Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Regular/Supplementary Examinations July 2025

Paper I – Clinical Research

Time: 3 Hours **Total Marks: 70**

- ***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***

Essay: **(3x10=30)**

1. Explain the principles of ICH-GCP Guidelines and its importance in Clinical Research.
2. Discuss the various methods of post-marketing surveillance with suitable examples.
3. Explain the role of investigator and clinical research associate in conducting a clinical trial.

Short notes: **(8x5=40)**

4. Design of Clinical Trial.
5. Informed consent Form.
6. What are the functions of Institutional Review Board.
7. Case Report Form.
8. What is IND application. How it is useful in Clinical Research.
9. Ethical Guidelines in Clinical Research.
10. Investigator’s Brochure.
11. Brief on various phases of Clinical Trials.

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