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OM—01—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

July, 2026

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE

MQA-101-T

(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*) Write the answer to the point only.

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

1. Answer the following questions : 10×2=20

(*a*) Name *two* common applications of UV-spectroscopy.

(*b*) What are quenchers and how do they influence fluorescence measurement ?

(*c*) What are quantum numbers and how do they relate to NMR spectroscopy ?

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(*d*) Enlist ions formed in mass spectrum.

(*e*) Define the term 'cation exchanger' and anion exchanger.

(*f*) List of *two* application of GC.

(*g*) What do you meant by 'retention time' in chromatographic terms ?

(*h*) What is role of mobile phase in HPLC ?

(*i*) What is purpose of using buffer in electrophoresis ?

(*j*) What are thermal transition in the context of thermal techniques ?

2. Solve any *two* : 2×10=20

(*a*) State Beer-Lambert's law, including its mathematical expression, limitaion and practical application in quantitative analysis.

(*b*) Discuss in detail steps involved in HPTLC.

(*c*) Explain the working principle of quadrupole and TOF analysers in mass spectroscopy. Discuss their applications and performance characteristics.

3. Attempt any *seven* : 7×5=35

(*a*) Compare dispersive and FTIR spectrometer.

(*b*) Discuss solvent requirements in NMR spectroscopy.

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(*c*) Explain principle of AAS and give the role of HCL.

(*d*) Discuss different columns used in GC.

(*e*) Compare and contrast ESI and MALDI.

(*f*) Discuss the role of detector in HPLC and explain how UV-detectors works.

(*g*) What are advantages of capillary electrophoresis over traditinoal gel electrophoresis.

(*h*) Discuss the different types of crystals that can be studied using X-ray diffraction.

(*i*) Compare and contrast the advantages and disadvantages of DTA in thermal analysis.

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OM—16—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

July, 2026

QUALITY MANAGEMENT SYSTEM

(MQA-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.

(*iii*) Answer to the point only.

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

(*a*) What are advantages of Benchmarking ?

(*b*) Expalin quality measurement in manufacturing.

(*c*) What is Quality by Design (QBD) ?

(*d*) What is CAPA ?

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(e) What is risk assessment ?

(f) What are mission and vision statement ?

(g) What is customer satisfaction ?

(h) Explain OOS.

(i) What are OSHAS guidelines ?

(j) What is OOT ?

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

(a) Explain in detail WHO-GMP requirements.

(b) Describe ICH guidelines for stability testing of drug substances and drug products.

(c) Explain in detail principles of six sigma.

3. Solve any *seven* : 7×5=35

(a) Discuss different types of Benchmarking

(b) Describe NABL Certification and Accreditation.

(c) Explain the concept of self-inspection.

(d) Write a note on pharmaceutical quality management.

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(*e*) Define SPC and give its importance.

(*f*) Discuss models of cost of quality.

(*g*) Give classification of customers and explain customer behaviour.

(*h*) Explain ISO-9001 quality system.

(*i*) Describe in detail knowledge management.

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OM—30—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

July, 2026

QUALITY CONTROL AND QUALITY ASSURANCE

(MQA-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*) Figures to the right indicate full marks.

(*iii*) Illustrate your answer with neat sketch wherever necessary.

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

(*a*) Define GLP.

(*b*) What is GMP ?

(*c*) Give personnel responsibilities in a pharma industry.

(*d*) What do you mean by IPQC ?

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(e) Enlist quality control tests for containers and closures.

(f) Explain three-tier documentation.

(g) Give the difference between specifications and test procedures.

(h) Define Mix-up and cross contamination.

(i) What is process deviation ?

(j) What is salvaging ?

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

(a) What are CPCSEA guidelines ?

(b) Discuss in brief about EMEA.

(c) What is DMF ? Explain types of DMF.

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

(a) Describe sanitation of manufacturing premises.

(b) Explain drug product inspection.

(c) Give in detail account of batch manufacturing record.

(d) Discuss quality audit.

(e) Explain IPQC tests for parenterals.

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(*f*) How analysis of raw materials is carried out ?

(*g*) How sterile areas are maintained in pharmaceutical industry ?

(*h*) Discuss role of good documentation practice in pharma industry.

(*i*) Explain the concept and evolution of quality.

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OM—44—2026

FACULTY OF SCIENCE AND TECHNOLOGY

M.Pharm. (First Semester) EXAMINATION

July, 2026

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

(MQA-104T)

(Wednesday, 8-7-2026) **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.

(*iii*) Draw structures wherever necessary.

1. Answer the following questions : 10×2=20

(*a*) What is impurity profiling ?

(*b*) What is secondary packaging ?

(*c*) What are the ideal properties of containers ?

(*d*) What is process validation ?

(*e*) What is SUPAC ?

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(*f*) What is stability testing ?

(*g*) What is technology transfer ?

(*h*) What is co-solvency ?

(*i*) Define post approval change.

(*j*) Draw the layout of pilot plant.

2. Answer any *two* : 2×10=20

(*a*) Explain in detail methods to improve solubility of drugs.

(*b*) Elaborate on the new era of drug products. What are opportunities and challenges does this bring in product development and technology transfer ?

(*c*) Describe in detail manufacturing techniques of large scale.

3. Answer any *seven* : 7×5=35

(*a*) Discuss product registration guidelines of VSFDA.

(*b*) Describe in short different types of pharmaceutical packaging materials.

(*c*) Describe post-marketing surveillance of a new drug.

(*d*) Discuss container closure integrity tests and quality control tests for packaging systems.

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(*e*) What is a "supplemental new drug application" (SNDA) ? When is it needed ?

(*f*) Write short notes on :

(*i*) Aseptic packaging systems

(*ii*) Medical device packaging

(*iii*) Enteral packaging.

(*g*) Explain scale-up challenges for solid dosage form, when moving from pilot plant to commercial scale.

(*h*) Explain surfactants and their role in improving solubility of drugs.

(*i*) Differentiate between qualitative and quantitative models of technology transfer.

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