

QP CODE: 114332

Reg. No:.....

**First Semester M.Pharm Degree Regular/Supplementary Examinations  
April 2025  
M.Pharm (Pharmacy Practice)  
Paper IV: Clinical Research (MPP 104T)  
(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. Explain the essential documents required for filing during clinical trial
2. Define and describe the components of investigational new drug application
3. Explain the standard operating procedures in Clinical trial data management

**Short Notes**

**(9x5=45)**

4. Brief on close out visit report content
5. Explain ethical issues in biomedical research
6. Write the functions of Institutional Review Board
7. How data system been validated
8. List the type of audits and its importance in clinical trials
9. Brief on Case Report Form
10. Explain the responsibilities of an investigator
11. Brief on Electronic data capture systems
12. What is Bioavailability study and how it is conducted

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