Explain in detail about Fundamentals of accident prevention.
8. Add a note on ICH Guidelines on risk assessment and risk management methods and tools.

Code No: [illegible]

FACULTY OF PHARMACY

M. Pharmacy (PCI) II - Semester (Pharm. Quality Assurance) (Backlog) Examination, June 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 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 of 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 [illegible] by design and its limitations.

Code No: [illegible]

FACULTY OF PHARMACY

M. Pharmacy [illegible] Semester [illegible] (Main & Backlog) Examination, June 20[illegible]

Subject: Research Methodology and Biostatistics

Time: 3 Hours | Max Marks: 75

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

1. (a) Write a note on types of research. (7)
   (b) What are the strategies to [illegible]? (8)

2. (a) Write a note on paired and unpaired [illegible]. (7)
   (b) Explain in brief about importance of sample size in research. (8)

3. (a) Describe in brief about [illegible] in medical [illegible]. (7)
   (b) Write a note on [illegible]. (8)

4. (a) Describe about the [illegible] to maintain laboratory animals. (7)
   (b) Write a note on [illegible] in laboratory animals. (8)

5. (a) Write a note on history of [illegible] of hospitals. (7)
   (b) Write the basic principles of [illegible] research. (8)

6. (a) Explain in brief about [illegible] of research. (7)
   (b) Write a note on [illegible] blinding technique. (8)

7. (a) Write about [illegible]? (7)
   (b) Write a note on [illegible] coefficient. (8)

8. (a) Explain about [illegible] and medical research [illegible]. (7)
   (b) Write a note on [illegible] of laboratory animals. (8)

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Code No: P1332PC

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II Semester (PC) (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) Overview Master Plan [5]
   (c) Qualification of glassware [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 Vacuum [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 analytical validation. Explain the process validation of various factors. [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 applicable forms and guidelines [7]

Code No: [illegible]

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 short note on Hazards based on Radioactivity.
3. Add a note on Online Hazard Management System.
4. Explain in detail about Regulations 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: [illegible]

FACULTY OF PHARMACY

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

Subject: Pharmaceutical Manufacturing Technology

Time: 3 Hours Max. Marks: 70

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 quality aspects and evaluation of packaging material.

8. Discuss about Quality by Design.

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Code No: P-7333/PC

FACULTY OF PHARMACY

M. Pharmacy II Semester (PCE/Pharm. Quality Assurance) (Backlog) Examinations, June 2024

Subject: Audits & Regulatory Compliances

Time: 3 Hours. Max. Marks: 75

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

1. (a) What is audit plan? 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 by design approach".

3. (a) With the help of a suitable example, describe corrective & preventive actions (CA & PA) in pharma GMP.
   (b) "Control of deviations is essential in pharma industry". Justify the statement.

4. (a) Describe the importance and procedure of audit of HR records.
   (b) Explain the audit procedure in the production department of labelling and Coating.

5. (a) Write a note on the quality audit of building of a microbiological laboratory.
   (b) Write a short note on the scope of active pharmaceutical ingredient raw material control.

6. (a) Write about auditing of HVAC components.
   (b) Discuss the unique features of auditing the personnel in sterile area.

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

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

Code No: [illegible]

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II-Semester (PCI) (Main & Backlog)

Examination, November 2023

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. 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 qualified? [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: [illegible]

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 the vendor of API. [7]
   (b) Explain how granulation procedure to be audited in tablet manufacturing. [8]

5. (a) Write a note on the quality assurance in manufacturing of Water for injection. [7]
   (b) Write a note on the quality audit of working of a microbiological laboratory. [8]

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 inspection items in a GMP audit of a finished product manufacturing facility? [15]

Code No: [illegible]

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I-Semester (PCI) (Main & Backlog) Examination, November 202[illegible]

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 aseptic 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 parenterals and large volume parenterals.
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.

Code No: [illegible]

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) II Semester (PC) (Main & Backlog)

Examinations, October 2022

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 Mineral industries.
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 industrial hazards.
6. Write a note on Regulation of Chemical hazards.
7. Explain in brief about Fundamentals of Accidents prevention.
8. Write a note on Effluent treatment plant.

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Code No: [illegible]

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 mineral Resources.

2. Add a detail note on Hazards based on Microbiological, 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 Prevention and Protection 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 No: [illegible]

FACULTY OF PHARMACY

M. Pharm. (Pharm. Quality Assurance) I–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 ETPs by pollution control authorities. [8]

6. (a) How do you audit a capsule manufacturing facility. [7]
   (b) Give a brief note on the auditing procedure 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 essential items in a systematic cGMP audit of a sterile product manufacturing facility.

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Code No: [illegible]

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? [8]
   (b) Write about pharmaceutical water system validation. [7]
5. Describe the method validation parameters for a new analytical method as per ICH guidelines. [15]
6. Define process validation. Explain the different stages 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]

Code No: [illegible]

FACULTY OF PHARMACY

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

May [illegible]

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 [illegible] product manufacturing.

3. Describe process automation in small volume parenterals and large volume parenterals.

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: [illegible]

FACULTY OF PHARMACY

B. Pharmacy (Quality Assurance) II – Semester (PCI) (Main) Examination, December [illegible]

Subject: Hazards and Safety Management

Time: [illegible] 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-121(U/PC)

FACULTY OF PHARMACY

M. Pharmacy (Pharma. Quality Assurance) II Semester (PC) (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 ensuring pharmaceutical quality? [7]
   (b) Discuss the functions of management audit and planning activities. [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 "Double Supplier Approach"? [3]
   (b) Write a short note on the audits of quality and control raw material control. [12]
5. (a) Write a note on the maintenance audit of HVAC in pharma industries. [7]
   (b) Write a note on auditing of GLP by pollution control authorities. [8]
6. (a) How do you audit a packaged 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 idea on manufacturing to quality system approach. [5]
8. Explain the auditing procedure of control of drug product containers and closures. [15]

Code No: E-12113/PO

FACULTY OF PHARMACY

M. Pharmacy (Pharm. Quality Assurance) I - 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 stages in process validation. [15]

7. Write short note on following:
   (a) Digital signature in 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]

Code No: [illegible]

FACULTY OF PHARMACY

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

Subject: Pharmaceutical Manufacturing Technology

Time: 3 Hours Max.Marks: 7[illegible]

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 emulsions 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. Discuss Process analytical technology.
