Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Examinations June 2019

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Explain various phases of clinical trials
2. Explain the ethical principles as per International Council for Harmonization for technical requirements for pharmaceuticals for human use (ICH)
3. What is the importance of an informed consent in clinical trial. Explain on designing of an informed consent form

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

4. Lead optimization during the drug development process
5. Objectives of phase I and phase II studies
6. Active surveillance studies with its merits and demerits
7. Helsinki declaration
8. What are the challenges in implementing ethical guidelines for conducting clinical trials in India
9. The roles and responsibilities of an investigator in clinical trials
10. Clinical Trial Registry in India (CTRI)
11. What are the sections to be considered while designing a case report form

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