Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Supplementary Examinations December 2024

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. Explain the scope and purpose of ICH-GCP guidelines and outline its principles.
2. Explain in detail the different phases of clinical trials with suitable examples.
3. With the help of a neat diagram, explain the stages of drug discovery and development.

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

4. Define Audit and audit trail as per GCP guidelines. Outline the responsibility of the quality assurance unit.
5. Write a short note on the regulatory environment in India, the USA, and Europe with respect to drug application review and approval.
6. Explain subject selection criteria for a clinical study.
7. Describe the IND application review process.
8. Discuss premature termination/suspension of a clinical trial according to ICH-GCP.
9. Explain the composition and functions of the Institutional Ethics Committee.
10. Outline the procedures for acute and chronic toxicity studies.
11. Discuss the roles and responsibilities of contract research coordinators in a clinical trial.

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