Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations December 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. Classify and explain various phases of clinical trial
2. Elaborate the essential components in a clinical research protocol
3. Describe safety monitoring in clinical research

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

4. Explain the requirements to prepare an informed consent form
5. Explain the methods of post marketing surveillance
6. What are the roles and responsibilities of sponsors in clinical trial
7. Explain the role and responsibilities of CDSCO to ensure good clinical practice
8. Explain the record keeping and archiving of clinical trial data
9. DISCUSS THE IMPORTANCE OF DRUG CHARACTERIZATION IN DRUG DEVELOPMENT PROCESS.
10. Briefly explain Abbreviated New Drug Application (ANDA)
11. Discuss the challenges in the implementation of clinical research guidelines

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