

**Q.P. Code: 201340**

**Reg. no.: .....**

**Second Pharm D Post Baccalaureate Degree Examinations June 2018**

**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 drug development process.
2. Discuss the importance of ethical guidelines and challenges in implementation of it in clinical research.
3. Explain the components of CDSCO guidelines for good clinical practice.

**Short notes:**

**(8x5=40)**

4. Institutional review board.
5. Methods of post marketing surveillance.
6. Data management in clinical research.
7. Abbreviated new drug application.
8. IND application.
9. Clinical research associate.
10. Investigator's brochure.
11. Informed consent process.

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