**Q.P. Code: 501326** **Reg. no.: ……**

Fifth Year Pharm D Degree Examinations, June 2016

# 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 and contract research organization in the conduct of clinical trial as per ICH-GCP guidelines.
2. Explain various approaches to drug discovery.
3. Explain the ethical guideline in clinical trial. Add a note on informed consent process.

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

4. Principles of ICH- GCP guidelines.
5. What is case report form and add a note on designing of case report form.
6. Various methods of post marketing surveillance.
7. Roles of institutional ethics committee in conduct of clinical trial.
8. Roles and responsibilities of auditor as per the ICH-GCP guidelines.
9. Regulatory environment in India.
10. Abbreviated new drug application (ANDA) submission.
11. Designing of protocol in clinical trial.

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