QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations
August 2024
M.Pharm (Pharmaceutics)
Paper IV – Regulatory Affairs (MPH 104T)
(Common for 2017 and 2019 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 ANDA regulatory approval process.
2. Discuss Investigational Medicinal Product Dossier (IMPD).
3. Write a detailed note on chemistry, manufacturing, and control (CMC)

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

4. Write a note on post-marketing surveillance.
5. Write regulatory requirements for product approval of biologics.
6. Explain the code of federal regulation.
7. Explain the terms Common Technical Document (CTD) and electronic common technical document (e-CTD).
8. What is the informed consent and investigator brochure.
9. Development of clinical trial protocol.
10. Functions of institutional review board.
11. Drug Master File (DMF).
12. Expand and explain HIPAA.

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