Q.P. Code: 501326 **Reg. no.: ……..**

Fifth Year Pharm D Degree Supplementary Examinations December 2017

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. What is clinical trial. Describe various phases of clinical trials.
2. Explain the roles and responsibilities of clinical research coordinator and sponsor as per ICH-GCP.
3. Discuss on ICH-GCP guidelines for the conduct of clinical trials.

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

4. What is informed consent form. Mention contents of an informed consent form.
5. Procedure of new drug application (NDA) submission
6. Designing of clinical study protocol.
7. Ethical issues of clinical trials in India
8. Procedure involved in reporting of a serious adverse event in clinical trial in India.
9. Components in clinical data management
10. Pharmacological and toxicological approaches to drug discovery
11. Clinical trial registry - India

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