QP CODE: 114332 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations
March 2020
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. Explain different concepts in drug discovery development (DDD) process with a note on precision medicine.

2. What is meant by clinical trial. Explain various phases of clinical trials with their objectives.

3. Explain quality assurance (QA) and quality control (QC) process in clinical trial

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

4. Explain the ethical principles for biomedical research according to Indian council of medical research (ICMR).

5. What are the differences between new drug application (NDA) and abbreviated new drug application (ANDA).

6. Explain quasi experimental research study design.

7. Give an account on cohort study design with its advantages.

8. Discuss roles and responsibilities of contract research organizations (CROs) in clinical trials according to ICH-GCP.

9. Explain guidelines for preparation of clinical investigator's brochure (CIB).

10. "Close-out visit report" of clinical trials.

11. Mention various components of clinical data management with the help of an algorithm.

12. Give an account on essential documents for clinical trials.

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