Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations December 2019

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Discuss on informed consent process for a clinical trial involving vulnerable population
2. Explain the various methods of post marketing surveillance
3. Describe the roles and responsibilities of a regulatory authority in the conduct of clinical trial in India

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

4. What are the advantages and disadvantage of active surveillance studies
5. Comparative observational studies
6. What are the contents of an Abbreviated New Drug Application (ANDA)
7. List out the various activities of Clinical Research Associate (CRA) while monitoring a clinical trial
8. The roles and responsibilities of auditors in clinical trail
9. Designing of clinical trial protocol
10. Write the functions of central drugs standard control organization (CDSCO) in the conduct of a clinical trial
11. Thalidomide disaster

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