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BM—39—2024

FACULTY OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

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

MARCH, 2025

PHARMACEUTICAL REGULATORY AFFAIR

Paper MPH-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. Solve *all* the questions : 10×2=20

(*a*) Define MFR and DMF.

(*b*) What is meant by IND and ANDA ?

(*c*) Define CTD and ECTD.

(*d*) Enlist work responsibilities of FDA.

(*e*) To which segment ICH guideline Q and E is related ?

(*f*) What is meant by IMPD and IB ?

(*g*) What is meant by HIPAA ?

(*h*) What is meant by CFR ? Give its types.

(*i*) Write in brief regulatory requirement for API product approval.

(*j*) What is meant by MHRA and TGA ?

P.T.O.

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

(*a*) What are different types of DMF ? Describe in detail all types of DMF along with its submission process.

(*b*) Describe in detail CTD, ECTD documentation and industry-FDA liasion.

(*c*) What is the role of Institutional Review Board in Clinical trial study and explain pharmacovigilance safety monitoring in clinical trials ?

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

(*a*) Describe Hatch-Waxman Act and its amendments.

(*b*) Describe in detail CFR.

(*c*) Write in brief about Post-Marketing Surveillance.

(*d*) Write about regulatory requirement for product approval of ANDA.

(*e*) Write in brief about regulation for combination products and medical devices.

(*f*) Write in brief about regulatory requirement of EV and MHRA.

(*g*) Describe in detail about IMPD and IB.

(*h*) Describe in detail about formulation and working procedure and consent process for clinical trial.

(*i*) Describe in brief ICH guideline 'S' and 'M'.

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BM—27—2024

FACULTY OF SCIENCE & TECHNOLOGY

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

MARCH, 2025

MODERN PHARMACEUTICS

Paper MPH-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 the following : 10×2=20

(*a*) What are the theories of dispersion ?

(*b*) Define small volume parenteral.

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

(*d*) What is operational qualification ?

(*e*) What are the disadvantages of validation ?

(*f*) Give the policies of cGMP.

(*g*) Define consolidation.

(*h*) Give the concepts of total quality management.

(*i*) Give the significance of ANOVA test.

(*j*) Enlist optimization parameters.

P.T.O.

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

(*a*) Explain in detail dissolution and diffusion parameters.

(*b*) Discuss in detail layout of buildings, services, equipments and their maintenance production management of cGMP.

(*c*) What is optimization ? Explain in detail contour design and its applications.

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

(*a*) Describe in brief about drug — excipient interactions.

(*b*) Write in detail optimization techniques in pharmaceutical formulation.

(*c*) Discuss about types of validation.

(*d*) Explain in brief about inventory management.

(*e*) Write in detail physics of tablet compression.

(*f*) Describe in brief about similarity factors of F_1 and F_2.

(*g*) Discuss about physiological and formulation consideration of parenterals.

(*h*) Explain in detail validation and calibration of master plan.

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

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BM—15—2024

FACULTY OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

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

MARCH, 2025

DRUG DELIVERY SYSTEM

Paper MPH-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 the following questions : 10×2=20

(*a*) Define controlled drug delivery systems.

(*b*) Define personalised medicine.

(*c*) Give advantages of sustained release drug delivery systems.

(*d*) Enlist categories of patients for personalised medicine.

(*e*) Define polymers.

(*f*) Give principle of CRDDS.

(*g*) Give advantages of GRDDS.

(*h*) Enlist the barriers of drug permeation in occular DDS.

(*i*) Give components of transdermal drug delivery systems.

(*j*) Define vaccine drug delivery system.

P.T.O.

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

(a) Explain in detail approaches used in the formulation of sustained release drug delivery systems.

(b) Discuss in detail rate controlled drug delivery system.

(c) Give principle, concept and approaches of GRDDS.

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

(a) Write in brief about mucosal and transdermal delivery of vaccines.

(b) Give formulation of protein and peptide delivery systems.

(c) Give evaluation of transdermal drug delivery system.

(d) Describe different methods to overcome barriers in occular DDS.

(e) Give evaluation of GRDDS.

(f) Give principle of mucoadhesion.

(g) Give the advantages and disadvantages of buccal drug delivery system.

(h) Write a note on 3D printing of pharmaceuticals.

(i) Write a note on bioelectronic medicines.

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BM—02—2024

FACULTY OF PHARMACEUTICAL SCIENCE & TECHNOLOGY

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

MARCH, 2025

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Paper MPH-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 effect of solvent on UV-visible spectrum ?

(*b*) What do you mean by Quenchers of fluorescence ?

(*c*) Mention the regions of IR.

(*d*) What is quantum number ?

(*e*) Define metastable ions with example.

(*f*) Enlist *four* carrier gases used in gas chromatography.

(*g*) Write reason for use of buffer in paper electrophoresis.

(*h*) State Bragg's law.

(*i*) What is process of deshielding ?

(*j*) Give principle of affinity chromatography.

P.T.O.

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

(*a*) Describe in detail about types of electronic transitions in UV-visible spectroscopy.

(*b*) Explain types of ions produced in mass spectroscopy. Discuss in detail about FAB and MALOI technique.

(*c*) Discuss in detail about instrumentation of NMR.

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

(*a*) Explain gel electrophoresis and capillary gel electrophoresis.

(*b*) Describe instrumentation of gas chromatography with neat labelled diagram.

(*c*) Discuss difference between atomic absorption spectroscopy and flame emission spectroscopy.

(*d*) Explain excitation process and relaxation process in NMR spectroscopy.

(*e*) Write in detail about factors affecting fluorescence and phosphorescence.

(*f*) Explain sampling solids in IR spectroscopy.

(*g*) Discuss various types of column used in HPLC.

(*h*) Write about mass fragmentation rule.

(*i*) What do you mean by electrophoresis ? Write types of crystal affecting X-ray diffraction result.