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

Total No. of Questions : 06

M.Pharmacy(Regulatory Affairs) (2017 Batch) (Sem.–2)

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Subject Code : MRA-202T

M.Code : 74938

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

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

Q1. Write in the detail about various data requirements for Pre-clinical and clinical studies in India. (15)

Q2. Write notes on the following :

(a) Biosimilars (6)

(b) Pharmacovigilance (9)

Q3. (a) Elaborate on the process for IND and NDA in USA. (7)

(b) What are the various requirements and procedures for registering and marketing vaccines in India? (8)

Q4. Discuss in detail various legislator requirements for herbal drugs/CAM in US market. Also discuss in detail about DSHEA. (15)

Q5. Write notes on following :

(a) Plasma master file (6)

(b) Labeling and packaging requirements for Blood products for European market (5)

(c) Process and requirements for BLA (4)

Q6. Compare the pre-clinical and clinical development considerations for biologicals in USA and European Union. (15)

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.