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 the role of Business Process Outsourcing (BPOs) in conducting clinical research in India
6. Write a note on regulation for OFF-label drug use
7. Explain composition and responsibilities of IRB
8. Write a note on Quality Assurance (QA) and Quality Control (QC) in clinical data management
9. Explain the basic methodologies and study designs of BA/BE studies
10. Explain informed consent process
11. Explain Safety monitoring in clinical trials

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