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. Discuss the following with suitable examples and/or flow charts :
   a. ECTD 5
   b. Scale-up process approval 5
   c. Regulation for combination products 5
2. a. Discuss the NDA regulatory approval process with suitable example. 8
   b. Write a note on outsourcing BA-BE studies to CRO. 7
3. Write short notes on the following :
   a. Drug product performance 5
   b. Master formula record 5
   c. Post marketing surveillance 5
4. Give a detailed account on development of clinical trial protocol for an anti- depressant drug. 15
5. Write short notes on the following :
   a. ICH-S guidelines 8
   b. Regulatory requirements of MHRA 7
6. Discuss the following with suitable examples :
   a. IND 5
   b. Dossier (IMPD) 5
   c. HIPAA 5

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.