Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Regular/Supplementary Examinations November 2020

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. Describe the importance and various methods of post marketing surveillance in patient care

2. Discuss the composition and responsibilities of institutional review board.

3. Explain the various clinical study documents needed for conducting a clinical trial.

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

4. IND application.

5. Abbreviated new drug application submission.

6. Challenges in the implementation of guidelines.

7. Role of auditors in clinical trial.

8. Design of clinical trial.

9. Ethical guidelines in clinical research.

10. Investigator's brochure.

11. Safety monitoring in clinical trial.

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