QP CODE: 114332 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations
January 2021
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 on international conference on harmonization – good clinical practice guidelines on conduct of clinical trials.

2. Explain on various phases of clinical trials.

3. Describe on guidelines for the preparation of clinical trial protocols

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

4. Constitution and functions of ethics committee.

5. The advantages and disadvantages of case control study.

6. Clinical trial agreement execution.

7. What is trial master file and add a note on its importance.

8. Safety reporting in clinical trials.

9. What is case report form and mention its components.

10. What are the responsibilities of stake holders in clinical trial audit process.

11. Clinical trial data migration and archival.

12. Data mining and warehousing.

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