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

Total No. of Pages : 01

Total No. of Questions : 06

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

REGULATORY ASPECTS OF DRUGS & COSMETICS

Subject Code : MRA-201T

Paper ID : [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.

1. Write down the following :

   a. What is Drug Master Files (DMF)? Discuss different types of DMFs.

   b. Discuss format and process of NDA.

2. Give regulatory requirements for Investigational New Drug (IND) submission, Format & content of IND, content of Investigation Brochure.

3. Write down the following :

   a. What are the procedures for approval of Drug in EU?

   b. Hatch Waxman Act.

4. Write a role of FDA in various countries in the new drug development.

5. Explain the Pharmaceuticals and Medical Devices Agency (PMDA) and discuss its functions.

6. What are the Legislation and Regulations for manufacture and sale of cosmetics in ASEAN and CIS?