QP CODE: 114327 **Reg. No:……**

First Semester M.pharm Degree Examinations April 2018

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 Hatch- Waxman act & amendments and ANDA regulatory approval process.
2. Describe the general guidelines for developing clinical trial protocols
3. Explain the regulatory requirements of medical devices for market authorization

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

4. The scale up and post approval changes (SUPAC).
5. The regulatory requirement for product approval of biologics.
6. The importance of CTD in regulatory application submission.
7. The regulatory requirements of MHRA.
8. The dossier (IMPD) and investigator brochure (IB).
9. The non-clinical drug development for submitting NDA.
10. Informed consent process and procedures.
11. The mechanism of pharmacovigilance in India.
12. Principle about drug master file (DMF).

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