

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

Subject: Audits and Regulatory Compliance

Time:3Hours**Max.Marks:75****Note: Answer any five following questions.****(5x15=75Marks)**

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 c GMP regulations related to management responsibilities. [9]
(ii) Write a brief note on "quality systems approach". [6]
3. (i) Discuss c GMP regulations related to resources and manufacturing operations. [8]
(ii) How do you address non conformities 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 over view 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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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 ability 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 off abilities [7]
7. Write brief note on following
 - (i) Validation of facilities in sterile plant [8]
 - (ii) Digital signature 21CFR 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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FACULTY OF PHARMACY

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

December 2025

Subject: Modern Bioanalytical techniques

Time: 3 Hours

Max. Marks: 75

Note: Answer any five following questions.

(5x15= 75 Marks)

1. a) Summarize the general principle and procedure involved in protein precipitation sample treatment methods.
b) Explain the Bio analytical method validation as per USFD Guidelines.
2. a) Describe the compendia 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 calculator media.
b) Discuss different techniques for the characterization of cells along with their applications.
5. a) Write about the clinical significance of Bioequivalent lance studies.
b) Explain different methods for assessment of the bioavailability of new drug products.
6. a) Write about basic equipment use 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.

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.

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.

(5x15= 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.



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.



Code No: G-13180/PCI

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

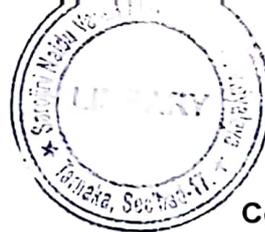
Subject: Pharmaceutical Manufacturing Technology

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.



Code No: G-13214/PCI

FACULTY OF PHARMACY

**M. Pharmacy (Common to All) III - Semester (PCI) (Main & Backlog) Examination,
June 2025**

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 eliminate errors/bias? (8)
2. (a) Write a note on paired and unpaired student t test. (7)
(b) Explain in brief about importance of sample size in research. (8)
3. (a) Describe in brief about values in medical ethics. (7)
(b) Write a note on euthanasia and informed consent. (8)
4. (a) Describe about the necessary SOPs required to maintain laboratory animals. (7)
(b) Write a note on treatment and control of diseases in laboratory animals. (8)
5. (a) Write a note on history of declaration of Helsinki. (7)
(b) Write the basic principles of medical research. (8)
6. (a) Explain in brief about objectives of research (7)
(b) Write a note on placebo and blinding technique. (8)
7. (a) Write about t-test. (7)
(b) Write a note on correlation co-efficient. (8)
8. (a) Explain about the double effect and medical research ethics committee. (7)
(b) Write a note on transport of laboratory animals. (8)
