QP CODE: 114332 **Reg. No:……**

First Semester M.Pharm Degree Supplementary Examinations July 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. Define investigational new drug application and explain the process of submission of investigational new drug application.

2. Explain the procedure involved in the procurement and storage of investigational products in clinical trails and also give a brief on electronic data capture systems used in data management

3. Explain the role and responsibilities of investigator in clinical trials and write the content of investigator's brochure.

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

4. What are the roles and responsibilities of sponsor.

5. Mention various types of research designs used in clinical research and explain any one.

6. Write about the audit process used in clinical trials.

7. What are the regulatory requirements for the conduct of clinical trials in India.

8. Explain various sampling methods used in clinical trials.

9. Archival requirement in closed out visit in clinical trials.

10. Quality control and quality assurance in clinical data management.

11. What is trial master file. Enlist the essential documents for the conduct of a clinical trial based on their location.

12. Discuss the roles and responsibilities of contract research organizations.

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