Q.P. Code: 501326 **Reg. no.: ……**

Fifth Year Pharm D Degree Supplementary Examinations, February 2016

Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Explain the qualification and duties of an investigator in clinical trial as per ICH-GCP guidelines.
2. Define clinical trial. Explain about the different post marketing surveillance studies.
3. Describe the composition, responsibilities and procedure of institutional ethics committee.

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

4. Ethical issues in clinical trial.
5. Various components of informed consent process.
6. Roles and responsibilities of a clinical trial associate in clinical trial as per ICH-GCP guidelines.
7. Roles of data safety monitoring board (DSMB) in clinical trial.
8. What is serious adverse event and add a note on reporting of serious adverse events.
9. Regulatory environment in Europe.
10. What is investigational new drug (IND) application and add a note on investigational new drug application submission.
11. Phase I and Phase II studies.

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