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 carries FIFTEEN marks.**

1. Give detailed account on documentation in pharmaceutical industries with suitable examples. 15

2. Write short notes on :

   a. ANDA 5

   b. NDA 5

   c. Scale up process after approval 5

3. Discuss various aspects of CRO in detail with suitable examples. 15

4. Briefly discuss the following :

   a. Hatch-Waxman act and amendments 7

   b. Regulatory requirements of EU 8

5. Write short notes on:

   a. *In-vitro* product performance 5

   b. Generic drugs 5

   c. IND 5

6. a. Write clinical trial protocol for new anti-cancer drug. 9

   b. Elaborate on the role and responsibilities of institutional review boards / independent ethics committee in clinical trials. 6

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.