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

Total No. of Questions : 06

M.Pharmacy (Pharmaceutics) (Sem.–1)

REGULATORY AFFAIRS

Subject Code : MPH-104T

M.Code : 74660

Date of Examination : 17-01-23

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. a) What are combination products? Give examples. Highlight the regulatory requirements to be fulfilled for them.

   b) What is a CRO? Highlight the essential requirements for a CRO.

2. a) What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial.

   b) What is meant by HIPPA? Highlight its key features aimed at protecting sensitive patient data.

3. a) What is the purpose of maintaining drug distribution records? Write a note on ICH requirements pertaining to drug distribution records.

   b) Briefly discuss Master Formula Record and its importance.

4. a) Discuss the requirements for filing ANDA application.

   b) What is post marketing surveillance? Highlight its purpose and briefly discuss the methods to conduct PMS.

5. a) Write a short note on IMPD.

   b) Give a note on Residual solvents in medicines.

6. a) What is meant by bio-equivalence? Briefly explain the requirements for proving two products bioequivalent.

   b) Write a note on ICH guidelines for quality and efficacy.

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.