

Seat No: _____

Enrollment No: _____

PARUL UNIVERSITY
FACULTY OF PHARMACY
Pharm.D / Pharm.D (PB) Examination, April-2019

Year: 5 / 2

Subject Code: 08207501

Subject Name: Clinical Research

Date: 15/04/2019

Time: 10:00am to 1:00pm

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. What is clinical trial? Discuss the various phases of clinical trial.
2.
 - a. Explain the qualification and duties of clinical investigator as per ICH GCP.
 - b. Explain the functions of regulatory authority.
3.
 - a. Explain the ethical guidelines in clinical research.
 - b. Add a note on procedure for NDA submission.

Q.2 Short Essay Type Questions. (any 4 out of 5) (5 Mark Each)

(20)

1. Write different methods of post marketing surveillance.
2. Explain the components of data management.
3. Describe safety monitoring parameters in clinical trials.
4. Explain role and responsibilities of auditors.
5. Write the components of case record form (CRF).

Q.3 Short Answers. (2 Mark Each)

(20)

1. What are IND applications?
2. Write a note on ICF.
3. Write a note on objectives of ICH GCP.
4. Write the steps of drug development process.
5. Write a note on blinding.
6. Write a note on role of pharmacist in clinical trials.
7. Write a note on CDSCO.
8. Enlist the members of IRB/ IEC.
9. Write the 10 points of Nuremberg Code.
10. Define
 - a. Auditors
 - b. Sponsor