

QP CODE: 114335

Reg. No:.....

First Semester M.Pharm Degree Regular Examinations April 2025

M. Pharm Pharmaceutical Quality Assurance

PAPER IV – Product Development and Technology Transfer (MQA 104T)

(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 in brief the development and informational content for New Drug Application (NDA).
2. Explain in detail the various methods used to improve the solubility of drugs with examples for each.
3. Describe in detail the significance, design and layout for the pilot plant scale up study for semisolid dosage forms.

Short Notes

(9x5=45)

4. Write a short note on SUPAC.
5. Discuss in brief the importance of various physicochemical properties in the solubility of drugs.
6. Write a short note on the large-scale manufacturing techniques for liquid dosage forms.
7. Explain in brief aseptic packaging systems.
8. Describe in brief the issues faced during modern drug packaging.
9. Discuss in brief the quality control tests carried out for glass containers.
10. Write a short note on Technology transfer from R&D to production unit.
11. Explain in detail the various steps involved in the development of technology by R&D.
12. Write a note on the stability testing of drugs during product development.
