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BM—01—2024

FACULTY OF SCIENCE & TECHNOLOGY

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

MARCH, 2025

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MQA-101T

(Tuesday, 11-3-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

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

(a) What is the role of a monochromator in the AAS ?

(b) Enlist various materials required for agarose gel electrophoresis.

(c) Give the application of NMR in protein structure predictions.

(d) Write the essential parts of the diffractometer used in XRD.

(e) What is metastable peak ? Write its importance.

(f) What is the range of IR spectroscopy ?

(g) Enlist the factors affecting resolutions in UPLC.

(h) Give the significance of Isotopic peak.

(i) Distinguish between H-NMR and 13CNMR.

(j) Write various factors affecting on resolutions in chromatographic techniques.

P.T.O.

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

(*a*) Give the principles of zone and capillary electrophoresis. Discuss instrumentation of any *one* technique.

(*b*) Explain various factors affecting on vibrational frequencies and give application of IR spectroscopy.

(*c*) Discuss mass fragmentation and its rules.

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

(*a*) What is Bragg's law ? Explain rotating crystal technique.

(*b*) Distinguish between HPLC and UPLC.

(*c*) Give the principles of affinity chromatography. Write applications of it.

(*d*) Explain various factors affecting on DSC curve.

(*e*) Discuss advantages and disadvantages of DTA.

(*f*) Explain in detail about FAB and MALDI.

(*g*) Describe various factors affecting on chemical shift.

(*h*) Explain various vibrations present into molecules identified by IR spectroscopy.

(*i*) Discuss in detail about spectrophotometer.

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BM—14—2024

FACULTY OF PHARMACEUTICAL SCIENCE

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

MARCH, 2025

QUALITY MANAGEMENT SYSTEM

Paper MQA-102T

(Thursday, 13-3-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

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

(*a*) What is quality ?

(*b*) Define internal and external customer.

(*c*) What is statistical process control ?

(*d*) What is IPQC ?

(*e*) Enlist factors affecting cost of quality.

(*f*) What is OHSAS 18001 : 2007 ?

(*g*) Define OOT.

(*h*) Give the important features of ICH Q9.

(*i*) Enlist components of TQM.

(*j*) What is control chart ?

P.T.O.

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

(a) Discuss McKinsey 7s model in industry.

(b) Discuss Quality by Design and process development in pharmaceuticals.

(c) Discuss in detail about WHO-GMP requirements.

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

(a) Discuss various dimensions of quality.

(b) Discuss NABL certification process.

(c) Explain various techniques used for quality measurements in manufacturing.

(d) What are customer complaints ? Discuss handling of customer complaints in detail.

(e) Discuss various types of Benchmarking.

(f) Explain six sigma model for packing and labelling.

(g) Discuss corrective and preventive actions in industry.

(h) Discuss ICH Q8 guidelines.

(i) Discuss systematic process involved in product returns and recalls.

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BM—26—2024

FACULTY OF PHARMACEUTICAL SCIENCE

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

MARCH, 2025

QUALITY CONTROL AND QUALITY ASSURANCE

Paper MQA-103T

(Monday, 17-3-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

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

(*a*) Give qualification of IACE member.

(*b*) What is SOP ?

(*c*) What is copyright ?

(*d*) What are main objectives of ICH ?

(*e*) Enlist quality control test parameter for ointments.

(*f*) What is raw material specification ?

(*g*) Give importance of documentation.

(*h*) What is audit ?

(*i*) Give the importance of waste management.

(*j*) What is salvaging ?

P.T.O.

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

(*a*) What is GCP ? Discuss various features of GCP.

(*b*) Explain role of quality control and quality assurance in pharmaceutical industry.

(*c*) Explain ICH guidelines on specification and test procedures.

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

(*a*) What is DMF ? Explain its types.

(*b*) Explain sanitation of manufacturing premises.

(*c*) Explain in detail regulatory requirement of pharma facilities with reference to schedule M.

(*d*) Discuss significance of GLP in non-clinical laboratory testing.

(*e*) Explain various measures to be taken while handling electronic data.

(*f*) What is cross contamination ? How to avoid cross contamination in manufacturing area ?

(*g*) Discuss ICH Q1A (R_2) guideline.

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BM—38—2024

FACULTY OF SCIENCE & TECHNOLOGY

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

MARCH, 2025

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Paper MQA-104T

(Wednesday, 19-3-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 Hours *Maximum Marks—75*

N.B. :— (1) *All* questions are compulsory.

(2) Answer to the point only.

(3) Figures to the right indicate full marks.

1. Answer *all* the questions : 10×2=20

(*a*) What is meant by SUPAC ?

(*b*) What are the different goals of preformulation studies ?

(*c*) What is the significance of pilot plant scale up study ?

(*d*) Define primary and secondary packaging.

(*e*) What is the role of technology transfer in pharmaceutical industry ?

(*f*) Differentiate between IND and NDA.

(*g*) Write the role of surfactant in improvement of solubility.

(*h*) Draw the layout of pilot plant scale up.

(*i*) Why is plastic not suitable material for packaging ? Give reason.

(*j*) What is technology transfer ?

P.T.O.

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

(a) Explain in detail the process of drug discovery and development.

(b) Describe in detail different methods to improve solubility of drug.

(c) Discuss qualitative and quantitative models of technology transfer.

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

(a) Briefly explain the CDSCO guidelines for pharmaceutical product registration.

(b) What is performulation ? Explain the techniques for the study of crystal properties.

(c) Which are the different opportunities and challenges of new era of drug product ?

(d) Describe different types of pharmaceutical packaging materials.

(e) Highlight the key features of technology transfer and the documentation involved in this process.

(f) Draw and explain well labelled layout of parenteral pilot plant.

(g) What is an Aseptic packaging system ? What are advantages and types of Aseptic packaging system ?

(h) Discuss environmental factors affecting pilot plant scale up.

(i) Briefly discuss the quality control tests performed for assuring quality of containers and closures.