Roll No. | | | | | | | | | | | | | Total No. of Pages : 1

Total No. of Questions : 06

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

REGULATORY AFFAIRS

Subject Code : MPH-104T

Paper ID : [74660]

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) Write a note on Drug Master Files. (7.5)

   b) Distinguish between Generic drugs and Proprietary medicines. Write a note on development of generic versions of a drug. (7.5)

2. a) What is a CRO? Highlight the essential requirements for a CRO. (7.5)

   b) What is the purpose of maintaining drug distribution records? Write a note on ICH requirements pertaining to drug distribution records. (7.5)

3. a) What are combination products? Give examples. Highlight the regulatory requirements to be fulfilled for them. (7.5)

   b) Briefly discuss Master Formula Record and its importance. (7.5)

4. a) What is the constitution of Institutional Ethics Committee? Highlight the functions of Ethics Committee. (7.5)

   b) What is meant by HIPPA? Highlight its key features aimed at protecting sensitive patient data. (7.5)

5. a) What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial. (7.5)

   b) Mention the composition and functions of Institutional Review Board. (7.5)

6. Write short notes on : (5×3=15)

   a) Pharmacovigilance

   b) e CTD

   c) Investigator Brochure