QP CODE: 113333 **Reg. No:……**

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

M. Pharm Pharmaceutical Regulatory Affairs

PAPER - III – Clinical Research Regulations (MRA 103T)

(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. Discuss in detail about the types of clinical studies and add a note on Clinical Trial Protocol
2. Write in detail about good clinical practices as per ICH E6 guidelines
3. Describe in detail about bioavailability and bioequivalence requirements as per 21CFR Part 320

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

4. Write briefly about declaration of Helsinki
5. Explain the scope of ICH- E7 guidelines
6. Write about 21 CFR part 312
7. Write short notes on acceptance of foreign clinical studies as per US FDA
8. Write the responsibilities of clinical investigator
9. Explain the 21 CFR part 50
10. Randomized clinical trials
11. Write briefly on clinical trial requirement for approval for generic drug products
12. Discuss briefly on post marketing surveillance requirement as per 21 CFR part 822

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