Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations, January 2017

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Discuss the ethical principles of central drugs standard control organization (CDSCO) guidelines.
2. Describe the roles and responsibilities of auditor and clinical research associate in conduct of clinical trial.
3. Explain the safety monitoring in clinical trials.

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

4. Phase I and phase II clinical trials.
5. Explain about abbreviated new drug application (ANDA) submission.
6. Role of data safety monitoring board in clinical trial.
7. Regulatory environment in Europe.
8. Thalidomide disaster and Helsinki declaration.
9. What are the challenges in implementing ethical guidelines in clinical trial in India.
10. Data validation in clinical data management.
11. Essential documents required for conduct of clinical trials.

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