This question paper contains 3 printed pages]

JM—05—2025

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharmacy (First Year) (First Semester) EXAMINATION

FEBRUARY, 2026

(CBCS PCI)

GOOD REGULATORY PRACTICES

Paper MRA-101T

(Tuesday, 24-2-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Figures to the right indicate full marks.

1. Answer all of the following : 10×2=20

(*a*) What are principles of Total Quality Management ?

(*b*) Enlist important parts of CFR.

(*c*) What are principles of good laboratory practices ?

(*d*) Does GLP apply for veterinary products.

P.T.O.

(e) What are prime objectives of TQM ? s

(f) How are medical devices different than IVD ?

(g) Define LIMS raw data.

(h) What is EPA ?

(i) What are goals of GALP ?

(j) Write importance of validation Master plan in Pharmaceutical Manufactu

2. Answer any *two* of the following : 2×10=20

(a) Explain label and instructions for use in IVD as per GHTF.

(b) Describe about six sigma concept.

(c) Elaborate concept of Quality by Design.

3. Answer any *seven* of the following : 7×5=35

(a) Describe handling out of specifications.

(b) Give guidelines for documentation as per GDP.

(c) Write types of change control.

(d) How to perform laboratory management as per GALP ?

(e) Give important provisions of CFR 211.

(f) Elaborate on GAMP 5 category/software.

(g) What is range finding study as per GLP ?

(h) Give regulations for medical foods as per GLP.

(i) Write about GHTF.

This question paper contains 3 printed pages]

JM—17—2025

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm. (First Year) (First Semester) EXAMINATION

FEBRUARY, 2026

(CBCS PCI)

DOCUMENTATION AND REGULATORY WRITING

Paper MRA-102T

(Thursday, 26-2-2026) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Figures to the right indicate full marks.

(*iii*) Answer to the point only.

1. Solve *all* the following : 10×2=20

(*a*) Define audit and mention the types of audit.

(*b*) Define corrective action and preventive action.

(*c*) What is changes being effected in 30 days ?

(*d*) What is regulatory audit ?

P.T.O.

(*e*) What is prior approval supplement ?

(*f*) Define the control strategy and design space with example.

(*g*) What is drug master file and write about the types of drug master file ?

(*h*) Discuss about product development plan.

(*i*) What is difference between CTD and eCTD ?

(*j*) Write in brief about need.

2. Solve any *two* of the following : 2×10=20

(*a*) What are the different types of module in CTP as per ICH and write in detail about module 3 of ICH CTD ?

(*b*) Write in detail about the site master file.

(*c*) What is SUPAC ? Discuss in detail with reference to changes in components, composition site changes and changes in batch side.

3. Solve any *seven* of the following : 7×5=35

(*a*) Discuss in detail about module 2 of ICH CTD.

(*b*) Discuss about master formula record.

(*c*) Discuss about ISO 13485.

(*d*) Explain the preapproval inspection.

(*e*) Explain the ISO risk management standard.

(*f*) Discuss the post marketing reporting requirement.

(*g*) Explain the post approval labeling changes.

(*h*) Discuss the ACTD submission.

(*i*) What is GMP compliance audit ? Explain the different types of audit in pharmaceutical manufacturing.

This question paper contains 3 printed pages]

JM—29—2025

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm. (First Year) (First Semester) EXAMINATION

FEBRUARY, 2026

(CBCS PCI)

CLINICAL RESEARCH REGULATIONS

(MRA-103T)

(Saturday, 28-2-2026) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Figures to the right indicate full marks.

(*iii*) Answer to the point only.

1. Solve the following : 10×2=20

(*a*) How many types of clinical studies are there ?

(*b*) What is the Nuremberg code of the clinical trials ?

(*c*) What was the thalidomide case study ?

(*d*) Which regulatory body regulates clinical trials in India ?

P.T.O.

(e) What is IVD in medical devices ?

(f) What is 21 CFR in clinical trials ?

(g) What are the Indian GCP guidelines ?

(h) What are the ethical guicelines for biomedical and health research ?

(i) What is the FDA IWD safety reporting rule ?

(j) What is ISO 14155 for ?

2. Solve any *two* of the following 10×2=20

(a) Explain types and phases of clinical trials.

(b) Describe in detail about ethics of clinical research in special population.

(c) Describe in detail about schedule Y.

3. Solve any *seven* of the following : 7×5=35

(a) Describe framework of clinical investigation.

(b) Why was ICH GCP developed ?

(c) Write composition, role and responsibilities of ethics committee of clinical research.

(d) Describe clinical trial protocol as per ICH GCP guidelines.

(*e*) Describe NDA 505 (b) (1) of the FD & C Act.

(*f*) Write role of CDSCO in clinical research.

(*g*) What preclinical studies are required for IND ?

(*h*) Describe section 505 (j) of the FD&C Act.

(*i*) Write a note on ICH GCP E6 guidelines.

This question paper contains 3 printed pages]

JM—41—2025

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharmacy (First Year) (First Semester) EXAMINATION

FEBRUARY/MARCH, 2026

(CBCS PCI)

REGULATIONS AND LEGISLATIONS FOR DRUG AND COSMETICS, MEDICAL DEVICE BIOLOGICAL AND HERBALS AND FOOD AND NEUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHT

Paper MRA-104T

(Wednesday, 4-3-2026) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (*i*) *All* questions are compulsory.

(*ii*) Answer to the point only.

(*iii*) Figures to the right indicate full marks.

1. Solve the following : 10×2=20

(*a*) Are DPCO and NPPA the same ?

(*b*) What is the NCB Act in India ?

P.T.O.

(c) What is regulatory requirement for drug approach ?

(d) What is the 18A Drug and Cosmetic Act ?

(e) What are Indian pharmacopoeia standards ?

(f) What is BIS standards for food ?

(g) What is bioavailability data ?

(h) What is BCS class 4 drugs ?

(i) What is the difference between patent and generic medicine ?

(j) How many geographic indications are there in India ?

2. Solve any *two* of the following : 2×10=20

(a) Explain regulatory requirement and approval procedure for herbals.

(b) Describe in detail about administrative structure and function of drug regulatory authority of India.

(c) Describe in detail about pharmacopoeia standards.

3. Solve any *seven* of the following : 7×5=35

(a) Write a note on central register.

(b) Desribe offences and penalties to company for misleading advertisement.

(c) Write responsibilities of drug regulatory affair.

(*d*) Describe 7 principles of ISO 9001.

(*e*) Describe regulatory requirement and approval procedure for nutraceuticals.

(*f*) Describe six sigma in TQM

(*g*) How to design and control of BA and BE studies ?

(*h*) Describe BCS classification system database.

(*i*) Describe types of pharmaceuticals patents in India.