Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Regular/Supplementary Examinations June 2024

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 clinical trial personnel and regulatory authorities in clinical trials

2. Define Investigational New Drug. Discuss the process of submission of Investigational New Drug Application

3. Explain about safety monitoring in clinical trials

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

4. Briefly discuss about auditing and its importance in clinical trials

5. Discuss about the Institutional review board, its composition and responsibilities in clinical research

6. Briefly discuss about Abbreviated New Drug Application

7. What is data management in clinical research. Explain

8. Briefly discuss about various clinical study documents

9. What do you mean by Good Clinical Practice Guidelines. What are the challenges in implementation of guidelines in clinical trials

10. Discuss about the purpose of various phases of clinical trials and the number of participants in each phase

11. Briefly explain the drug regulatory environment in Europe

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