Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Examinations June 2017

Paper I – Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Explain the roles and responsibilities of investigator as per international conference on harmonization good clinical practice.

2. Discuss the drug development process and explain the pharmacological & toxicological approaches to drug discovery.

3. Explain the various methods of post marketing surveillance.

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

4. Regulatory environment in United States of America

5. Composition and responsibilities of institutional review board

6. Challenges in the implementation of ethical guidelines.

7. Designing of protocol.

8. Roles of regulatory authority in clinical trial.

9. Phase III clinical trial.

10. Roles of data safety monitoring board in clinical trial.

11. Procedure for reporting a serious adverse event in clinical trial as per schedule Y.

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