Seat No.: _____ **Enrolment No. _____**

PARUL UNIVERSITY

FACULY OF PHARMACY

M.Pharm. Summer 2017 - 18 Examination

Semester: 2 **Date: 22/05/2018**

Subject Code: Clinical Research and Pharmacovigilance **Time: 10:00AM TO 01:00PM**

Subject Name: MPL204T **Total Marks: 75**

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 Marks Each) **(30)**

1. What is role and responsibilities of principal investigator as per ICH GCP guidelines? Write a note on clinical trial design.
2. Define the term "Pharmacoeconomics". Enlist different types and write a note on any two types of pharmacoeconomic evaluations. Explain the term pharmacovigilance along with its importance.
3. Discuss roles and responsibilities of investigator, Study Coordinator and Sponsor in Clinical Trial Personnel.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) **(25)**

1. Discuss type of Informed consent.
2. Write about Investigator Brochure.
3. Explain objectives of various phases of clinical trial.
4. Write a note on Pharmacoepidemiology with its merits/demerits over randomized controlled trials.
5. Describe various detection methods of ADR.
6. Write a note on Passive and Active surveillance for pharmacovigilance.

Q.3 Short Answers. (2 Marks Each) **(20)**

1. Outline the composition of Human ethics committee.
2. Explain case control observation studies.
3. What is the scope of Pharmacoepidemiology?
4. Explain importance of Pharmacoeconomics in clinical pharmacy.
5. Define safety pharmacology and give its objectives.
6. Give a composition of Institutional Review Board Committee.
7. Difference between randomized controlled trial and non randomized controlled trial.
8. Explain role of pharmacovigilance centres in hospitals.
9. Write a note on Case Report Forms.
10. Discuss Independent Ethics Committee.