

**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.**