

QP CODE: 114332

Reg. No:.....

**First Semester M.Pharm Degree Supplementary Examinations
February 2022**

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 Indian council of medical research guidelines on conduct of clinical trials.
2. Explain on various randomization techniques.
3. Describe on guidelines for the preparation of informed consent form

Short Notes

(9x5=45)

4. Drug safety reporting.
5. The advantages and disadvantages of cohort study.
6. Pre-study visit.
7. What is investigator site file and add a note on its importance.
8. What is investigational product and add a note on storage of investigation product.
9. Clinical trial close-out visit
10. What is clinical trial audit. Mention the types of clinical trial audits.
11. Electronic data capture system.
12. Quality assurance in clinical data management.
