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

Total No. of Questions : 06

M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)

REGULATORY AFFAIRS

Subject Code : MPH-104T

M.Code : 74660

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

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

1. a) What are generic products? When can generics be marketed? Outline the process for obtaining approval for marketing generics.

   b) What is NDA? Outline the NDA approval process.

2. a) How are bioequivalence studies conducted? Mention the ICH requirements for products to be declared bioequivalent.

   b) Clarify the role of CROs in bioequivalence testing.

3. a) What is eCTD? What are the advantages of filing eCTD?

   b) Briefly explain the non-clinical investigations carried out for supporting approval process.

4. a) What is meant by “informed consent”? What is the role of informed consent in drug approval?

   b) Explain IMPDI dossier.

5. a) Write briefly about the ICH regulations pertaining to Safety.

   b) What is meant by pharmacovigilance? Explain the ICH requirements and outcomes of pharmacovigilance.

6. Write short notes on :

   a) HIPAA b) SUPAC guidelines c) Regulations for novel therapies

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.