Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Examinations, July 2014

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 sponsor & regulatory authority in the clinical trial as per international conference on hormonisation good clinical practice

2. Describe in detail the ethical guidelines in clinical research.

3. What is post marketing surveillance. Discuss in detail about the spontaneous reporting system and prescription event monitoring.

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

4. Content of informed consent in a clinical trial

5. Functions and procedure of institutional review board

6. Abbreviated new drug application

7. Toxicological methods of drug discovery and the importance of drug characterization in drug discovery process

8. What is case report form. Add a note on the components of case report form.

9. Regulatory environment in Europe

10. What is data management in clinical trial. Mention the components of data management.

11. What are the roles of auditors in a clinical trial.

****