Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations
September 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. Describe briefly about roles and responsibilities of clinical research associate in clinical trial
2. Explain the Pharmacological and toxicological approaches to the drug discovery
3. Explain the ethical guidelines in clinical research. What are the challenges in implementation of guidelines

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

4. Write a short note on IND
5. Define serious adverse events in clinical trials and responsibilities of investigators in reporting
6. Elaborate the steps involved in process to get NDA approval by US FDA
7. Explain the process of CRF designing in detail
8. Write a note on GCP guidelines
9. Explain methods of post marketing surveillance
10. Explain how bioequivalence study is conducted
11. Write a note on “Fast track” and “Priority review”

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