

Roll No.

Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Regulatory Affairs) (Sem.-1)

GOOD REGULATORY PRACTICES

Subject Code : MRA101T

M.Code : 79180

Date of Examination : 07-01-2026

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES:

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

1. a) Write a note on WHO cGMP guidelines.
b) Write a note on IVDs Global Harmonization Task Force guidelines.
2. a) Give SOPs of GALP.
b) Write a note on training documentation in GALP.
3. Discuss the ISO and QCI standard of GLP.
4. Comment on quality by design. Explain six sigma concept in detail.
5. a) What are different types of qualification? Write a note on validation master plan.
b) Discuss the analytical method validation in detail.
6. a) Write a note on requirements to fulfill the CDSCO guidelines.
b) Explain stability testing principles in detail.

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.



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M.Pharmacy (Regulatory Affairs) (Sem.-1)
DOCUMENTATION & REGULATORY WRITING

Subject Code : MRA-102T

M.Code : 79181

Date of Examination : 03-01-2026

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

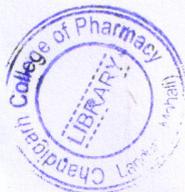
1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Discuss in detail about Product Development Plan (PDP).
2. Discuss in detail about contents and organization of dossier.
3. Discuss Internal and External Audits in detail.
4. Discuss in detail about planning, requirements, process and validation of electronic dossier submission.
5. Describe about the inspection of drug distribution channels.
6. Discuss Post Marketing Reporting Requirements in detail.

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M.Pharmacy (Regulatory Affairs) (Sem.-1)
CLINICAL RESEARCH REGULATIONS

Subject Code : MRA-103T

M.Code : 79182

Date of Examination : 09-01-2026

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. Describe the different types of studies for testing of medical devices and IVDs. Discuss about regulations governing medical devices and IVDs.
2. Discuss about origin of International conference on Harmonization. Discuss about Good clinical Practice guidelines and their principles.
3. Discuss about ethical principles governing informed consent process, patient information sheet, informed consent form and documentation.
4. Discuss about the contents and requirements for IND application and BA/BE studies.
5. Discuss about Pharmacovigilance for medicinal products for human use in detail.
6. Discuss about ethics of randomization and placebo in clinical trials. Discuss about ethics of clinical research in special populations.

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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 : MRA-104T

M.Code : 79183

Date of Examination : 12-01-2026

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) What his meant by DPCO? Enumerate the functions of DPCO.
b) Write a note on the provisions provided in the Prevention of Cruelty to Animals Act.
2. a) Give examples of Narcotics and Psychotropic substances. Highlight the punishments provided in this Act. a
b) Write a note on the procedure for obtaining drug retail license in a State in India.
3. a) Write a note on the regulations governing manufacture of Medical Devices in India.
b) Mention the obligations of sponsor during Clinical Trials.
4. a) Explain the Biopharmaceutics Classification Scheme with examples.
b) Highlight the stability testing conditions required for products to be stored at room temperature and in refrigerator.
5. a) Highlight the tests to be conducted for evaluating genotoxicity in animals.
b) Write a note on Copyright and the provisions contained in it.
6. Discuss the guidelines for Stem Cell Research in India. Highlight the advantages of using stem cells in clinical practice.

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