

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.-1)
**REGULATIONS & LEGISLATION FOR DRUGS & COSMETICS,
MEDICAL DEVICE, BIOLOGICALS & HERBALS, AND FOOD &
NUTRACEUTICALS IN INDIA & INTELLECTUAL PROPERTY
RIGHTS**

Subject Code : MRA104T

M.Code : 79183

Date of Examination : 27-01-23

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. a) How the prices of biological and herbals are fixed or revised by Government under DPCO?
b) Discuss all the provisions which NPPA notifies for medical devices as drugs under DPCO2013 for quality control & price monitoring.
2. a) Discuss the powers of Central Government to permit/control and regulate the sale of Narcotic and Psychotropic substances.
b) Write the Education regulation prescribed in Pharmacy Act.
3. Discuss the requirements/steps for obtaining spirit from non-bonded laboratories.
4. Discuss the role of CDSCO in the regulatory requirements and approvals of food and nutraceuticals.
5. Discuss the contents of regulatory dossier filing.
6. a) What are BA and BE studies? Discuss the regulatory requirements of bioequivalence studies.
b) Discuss the ICMR guidelines for stem cell research.

NOTE : Disclosure of Identity by writing Mobile No. or Marking of passing request on any paper of Answer Sheet will lead to UMC against the Student.