Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Regular/Supplementary Examinations June 2023

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 briefly about Abbreviated New Drug Application (ANDA) submission
2. Discuss about designing of protocol for clinical study
3. Explain spontaneous reporting of ADR with suitable examples. Write the merits and demerits of spontaneous reporting

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

4. Discuss electronic data processing
5. Explain about regulatory environment in India.
6. Explain about drug characterization in drug development process.
7. Explain composition and responsibilities of IRB
8. Write a note on Quality Assurance (QA) and Quality Control (QC) in clinical data management
9. Role and responsibilities of sponsor as per ICH GCP guidelines.
10. Explain informed consent process
11. Explain Safety monitoring in clinical trials

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