

Roll No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

PARUL UNIVERSITY  
PARUL INSTITUTE OF PHARMACY  
PHARM.D.5<sup>th</sup> YEAR · FIRST INTERNAL EXAMINATION: 2018-19

Subject Name: Clinical Research  
Subject Code: 08207501  
Time: 1 ½ hrs

Date: 08/10/2018  
Total Marks: 30

**Instructions:**

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

**I Long Essay (Answer Any One)**

10 X 1 = 10M

1. Write a detailed note on IRB.
2. Write a detailed note on Phase 1 & Phase 2 Trials.

**II Short Essay (Answer Any Two)**

5 X 2 = 10M

1. Write a note on Declaration of Helsinki.
2. Write a note on Declaration of Geneva.
3. Write a note on Nuremberg Code.

**III Short Answers (Answer All)**

2 X 5 = 10M

1. Explain in brief the type of Clinical Studies.
2. What is SAD & MAD?
3. Define the following:
  - a. Audit
  - b. Bias
4. Define the following:
  - a. Blinding
  - b. Case Report Form
5. What is Crossover study & Cross sectional study?

\*\*\*\*\* BEST OF LUCK \*\*\*\*\*