Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Supplementary Examinations November 2022

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. Define investigational new drug application and describe the components and categories of investigational new drug application

2. Define clinical trials. Explain the various phases of clinical trials

3. Discuss good clinical practice guidelines as per the central drug standard control organization

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

4. Significance of post marketing surveillance and its methods

5. Abbreviated new drug application

6. Composition and responsibilities of Institutional Review Board

7. Roles and responsibilities of investigators, auditors and regulatory authority in clinical trials

8. Components of a clinical study protocol

9. Informed consent process

10. Drug characterization and its importance in drug development process

11. Challenges observed in implementation of the regulatory guidelines in clinical trials

****