Q.P. Code: 201340 **Reg. no.: ……**

Second Pharm D Post Baccalaureate Degree Examinations June 2019

Paper I – Clinical Research

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

- Answer all questions
- Draw diagrams wherever necessary

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

1. Explain the various approaches to drug development process
2. Explain the components of a clinical trial protocol
3. What are the ethical guidelines in clinical research. Discuss on data management in clinical trials

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

4. Informed consent process in clinical studies
5. Safety monitoring in clinical trials
6. Differentiate between phase II and phase III clinical trials
7. The composition and responsibilities of Institutional Ethical Committee
8. The responsibilities of sponsor, contract research coordinators and clinical research associate in clinical trial
9. Comparison of the regulatory environment in United States of America and India
10. principles in good clinical practice
11. Preclinical testing in clinical research.

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