

**First Semester M.Pharm Degree Regular/Supplementary Examinations
April 2025
M.Pharm (Pharmaceutical Analysis)**

Paper III - Pharmaceutical Validation (MPA 103T)

(Common for 2019 and 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. Discuss validation of pharmaceutical water system and pure steam.
2. Discuss general principles of validation of analytical method.
3. Explain computerized system validation.

Short Notes

(9x5=45)

4. Role of intellectual property in pharmaceutical industry.
5. Requalification.
6. Qualification of Fourier transform infra-Red spectrophotometer.
7. Cleaning of equipment.
8. Rights and responsibilities of a patentee.
9. Qualification of burette.
10. Patent Application Forms and Guidelines.
11. Streamlining of qualification and validation process.
12. Validation of nitrogen.
