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

Total No. of Questions : 06

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

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA-201T

M.Code : 79816

Date of Examination : 04-07-22

Time : 3 Hrs. **Max. Marks: 75**

INSTRUCTIONS TO CANDIDATES :

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

l. (A) What is Hatch Waxman Act? Discuss the impact of this Act on drug approval. (10)

(B) Highlight the key aspects of SNDA. (5)

2. (A) Discuss the requirements for Investigational Medicinal Product Dossier approval. (10)

(B) Write briefly about packaging and labelling requirements in EU. (5)

3. (A) What is PMDA? Write about the master file system for drug substances in Japan. (10)

(B) Write briefly about post marketing surveillance in Japan. (5)

4. (A) Discuss the WHO requirements for product registration in South Africa. (10)

(B) Discuss the regulations concerning transgenic plants. ' (5)

5. (A) Discuss the key requirements for registration of drugsin ASEAN countries. (10)

(B) Briefly write about the pre-requisites for marketing authorization in CIS countries. (5)

6. Write short notes on :

(A) Documentation requirements for drug approval in UAE. (5)

(B) Certificate of suitability in EU (5)

(C) Legislation for sale of cosmetics in GCC countries. (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.