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OM—05—2026

FACULTY OF SCIENCE AND TECHNOLOGY

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

July, 2026

GOOD REGULATORY PRACTICES

(MRA-101T)

(Wednesday, 1-7-2026) **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*) What are good laboratory practices ?

(*b*) What are six sigma concept ?

(*c*) Write *two* handling requirements of returned goods.

(*d*) Name any *two* relevant ISO standards for GALP.

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(e) Give the objectives of ICH guidelines.

(f) In ISO 13485, what is the primary purpose of management review ?

(g) Give any *two* audit tools used in laboratory quality audit.

(h) Write the significance of part 211 in CGMP.

(i) What is the difference between a medical device and an IVD ?

(j) What is the purpose of self-inspection in GDP ?

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

(a) Describe in detail the validation of utilities of water, air and HVAC system.

(b) Write in detail USFDA GLP regulations and their subparts A to K with their responsibilities.

(c) What is the principle of GDP ? Discuss relevant CDSCO guidance and ISO standards applicable to GDP operations.

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

(a) Explain the role of QCI for implementing quality standards in laboratories.

(b) Write a short note on US cGMP and EC GMP comparison.

(c) Explain the concept of validation master plan.

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(*d*) Discuss the quality by design in detail.

(*e*) Explain the key elements of supply chain integrity as per USPGDP.

(*f*) Give the general checklist for 21CFR part II compliance.

(*g*) State the controlling of GLP inspection process.

(*h*) Write the ICH guidelines for quality.

(*i*) Give the objectives and goals of laboratory audit.

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OM—19—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

July, 2026

DOCUMENTATION AND REGULATORY WRITING

(MRA-102-T)

(Friday, 3-7-2026) **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.

1. Answer the following : 10×2=20

(*a*) Define documentation in pharmaceutical industry.

(*b*) What is master formula record ?

(*c*) State the importance of certificate of analysis (CoA).

(*d*) Define eCTD and mention its purpose.

(*e*) What is an internal audit ?

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(f) List type of inspections in the pharmaceutical industry.

(g) What is a Prior Approval Supplement (PAS) ?

(h) Mention the components of Product Development Plan (PDP).

(i) Define Corrective and Preventive Action (CAPA).

(j) What is an Establishment Inspection Report (EIR).

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

(a) Describe in detail the procedure of dossier preparation and submission as per CTD format.

(b) Discuss the steps involved in product life cycle management and its regulatory implications.

(c) Explain in detail the inspection process of pharmaceutical manufactures and its significance.

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

(a) Explain the structure and contents of a Drug Master File (DMF).

(b) Discuss the process of eCTD submission.

(c) Describe the procedure for conducting internal audit.

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(*d*) Explain types of audits with suitable examples.

(*e*) Discuss pre-approval insepction procedures.

(*f*) Outline the documentation requirement for product packaging records.

(*g*) Discuss post approval labelling changes as per FDA.

(*h*) Explain purpose of risk management standard (ISO13485)

(*i*) Summarize the importance of site master file in pharmaceutical documentation.

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OM—33—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

July, 2026

CLINICAL RESEARCH REGULATIONS

(MRA-103-T)

(Monday, 6-7-2026) **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*) What is the difference between institutional review board and independent ethics committee ?

(*b*) Are a DSMB and DMC the same ?

(*c*) What is the difference between Clinical Trial and Clinical Studies ?

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(*d*) What is an example of clinical study ?

(*e*) What are the *four* phases of clinical trials ?

(*f*) What are clinical trial protocols ?

(*g*) What is NCT for clinical trials ?

(*h*) What does a data safety monitoring board do ?

(*i*) What phase are proof of concept studies ?

(*j*) What is the difference between a medical device and IVD ?

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

(*a*) Explain regulations and guidelines specific to ethics releted to schedule Y and CDSCO-GCP.

(*b*) Describe in detail about participant information sheet and informed consent form in clinical research.

(*c*) Describe in detail about types and phases of clinical trials.

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

(*a*) Describe ethics of randomised clinical trials.

(*b*) Write role and responsibilities of Data and Safety Monitoring Board.

(*c*) Write technical guidance on clinical evaluation of medical devices.

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(*d*) Describe about design of clinical trials.

(*e*) Describe about Thalidomide study.

(*f*) What can we learn from placebos in clinical trials ?

(*g*) Describe types of clinical research.

(*h*) Describe about declaration of Helsinki.

(*i*) Describe about membership of Data and Safety Monitoring Board.

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