Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Regular/Supplementary Examinations October 2021

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 roles and responsibilities of clinical research co-ordinators and investigators in conducting a clinical trial.

2. Describe the importance of ICH-GCP guidelines in good clinical practice.

3. Explain the various phases of clinical trials.

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

4. Data management in clinical research studies.

5. Ethical guidelines in clinical research.

6. IND application.

7. Institutional review board.

8. Informed consent process.

9. Post-marketing surveillance.

10. Challenges in implementation of guidelines.

11. Safety monitoring in clinical trials.

****