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

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.–1)

CLINICAL RESEARCH REGULATIONS

Subject Code : MRA-103T

M.Code : 79182

Date of Examination : 25-01-23

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. Write about different types of Clinical studies. Describe about various phases of clinical trials in detail.

2. Discuss the historical perspective of Nuremberg code, thalidomide study, Nazis trials and Tuskegee syphilis study. Discuss about Belmont Report and Declaration of Helsinki.

3. Discuss the regulations to conduct drug studies as per USFDA. Discuss about NDA 505(b) (1) and NDA 505(b)(2) applications.

4. Describe the composition, roles, responsibilities and ethical review procedure of Institutional Ethics Committee.

5. Discuss about Good Clinical Practice Guidelines (ICH GCP E6)

6. Discuss about guidelines for Good Pharmacovigilance Practices and Pharmacoepidemiological Assessment.

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.