Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Supplementary Examinations September 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 composition, roles, and responsibilities of IRB/IEC as per ICH-GCP guidelines.

2. Discuss the need for an Abbreviated New Drug Application process. How does it differ from NDA.

3. Explain the need for informed consent. Who are vulnerable volunteers. Elaborate on the ethical issues to be considered for their participation in a clinical study.

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

4. Explain the roles and responsibilities of clinical investigators in clinical trials.

5. Explain clinical trial auditing.

6. Discuss the regulatory environment in India, the USA, and Europe with respect to drug application review and approval.

7. Describe the procedure for the carcinogenicity test.

8. Explain the methods of post-marketing surveillance.

9. Describe briefly on Helsinki declaration.

10. Explain the sponsor's activities related to quality assurance, data handling, and investigator selection for a clinical trial.

11. Discuss the format and content of the clinical study protocol.

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