QP CODE: 114332 **Reg. No:……**

First Semester M.pharm Degree Examinations April 2018

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 clinical trial. Discuss various clinical trial start-up activities.
2. Discuss different types and study designs used in conduct of clinical research.
3. Discuss various phases of a typical drug discovery development (DDD) process with the help of a diagram

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

4. What are the challenges in implementation of good clinical practice (GCP) and ethical principles. Give any two solutions for the same.
5. Explain regulations of investigational new drug (IND) application process.
6. Explain phase II and phase III clinical trials with objectives.
7. Give a brief account on health outcome measures.
8. Discuss roles and responsibilities of sponsor in clinical trials according to ICH-GCP.
9. Discuss procurement and storage of investigation product in study site
10. What are the various parts of the study protocol according to ICH-GCP
11. Explain responsibilities of stakeholders in audit process of clinical trials.
12. Give an account on quality assurance (QA) and quality control (QC) in clinical trial data management (CDM).

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