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PPM—01—2025

FACULTY OF SCIENCE & TECHNOLOGY

M.Pharma (I Sem.) EXAMINATION

JUNE, 2025

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUE

MPA-101(T)

(Tuesday 17-6-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

(*ii*) Answer to the point only.

1. Attempt the following : 10×2=20

(*a*) State Beer-Lambert's law in your own words.

(*b*) What is role of sample holder in IR spectroscopy ?

(*c*) Differentiate between FT-NMR and 13C NMR in terms of basic principle.

(*d*) How does atomic absorption spectroscopy differ from flame emission spectroscopy ?

(*e*) What are isotopic peaks ?

(*f*) What is role of stationary phase in TLC ?

(*g*) What role do ions play in the separation of ion-exchange chromatography ?

(*h*) Name *two* types of detectors used in UHPLC.

(*i*) What is X-ray powder diffraction method ?

(*j*) Define glass trasnsition temperature (Tg) in thermal analysis.

P.T.O.

2. Attempt any *two* : 2×10=20

(*a*) Provide detailed overview of the instrumentation of FTIR spectrophotometer

(*b*) Analyze the applications of NMR spectroscopy in various fields.

(*c*) Explain the chromatographic parameters such as retention factor, resolution and efficiency and how they are used to evaluate G.C. performance.

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

(*a*) What is derivative spectroscopy and how does it differ from traditional UV-visible spectroscopy ?

(*b*) Discuss solvent requirements in NMR spectroscopy. Why are certain solvents preferred over others ?

(*c*) Explain process of electron impact ionization and its typical applications.

(*d*) Discuss roles of detectors in HPLC and explain how UV-vis-detector work ?

(*e*) What are key factors affecting separation in get electrophoresis ?

(*f*) What is rotating crystal technique and how it is used to determine crystal structure ?

(*g*) Discuss the advantages and limitations of potentiometry in analytical chemistry.

(*h*) Explain working principle of DSC.

(*i*) Explain principle and working mechanism of TGA.

This question paper contains 3 printed pages]

PPM—14—2025

FACULTY OF SCIENCE AND TECHNOLOGY

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

JUNE, 2025

QUALITY MANAGEMENT SYSTEM

Paper MQA-102T

(Thursday, 19-06-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

(*ii*) Answer to the point only.

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

1. Answer the following : 10×2=20

(*a*) Define six sigma.

(*b*) Define quality and enlist the different dimensions of quality.

(*c*) Define strategy and goal.

(*d*) Define internal customer and external customer.

(*e*) What is customer satisfaction ?

P.T.O.

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

(*g*) Mention the accelerated, intermediate and long term temperature condition for stability study.

(*h*) Enumerate the different tools and techniques of investigation.

(*i*) Define the different zones of stability study.

(*j*) Write the steps involved in QbD approach.

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

(*a*) Discuss in detail about stability of new drug product.

(*b*) Discuss in detail about evolution of quality and *eight* dimensions of quality.

(*c*) Describe in detail process involved in vendor qualification annual product review and batch release.

3. Solve *seven* out of nine : 7×5=35

(*a*) Write in detail about NABL certification.

(*b*) What is quality management system ? Write in detail about different principles of quality management system.

(*c*) Explain the ISO 9001 : 2008.

(*d*) Discuss in brief about handling of market complaints.

(*e*) Explain the ICHQ8.

(*f*) What is customer perception ? Write in brief about the factors affecting the customer perception.

(*g*) Discuss in brief about product recall.

(*h*) Discuss in brief about CAPA management.

(*i*) Explain various types of benchmarking.

This question paper contains 3 printed pages]

PPM—38—2025

FACULTY OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

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

JUNE, 2025

PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER

MQA-104T

(Tuesday, 24-06-2025) **Time : 2.00 p.m. to 5.00 p.m.**

Time—3 *Hours* *Maximum Marks*—75

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

(*ii*) Answer to the point only.

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

(*a*) What do you mean by NDA ?

(*b*) Define Technology Transfer.

(*c*) What do you mean by Impurity profiling ?

(*d*) Write a short note on co-solvency.

(*e*) Give steps involved in drug development.

(*f*) Enlist the techniques for study of crystal properties.

P.T.O.

(*g*) Give the challenges in new era of drug products.

(*h*) Classify the pharmaceutical packaging.

(*i*) Enlist the special equipment used in liquid dosage form.

(*j*) Draw a layout of pilot plant scale up for parenteral dosage form.

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

(*a*) What is NDA application ? Discuss in brief about content and format of NDA.

(*b*) Discuss in brief about preformulation studies giving special emphasis on solubility partition coefficient and polymorphism.

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

(*a*) What are aseptic packaging systems ? What are advantages and types of aseptic packaging systems ?

(*b*) Describe procedure for filing of ANDA in India.

(*c*) What is the concept of solubility ? Explain any *two* methods to enhance solubility in detail.

(*d*) Give significance of pilot plant scale up. Discuss steps involved in pilot plant scale up for solid dosage form.

(*e*) Define medical device packaging with its quality control tests.

(*f*) Write about various qualitative and quantitative models for technology transfer.

(*g*) Elaborate various challenges occur during the scale up of new product development.

(*h*) Write in detail about formula, equipment. process, stability and quality control of semisolids.

(*i*) Describe the packaging of pharmaceuticals and material used for packaging.