QP CODE: 114332 **Reg. No:……**

First Semester M.Pharm Degree Regular/Supplementary Examinations November 2021

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. Describe the composition, roles and responsibilities of IRB/IEC as per ICH-GCP guidelines.
2. Describe the format and content of investigator's brochure.
3. Explain in detail the different phases of clinical trials with suitable examples.

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

4. Discuss the challenges in the implementation of ethical guidelines.
5. Describe about case report forms used in clinical trials.
6. Discuss the responsibilities of sponsor.
7. Describe various randomization techniques used in clinical trials.
8. Discuss briefly clinical trial start-up activities.
9. Discuss on the audit process used in clinical trials.
10. Describe the procedure for safety reporting to the regulatory authorities.
11. Explain the role of study coordinator in clinical trials
12. Describe clinical data management

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