Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Regular/Supplementary Examinations October 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. Discuss in detail the overview of regulatory environment in Europe and USA.
2. What is informed consent. Explain content of informed consent as per regulatory authorities in clinical trials.
3. What are the different methods of post marketing surveillance

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

4. Case report form.
5. Safety monitoring in clinical trials.
6. Role and responsibility of clinical research coordinator.
7. Impartial witness.
8. Differentiate between double- blind clinical trials and open labeled clinical trials.
9. Purpose of an audit in clinical trial.
10. Investigational new drug application.
11. Why randomization is important in clinical research

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