Roll No. | | | | | | | | | | | | |

Total No. of Pages : 1

Total No. of Questions : 06

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

REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS

Subject Code : MRA-202T

Paper ID : [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. a) Elaborate about regulatory requirements for clinical evaluation, marketing authorisation and registration of biologics. (8)

b) Discuss about haemovigilance and international haemovigilance network. (7)

Q2. a) Discuss about GMP requirements for packaging and labeling. (8)

b) Describe about GMP requirements for equipment, container and closures. (7)

Q3. a) Discuss about stability, safety guidelines in European Union. (8)

b) Discuss about scientific guidelines and guidance related to biologics in EU. (7)

Q4. a) Write about the regulatory data requirements for preclinical studies. (8)

b) Write about the regulatory data requirements for clinical studies. (7)

Q5. a) Differentiate between generic drug and biosimilars. Discuss about laws and regulations on biologics and biosimilars. (8)

b) Discuss about clinical evaluation, marketing authorisation and registration of biologics. (7)

Q6. a) Discuss about format and contents of an IND application. (8)

b) Describe about regulations for quality and safety of herbal products in India. (7)