

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

Paper II: Advanced Pharmaceutical Analysis (MPA 102T)
(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. Explain the control, qualification and specifications of degradation products in drug products.
2. Discuss the stability testing protocol for batch selection, sampling frequency and selection of containers.
3. Explain the bioassay of Tetanus Antiserum and Human Anti Haemophilic Vaccine.

Short Notes

(9x5=45)

4. Write the principle and procedure involved in PCR studies.
5. Discuss the bioassay of adsorbed tetanus vaccine.
6. Explain the method of production of Antibodies for immunoassays.
7. Explain the analytical procedures for quantification of Class III residual solvents.
8. Define stability and discuss about the test parameters and recording of results for stability testing.
9. Explain the concept of analytical method development and add a note on types of validation.
10. Discuss the bioassay of Oxytocin.
11. Quantification and applications of immunoassay.
12. Explain the analytical procedures for quantification of elemental impurities.
