

QP CODE: 212335

Reg. No:.....

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

**M.Pharm Pharmaceutical Quality Assurance
Pharmaceutical Validation (MQA 202T)
(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 qualification process of Dry Powder Mixers and Fluid Bed Dryers with emphasis on the stages of qualification and critical parameters.
2. Explain the qualification and validation of nitrogen systems used in pharmaceutical industries, focusing on purity testing, control measures, and documentation.
3. Discuss the different types of validation with appropriate examples.

Short Notes

(9x5=45)

4. Explain the USFDA guideline on process validation.
5. Explain the development of cleaning methods for pharmaceutical equipment.
6. Write short notes on streamlining qualification and validation processes
7. Write short notes on the qualification of Tablet Compression Machines.
8. Explain the documentation and maintenance of qualification records for laboratory and utility systems.
9. Write short notes on re-validation criteria in pharmaceutical manufacturing.
10. What are Intellectual Property Rights (IPR) and how do they protect innovations.
11. What is Media Fill Validation in aseptic filling. Explain its importance.
12. Explain the rights and responsibilities of a patentee and the practical aspects of maintaining a patent file.
