Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Examinations June 2017

Clinical Research

Time: 3 Hours **Total Marks: 70**

- Answer all questions
- Draw diagrams wherever necessary

Essay: **(3x10=30)**

1. Explain the challenges in the implementation of guidelines in clinical research.
2. Discuss the responsibilities and procedures of IRB/IEC.
3. Define clinical Trials. Discuss in detail five various phases involved in drug development process.

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

4. IND Application.
5. Central drug standard control organization and food and drug administration.
6. Role of Investigator in clinical trial.
7. Ethical consideration in the conduct of clinical trials.
8. Differentiate phase II and phase III clinical trials.
9. Schedule Y
10. Explain data management in clinical trials.
11. Overview of regulatory environment in Europe.

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