QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations
January 2021
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. Discuss the process of ANDA for US registration in detail
2. Describe ICH guidelines for ICH-Q, S, E, M
3. Explain the design of clinical study with respect to various phases of clinical trial

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

4. SUPAC (scale up and post approval changes)
5. Hatch-Waxman act and amendments
6. Discuss post marketing surveillance.
7. Explain regulatory requirements of MHRA.
8. Global submission of IND
9. Institutional review board.
10. Discuss the benefits and structure of CTD.
11. Explain the significance of HIPAA.
12. Master formula record.

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