Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations
December 2018

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Explain about pre-clinical development of drugs
2. Explain the qualification of an investigator and the roles and responsibilities of investigator as per ICH-GCP
3. Discuss the importance of post marketing surveillance (PMS) studies. Explain different methods of PMS studies with their advantages and disadvantages

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

4. Composition and responsibilities of Institutional ethics committee
5. Informed consent process
6. What is investigational new drug (IND). What are the contents and format of IND application
7. Nuremberg code
8. The functions of regulatory agency in conducting clinical trials
9. Components of data management in clinical trials
10. What are the principles of ICH- GCP guidelines
11. Different sections of case report form with its importance in data management

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