QP CODE: 114332 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations
August 2024
M.Pharm (Pharmacy Practice)
Paper IV: Clinical Research (MPP 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. Discuss in detail about various methods used in post marketing safety monitoring process.
2. Explain the guidelines to prepare various clinical trial documents
3. Explain ICH GCP guidelines and ICMR guidelines in the conduct of clinical trials

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

4. Define the terms: Cohort study & case control study, Retrospective and Cross sectional study
5. Roles and responsibilities of Monitor
6. Explain Data migration and archiving
7. What is bioequivalence study. How it is conducted
8. Describe the electronic data capturing system
9. What is drug discovery. Explain the various approaches to drug discovery
10. Brief on the various phases of clinical trial
11. Brief on study designs in a clinical trial
12. What is mean by routine audit. Who will conduct

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