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

Total No. of Questions : 06

M.Pharmacy (Pharmacy Practice) (Sem.–1)

CLINICAL RESEARCH

Subject Code : MPP 104T

M.Code : 79246

Date of Examination : 27-01-23

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. Briefly describe the following:

a) Ethical issues in Biomedical Research

b) Methods of randomization in clinical studies

c) Various approaches of drug discovery.

2. Describe the various requirements and designs for bioavailability and bioequivalence studies as per ICMR guidelines.

3. a) Describe the content requirements for preparation of informed consent documents.

b) Describe the significance of pre-study visit for site and investigator selection and finalizing clinical trial agreement.

4. a) Describe the role of pharmacist in procurement and storage of an investigational new drug.

b) Describe the preparation and maintenance of Trial Master file.

c) Describe the role of EC in conducting and monitoring study site visit.

5. Describe the infrastructure and system requirement for data management in clinical trials.

6. Write short note on following :

a) Fraud and misconduct in clinical trials

b) Health outcome measures.

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