Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Examinations, August 2015

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. What is clinical trial. Describe the various phases of clinical trial.
2. Explain the functions of regulatory authority. Add a note on procedure of NDA submission.
3. Explain about different essential documents related to a clinical trial.

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

4. Toxicological approaches in clinical trial.
5. Informed consent process.
6. Roles and responsibilities of an investigator in clinical trial as per ICH-GCP guidelines
7. Essential components of data management in clinical trial.
8. What is safety monitoring and add a note on safety monitoring in clinical trial.
9. Regulatory environment in United States.
10. What is abbreviated new drug application. Add a note on abbreviated new drug application submission.
11. Designing of a protocol in clinical trial.

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