QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations July 2023

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 Outsourcing protocol for bioavailability studies to Contract Research Organization.

2. Write about the documents of generic product development.

3. Explain the drug approval process in USFDA.

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

4. Add a note on IMP dossiers.

5. Explain the functions of modalities for institutional review board.

6. Define NDA. Explain the regulatory requirement of NDA.

7. Add a note on HIPAA.

8. Write a note on importance of clinical trials.

9. Benefits of ECTD.

10. Write a short note on distribution records in pharmaceutical industries.

11. Explain the regulatory requirements for ANDA.

12. Write about the different codes used in code of federal regulations.

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