Roll No. ☐☐☐☐☐☐☐☐☐☐☐☐ Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmacology) (2017 & Onwards) (Sem.–2)

CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

M.Code : 74946

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

Ql. a) Describe the function and constitution of IRB.

b) Describe the ethical principles governing informed consent process.

Q2. Explain the various study designs of observational studies.

Q3. a) Describe the basic requirements and design of Case Report Form (CRF)

b) Briefly describe the documentation and preparation of clinical study report.

Q4. Write short note on the following :

a) Significance of monitoring safety of drugs in population.

b) Pharmacovigilance in India and international aspects.

Q5. Define pharmacoepidemiology and describe its various applications.

Q6. a) Differentiate between active and passive surveillance methods.

b) Briefly describe the functioning of spontaneous reporting system.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.