QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations June 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 regulatory requirements for ANDA in drug approval process.
2. Define CRO and Explain the problems faced by CRO in outsourcing Bioavailability & Bioequivalence.
3. Explain HATCH – WAXMAN Act and its significance.

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

4. Write a short note on Master formula record.
5. Investigator Brochure.
6. Regulatory requirement for API product approval.
7. Explain about the ICH Q, M & S.
8. Regulatory requirement for MHRA.
9. Regulatory requirement for ROW countries.
10. Benefits of CTD.
11. *In vitro* documentation in Pharmaceutical Industries.
12. Write a note on regulations for medical devices.

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