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QT—02—2023

FACULTY OF SCIENCE AND TECHNOLOGY

M. Pharm. (CBCS PCI) (First Semester) EXAMINATION

NOVEMBER/DECEMBER, 2023

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MPH101T

(Tuesday, 26-12-2023) **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. Answer the following questions : 10×2=20

(*a*) What is Bragg's equation ?

(*b*) Write importance of isoelectric focussing.

(*c*) Write application of AAS.

(*d*) Write relationship between dipole-moment and molecular vibrations.

(*e*) Give the factors affecting fluorescence.

P.T.O.

(f) Enlist different types of signals obtained in NMR.

(g) Enlist different analytical techniques used for drug excipients.

(h) Write various detectors used in GC.

(i) Write the principle of isoelectrophoresis.

(j) Enlist various electronic transitions by absorption of UV in molecules.

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

(a) Write in brief about conventional and F.T.I.R .

(b) Write role of UV, IR, NMR and MS in structural elucidation with suitable example.

(c) Write in detail about instrumentation, principle and applications of HPTLC.

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

(a) Write a short note on Immunoelectrophoresis.

(b) What are factors of IR influencing vibrational frequencies ?

(c) Explain with example spin-spin coupling and J constant.

(d) What do you mean by cut-off wavelength for UV solvents ? Give its importance.

(e) Discuss various rules which are helpful for prominent peak in Mass Spectrum.

(f) Write a short note on ion exchange chromatography.

(g) Write comparative advantages and disadvantages of GC.

(h) What are the factors influencing fluorescence ?

(i) Write principle and applications of X-ray diffraction.

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QT—23—2023

FACULTY OF SCIENCES AND TECHNOLOGY

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

NOVEMBER/DECEMBER, 2023

Paper MPH103T

MODERN PHARMACEUTICS

(Saturday, 30-12-2023) **Time : 2.00 a.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 questions : 10×2=20

(*a*) What is preformulation ?

(*b*) Define large volume parenterals.

(*c*) Give the application of factorial design.

(*d*) What is optimization techniques ?

(*e*) Give the objectives of cGMP.

P.T.O.

(f) What is operational qualification ?

(g) Give the merits of validation.

(h) Define compression.

(i) What is Total Quality Management ?

(j) Give the significance of Chi-square test.

2. Solve any *two* : 2×10=20

(a) Discuss optimization techniques in pharmaceutical formulation and processing.

(b) Define validation. What are the types of validation ? Discuss validation of specific dosage form.

(c) Explain in detail material management and inventory management in pharmaceutical industry.

3. Solve any *seven* : 7×5=35

(a) Discuss about drug-excipient interaction.

(b) Explain physiological and formulation consideration of parenterals.

(c) Discuss the types of factorial design.

(d) Describe in brief about sales forecasting.

(*e*) Explain validation and calibration of master plan.

(*f*) Discuss distribution of forces in compression.

(*g*) Discuss about diffusion parameters.

(*h*) Write in brief about ANOVA test.

(*i*) Describe in detail kinetics of stability.

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QT—33—2023

FACULTY OF SCIENCE AND TECHNOLOGY

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

JANUARY, 2024

PHARMACEUTICS

Paper-MPH-104T

(Pharmaceutical Regulatory Affair)

(Tuesday, 2-1-2024) **Time : 2.00 p.m. to 5.00 noon**

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*) Give the role of institutional review board.

(*b*) Define bracketing and matrixing.

(*c*) What is 505 (b)(2) application ?

(*d*) Enlist the objectives of Hatch Waxman Act.

(*e*) Define the role of ethics committee in clinical research.

(*f*) What are the types of patent certification ?

(*g*) Give an account on NDA.

(*h*) Enlist ICH safety guidelines.

(*i*) What is regulatory affair ?

(*j*) Define CFR.

P.T.O

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

(*a*) What is New Drug Development process ? Discuss in detail the various phases of clinical trials.

(*b*) Explain the regulatory requirement for submitting drug substance product approval in US.

(*c*) Describe ANDA regulatory approval process.

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

(*a*) Explain ICH photo stability testing guideline for new drug substance.

(*b*) What is Drug Master file ? Discuss different types of DMFs.

(*c*) Describe product life-cycle management in pharmaceuticals.

(*d*) Write a note on post marketing surveillance.

(*e*) Describe various documentation involved in pharmaceutical industry.

(*f*) Explain master formula record in pharmaceuticals.

(*g*) Write a note on regulatory requirement of TGA.

(*h*) Explain about HIPPA and its usefulness in the clinical trials.

(*i*) Describe various features of good clinical practices (GCP).