QP CODE: 112333 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations April 2025

M. Pharm Pharmaceutical Regulatory Affairs

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

(Common for 2019 and 2024 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. Outline the details to be specified in Master formula and Batch manufacturing record.
2. Discuss the contents of Asian common technical document format.
3. Discuss the inspection protocol requirements for pharmaceutical manufacturers

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

4. How to develop product development report.
5. Give an overview on the modules of common technical document.
6. Specify the dossier form submission procedure in Sugam portal.
7. Mention the specifications for GMP compliance audit.
8. Describe the inspection outcome of root cause Analysis
9. Write the responsibilities of global harmonization task force study group.
10. Describe the testing requirements for post approval changes at different levels.
11. State the standards followed in ISO risk management.
12. Classify the types of drug master file.

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