QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations July 2019

M.Pharm (Pharmaceutics)

Paper IV – Regulatory Affairs (MPH 103T)

Time: 3 Hours **Total Marks: 75**

- Answer all Questions.
- Draw Diagrams wherever necessary.

Essays **(3x10=30)**

1. Explain the regulatory requirements and process for NDA approval
2. Discuss the regulatory requirements of TGA
3. Describe the regulation for combination products and medical devices

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

4. Discuss Hatch-Waxman act and amendments
5. Outsourcing BA and BE to CRO
6. DMF
7. Describe ICH guidelines for ICH-Q
8. Explain pharmacovigilance safety monitoring in clinical trials.
9. Institutional review board.
10. Discuss the significance of HIPAA.
11. CFR
12. Post marketing surveillance.

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