Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Regular/Supplementary Examinations July 2022

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. Discuss in detail the overview of regulatory environment in Europe.
2. Discuss in detail the various approaches to drug discovery.
3. Explain in detail about ICH guidelines.

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

4. Write the roles and responsibilities of contract research coordinators in clinical trial.
5. Explain the procedure for submission of investigational new drug application.
6. Discuss the roles and responsibilities of auditors in clinical research.
7. Challenges in the implementation of ICH-Good Clinical Practice guidelines.
8. Explain various methods of post marketing surveillance.
9. Explain Institutional Review Board.
10. Explain about the informed consent process.
11. Explain safety monitoring procedure in clinical trials.

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