

**QP CODE: 114332**

**Reg. No:.....**

**First Semester M.Pharm Degree Regular/Supplementary Examinations  
June 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. What are the various randomization methods used in clinical trials.
2. With a neat diagram. Explain the stages of drug discovery and development.
3. Discuss in detail the audit process for the quality control in clinical trials.

**Short Notes**

**(9x5=45)**

4. What are the challenges in the implementation of ethical guidelines.
5. Discuss about clinical data management.
6. Explain the procedure for safety reporting to the regulatory authorities.
7. Outline the content and format of IND application.
8. Describe the regulatory requirements for the conduct of clinical trials in India.
9. Discuss the role of study coordinator in clinical trials.
10. What are the types of study designs used in clinical research.
11. Discuss on informed consent form.
12. Explain the roles and responsibilities of a sponsor.

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