Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Regular/Supplementary Examinations June 2024

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. Discuss the various drug development processes in clinical research.

2. Discuss the role of ICH-GCP guideline in good clinical practice.

3. Explain the role of auditors and clinical research coordinators in conducting a clinical trial.

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

4. Post-marketing surveillance studies.

5. Ethical guidelines in clinical research.

6. ANDA submission.

7. Institutional review board.

8. Informed consent process.

9. Data management in clinical research.

10. Investigator's brochure.

11. IND application.

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