

QP CODE: 213335

Reg. No:.....

**Second Semester M. Pharm Degree Regular Examinations
November 2025**

**M.Pharm Pharmaceutical Quality Assurance
Audits & Regulatory Compliance (MQA 203T)**

(2024 Scheme)

Time: 3 Hours

Total Marks: 75

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw table/diagrams/flow charts wherever necessary*

Essays

(3x10=30)

1. Explain the cGMP regulations and their role in quality audits.
2. Explain the vendor audit process for bulk pharmaceutical chemicals and packaging materials.
3. Describe the planning process of an audit and the methods of information gathering.

Short Notes

(9x5=45)

4. Explain the classification of deficiencies found during audits.
5. Write short notes on HVAC system audits.
6. Describe the Different Types of Audits.
7. What is an audit checklist for the drug industry. Explain its use.
8. Write a note on auditing packaging operations in pharmaceutical industries.
9. Explain the importance of auditing raw materials in microbiological labs.
10. Explain the auditing process for water systems.
11. Explain the auditing of packaging materials in microbiological laboratories.
12. Write short notes on documentation required for engineering audits.
