Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Regular / Supplementary Examinations June 2023

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 roles and responsibilities of the investigator, sponsor, and auditor in a clinical trial.

2. What are the various phases of clinical trials and explain in detail the methods of post-marketing surveillance.

3. Define Informed consent as per ICH-GCP guidelines and explain the informed consent process for enrolling patients into a clinical study.

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

4. Explain the content and format of the IND application.

5. Differentiate between ADR, AE, and SAE with suitable examples. Give the timelines for reporting SAE to the sponsor and IRB/IEC.

6. Explain the two different methods for genotoxicity studies.

7. Explain clinical data management.

8. Discuss the challenges in the implementation of clinical trial guidelines.

9. Describe the role of regulatory authorities in the evaluation and approval of a clinical study.

10. Explain the procedure for protocol amendment and expedited review.

11. Explain the steps involved in preclinical drug development with illustrations.

****