QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations
November 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. Explain in detail about Master formula record and Drug Master File.
2. Investigational medicinal product dossier - explain in detail
3. What is clinical trial. Explain procedures for developing clinical trial protocols

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

4. Explain bioequivalence and drug product assessment in brief
5. Briefly discuss Health Insurance Portability and Accountability Act (HIPAA)
6. Pharmacovigilance safety monitoring in clinical trials
7. Explain Investigator Brochure (IB)
8. Explain regulatory requirements for product approval of biologicals
9. Post marketing surveillance procedures and significance
10. Explain Abbreviated New Drug application (ANDA)
11. New Drug Application (NDA)
12. Hatch Waxman Act

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