QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations July 2025

M.Pharm (Pharmaceutics)
Paper IV – Regulatory Affairs (MPH 104T)
(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 regulatory submission protocol for IND and NDA.
2. Discuss the role and applications of pharmacovigilance in safety monitoring.
3. Define clinical trials. Explain the steps involved in developing clinical trial protocol.

Short Notes **(9x5=45)**

4. Write a note on regulatory requirements of TGA.
5. Write a note on HIPAA.
6. Drug master file.
7. Post market surveillance.
8. Write a short note on functions of Independent ethics committee.
9. Add a note on ANDA.
10. Explain in brief about IMPD.
11. Explain the process involved in CTD.
12. ICH Guidelines.

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