Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations
February 2022

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. Write in detail about new drug development process.
2. Explain the various phases of clinical trials.
3. Enumerate in detail about overview of regulatory environment in India.

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

4. Explain the guidelines of Central Drug Control and Standard Organization in Good Clinical Practice.
5. Roles and responsibilities of investigators and auditors.
6. Explain composition and responsibilities of Institutional Ethical Committee.
7. Explain the methods and benefits of post marketing trial.
8. Discuss briefly about designing of clinical study documents.
9. What are the responsibilities of clinical research associate.
10. Significance of informed patient consent.
11. Explain ethical guidelines in clinical research.

****