

QP CODE: 113335

Reg. No:.....

**First Semester M.Pharm Degree Regular Examinations
April 2025**

M. Pharm Pharmaceutical Quality Assurance

PAPER III – Quality Control & Quality Assurance (MQA 103T)

(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 in detail the various components of Batch Manufacturing Record.
2. Write a note on maintenance, sanitation and environment control to be followed in a sterile manufacturing unit.
3. Enlist the various IPQC and FPQC tests carried out for parenteral dosage form. Discuss in brief the principle and procedure for sterility testing of parenteral.

Short Notes

(9x5=45)

4. Write a short note on Good Manufacturing Practice.
5. Discuss in brief control of animal house, report preparation and documentation in GLP certified animal house.
6. Write a short note on the concept and evaluation of Quality Control and Quality Assurance.
7. Describe in detail the various quality control tests carried out for glass containers as primary packaging materials.
8. Discuss in brief Good Warehousing Practice.
9. Explain in detail the various components of eCTD.
10. Discuss in brief charge in of components and expiry date calculation for pharmaceuticals.
11. Write a short note on the aseptic process control.
12. What is meant by change control. Explain in brief its importance.
