QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations
March 2020
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 vitro performance requirements for generic applications.
2. Describe the guidelines for non-clinical drug development for global submission
3. Explain the CMC (chemistry, manufacturing and control) for market authorization

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

4. The post marketing surveillance.
5. The regulatory requirement for product approval of API.
6. The importance of eCTD in regulatory application submission.
7. The regulatory requirements of TGA.
8. The importance of HIPAA in clinical studies
9. The clinical protocol for submitting NDA.
10. Institutional review board and procedures.
11. Outsourcing BA and BE to CRO.
12. ICH guidelines.

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