Seat No: _____ **Enrollment No: _____**

PARUL UNIVERSITY

FACULTY OF PHARMACY

Pharm. D. (PB) Examination - May 2018

Year: 2 **Date: 07/05/2018**

Subject Code: 08207501 **Time: 10:00 AM to 01:00 PM**

Subject Name: Clinical Research **Total Marks: 70**

Instructions

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Mark Each) **(30)**

1. Define Drug Development Process. Explain various approaches to drug Discovery a) Pharmacological; b) Toxicological and c) IND Application.
2. Explain in detail, clinical trials and various phases of clinical trials.
3. Explain the Abbreviated New Drug Application Submission.

Q.2 Short Essay (Answer Any 4) **(20)**

1. What is IRB? Write about composition and responsibilities of IRB.
2. Challenges in the implementation of guidelines.
3. Write short notes on Ethical guidelines in clinical research.
4. Roles and responsibilities of investigator as per ICH GCP.
5. Write short notes on Data Management and its Components.

Q.3 Short Answers (Answer All) **(20)**

1. Designing of clinical study CRF.
2. Explain the criteria to involve children in conducting clinical research.
3. Overview of regulatory environment in USA, Europe and India.
4. Note on CIOMS.
5. Declaration of Helsinki.
6. Write full form of : i) ICF, ii) PIC.
7. Functions of Drug Controller General of India (DCGI).
8. Participant Identification Centers.
9. What are Contract research coordinators?
10. Drug Characterization.