Roll No. | | | | | | | | | | | | | **Total No. of Pages : 01**

Total No. of Questions : 06

M.Pharmacy. (Pharmacology/Pharmaceutical Analysis) (Sem.–2)

CLINICAL RESEARCH & PHARMACOVIGILANCE

Subject Code : MPL-204T

M.Code : 74946

Date of Examination : 12-07-22

Time : 3 Hrs. **Max. Marks: 75**

INSTRUCTIONS TO CANDIDATES :

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

1. A) What is meant by informed consent? Discuss the ethical issues concerning informed consent for clinical trials.

   B) Give an account of the storage provisions to be provided in a pharmaceutical plant for raw materials and finished products.

2. A) Enumerate the different types of personnel required for a clinical trial. Mention their responsibilities in brief.

   B) Enumerate the different study designs for clinical trials. Describe any one.

3. A) Discuss the protocol for conducting a clinical trial. How is clinical study report documented?

   B) Differentiate between side effect and adverse drug reaction. How is severity and seriousness of ADRs assessed and recorded?

4. What are pharmacovigilance studies? Enumerate the approaches used for these studies. Give a detailed account of WHO regulations for this purpose.

5. Discuss the regulatory guidelines for ADRs reporting in India. Outline the procedure used for this purpose.

6. Write notes on (any three) :

   A) Vaccine safety surveillance

   B) Pharmacoepidemiology

   C) Statistical methods for evaluating medication safety data.

   D) Non RCT and its significance.

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.