

QP CODE: 114332

Reg. No:.....

First Semester M.Pharm Degree Supplementary Examinations July 2019

M.Pharm (Pharmacy Practice)

Paper IV: Clinical Research (MPP 104T)

Time: 3 Hours

Total Marks: 75

- Answer all Questions.
- Draw Diagrams wherever necessary.

Essays

(3x10=30)

1. Define drug discovery. Explain the various processes involved in the drug development.
2. Who all are in the clinical trial study team. Discuss their roles and responsibilities in the conduct of clinical trial.
3. Discuss in details the all clinical trial start up activities

Short Notes

(9x5=45)

4. Contract research organization.
5. What is close out visit. Discuss the archival process.
6. Document preparation and submission for ethics committee.
7. Define and explain the preparation of source document.
8. Investigator's brochure.
9. Discuss the different types of research.
10. ICMR guidelines in conduct of clinical trial.
11. Principles of ethics in biomedical research.
12. Discuss about the fraud and misconduct management.
