QP CODE: 114327 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations
February 2022
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 NDA regulatory approval process in USFDA
2. Explain the general guidelines for developing non clinical drug development
3. Explain the pharmacovigilance safety monitoring in clinical trials

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

4. Explain the in-vitro performance in drug development
5. Explain the regulatory requirement of USFDA for biologics.
6. Explain the importance of eCTD in regulatory application submission.
7. Regulatory requirements of MHRA
8. Explain the dossier (IMPD)
9. Describe ICH guidelines for ICH-Q.
10. Explain informed consent process and procedures.
11. Explain drug master file
12. The concept about CRO to conduct BA/BE

****