Roll No. | | | | | | | | | | | | Total No. of Pages : 02

Total No. of Questions : 06

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

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA-201T

M.Code : 74937

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) Discuss the regulation approval process for NDA. (8)

b) Explain the regulatory consideration for packaging and labeling of pharmaceutical in EU. (7)

Q2. a) Write the full form of the following : (6)

a. CFR

b. DMF

c. CIS

d. ANDA

e. ASEAN

f. FFDCA

b) Discuss the regulatory requirement for manufacturing of pharmaceuticals in EU. (9)

Q3. Write a note on **Any Three** : (5×3)

a) CFR

b) WHO in relation to registration

c) ANDA

d) Labeling of pharmaceuticals in Japan

Q4. Discuss in detail the organization and structure of EMA. Also discuss one marketing authorization procedure in EU. (15)

Q5. Explain the following is relation of Hatch Waxman act. (5×3)

a) 30 month stay

b) NCE exclusivity

c) Discuss the import of cosmetic in ASEAN countries.

Q6. a) What are the regulatory considerations for manufacturing in Japan? (7.5×2)

b) Write a detailed note on DMF.

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.