QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations
April 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 in vivo performance requirements for generic applications
2. Explain the regulatory requirements of MHRA
3. Explain the chemistry, manufacturing and control (CMC) for market authorization

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

4. Scale up and post approval changes
5. Regulatory requirements for combination products
6. Importance of CTD in regulatory application submission
7. Explain HIPAA
8. Importance of master formula records
9. Illustrate NDA approval process
10. Explain the organization for institutional review board and procedures
11. Hatch Waxman act and its amendments
12. ICH –Q Guidelines

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