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

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.–2)

REGULATORY ASPECTS OF HERBALS AND BIOLOGICALS

Subject Code : MRA-202T

M.Code : 79817

Date of Examination : 06-07-22

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. What are the guidelines in India for the following?
   a) Clinical trials of Biosimilars. (5)
   b) Marketing of Vaccines. (5)
   c) Quality testing of herbal products. (5)
2. a) What are the regulatory guidelines for biologics and herbal medicines in USA and the European Union? (8)
   b) What are the steps involved in development of biologics? (7)
3. What is the importance of Pharmacovigilance? What are the steps involved for herbal medicine and vaccines? (7+8)
4. a) What are the requirements for clinical trial application? (8)
   b) Write a note on blood and blood products regulation (7)
5. Compare the requirements for quality, efficacy, safety and stability testing of herbal products in India, USA and EU? (15)
6. Write note on :
   a) Marketing authorization for biologies. (5)
   b) Difference between Generic Drugs, Branded Drugs and Biosimilars. (5)
   c) Labelling requirements for Biosimilars. (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.