QP CODE: 111333 **Reg. No:……**

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

M. Pharm Pharmaceutical Regulatory Affairs

PAPER - I – GOOD REGULATORY PRACTICES (MRA 101T)

(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. Write in detail about Principles of GMP as per European Commission
2. Explain in detail about USFDA GLP regulations
3. Describe in detail about 21 CFR Part 11

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

4. Global Harmonization Task Force
5. GAMP 5
6. Audit tools
7. Describe in detail about self-inspection.
8. Good Automated Laboratory Practice
9. Write briefly about Out of Specifications
10. Change control
11. Write briefly about Software Evaluation Checklist
12. Quality Council of India Standards

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