Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Examinations, June 2016

Paper I – Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Discuss the various phases of clinical trials with examples.

2. Describe the ethical guidelines and challenges in implementation of ethical guidelines in clinical research.

3. Explain the role of a sponsor and investigators in conducting a clinical trial.

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

4. Abbreviated new drug application.

5. Toxicological approaches in drug discovery.

6. Data management in clinical research.

7. Institutional review board.

8. IND application.

9. CDSCO guidelines.

10. IPrinciples of ICH-GCP guidelines.

11. Informed consent process.

****