QP CODE: 114332 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations
April 2023
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. With the help of neat diagram, explain various stages of drug discovery and development.

2. Explain in detail about the audit process for the quality control in clinical trials.

3. Explain the filing procedures used in clinical trials.

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

4. Describe roles and responsibilities of contract research organizations.

5. What are the various types research designs used in clinical research. Explain any one.

6. Discuss drug safety reporting as per ICMR guidelines for clinical trials.

7. Describe various sampling methods used in clinical trials.

8. Discuss briefly on bioavailability and bioequivalence studies.

9. Explain roles and responsibilities of investigator.

10. Explain about informed consent forms.

11. Describe quality control and quality assurance in clinical data management.

12. Explain the process of submission of investigational new drug application.

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