QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations April 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 Code of Federal Regulation (CFR).
2. Write a detailed note on ICH guidelines for regulatory requirements of the EU.
3. Discuss the role of pharmacovigilance in clinical trials.

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

4. Master formula record.
5. Scale-up process approval changes (SUPAC).
6. NDA regulatory approval process.
7. Outsourcing BA/BE studies to a CRO.
8. CTD and ECTD format.
9. General regulatory requirements of TGA.
10. Investigational Medicinal Product Dossier
11. Development of a clinical trial protocol.
12. Formulation and working procedures of the Institutional Review Board.

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