QP CODE: 112333 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations August 2024

M. Pharm Pharmaceutical Regulatory Affairs

PAPER - II – Documentation and Regulatory Writing (MRA 102T)

(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. Describe in detail about Batch Manufacturing record and Master Formula record
2. Write in detail about Exploratory Product Development Brief (EPDB)
3. Explain in detail about Scale-Up and Post Approval Changes (SUPAC)

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

4. Write a brief procedure of USFDA Inspection
5. Discuss in brief about post approval labeling changes
6. Pre-approval Inspections
7. Explain in detail about external and internal Audit
8. Auditing strategies, audit analysis, audit report, audit follow up
9. Write in detail about contents and organization of dossier
10. Drug Master File
11. Batch Reconciliation
12. Explain in detail about FDA Enforcement

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