QP CODE: 114327 **Reg. No:……**

First Semester M.pharm Degree Examinations March 2019

M.Pharm (Pharmaceutics)

Paper IV – Regulatory affairs (MPH 104T)

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

- Answer all Questions.
- Draw Diagrams wherever necessary.

Essays **(3x10=30)**

1. Discuss regulatory approval process for global submission of new drug application (NDA) and Investigational New Drug Application (IND)

2. Explain institutional review board, its composition and working procedures

3. Explain Hatch Waxman Act and amendments

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

4. Define bioequivalence. Briefly explain the elements of a bioequivalence study protocol

5. Explain code of federal regulations

6. Explain common technical document (CTD) and electronic common technical document (ECTD) format

7. Explain Food and Drug Administration (FDA) liaison for industries

8. What is an informed consent. Explain its process and procedures

9. What is Abbreviated New Drug application (ANDA). Explain

10. Master formula record

11. Briefly explain about investigational medicinal product dossier

12. Pharmacovigilance safety monitoring in clinical trials

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