

QP CODE: 112335

Reg. No:.....

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

M. Pharm Pharmaceutical Quality Assurance

PAPER-II–Quality Management Systems (MQA102T)

(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. Describe strategic planning and its implementation in pharmaceuticals
2. Write a note on Statistical Process Control (SPC)
3. Explain total quality management in detail

Short Notes

(9x5=45)

4. Explain importance about concept of IPQC in pharmaceutical industry
5. Explain in detail models of cost of quality
6. Elaborate on NABL certification and accreditation
7. HACCP
8. Explain OSHAS guidelines
9. Write a note on
 - a) Out of Specifications (OOS)
 - b) Out of Trend (OOT)
10. Explain ICH Q8 in detail
11. Write a note on Six Sigma
12. Benchmarking
