**Q.P. Code: 201340** **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Supplementary Examinations, February 2016

**Paper I – Clinical Research**

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Discuss the principles of ICH-GCP guidelines.

2. Describe the various methods of post marketing surveillance.

3. Explain the role of investigator and clinical research associate in conducting a clinical trial.

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

4. Design of clinical trial.

5. Informed consent form.

6. Institutional review board.

7. Case record form.

8. IND application.

9. Ethical guidelines in clinical research.

10. Investigator's brochure.

11. Compare various phases of clinical trial.

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