Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations May 2021

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. Define investigational new drug application and its procedure for submission.
2. Roles and responsibilities of sponsor in clinical trial.
3. What are the different stages of drug development process

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

4. Define clinical trial and its various phases.
5. Explain in detail the roles and responsibilities of regulatory authority.
6. Write a brief note on Institutional Human Ethical Committee and its composition.
7. Describe about components of Investigators brochure.
8. What are the ethical guidelines in clinical research.
9. Describe in detail the various data management and its components.
10. Explain informed consent process.
11. Define good clinical practice.

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