Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Examinations June 2018

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. What are the essential documents for the conducting of clinical trials and its purpose
2. Explain the functions of IRB in clinical research.
3. Define investigator's brochure and describe about its components.

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

4. GCP.
5. Roles and responsibilities of regulatory authority in relation to clinical trial.
6. Explain the importance of pharmacological information in drug discovery.
7. Preclinical testing in clinical research.
8. Informed consent process
9. Challenges faced by investigator while conducting clinical trials.
10. Safety monitoring in clinical trials.
11. Explain briefly the ICH guidelines.

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