Roll No. ☐☐☐☐☐☐☐☐☐☐☐☐ Total No. of Pages : 02

Total No. of Questions : 06

**M.Pharmacy (Pharmaceutics) (Sem.–1)**

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**Subject Code : MPH-101T**

**M.Code : 74657**

**Date of Examination : 10-01-2023**

**Time : 3 Hrs.** **Max. Marks : 75**

**INSTRUCTIONS TO CANDIDATES :**

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries EQUAL marks.**

1. a) What is Beer-Lambert law? Derive its equation. Describe various factors responsible for its deviation. 10

   b) Arrange the following compounds in increasing orders of their C=0 stretching frequency. Support your answer with relevant explanations. 5

2. a) What are the structural pre-requisites for an organic molecule to be fluorescent? Describe various factors affecting fluorescence,. 10

   b) What is the principle of RIA? Describe its working with the help of an example. 5

3. a) Define the terms Precessional frequency, Magnetic shielding, Magnetic anisotropy, and Chemical shift. 8

   b) Predict the chemical shifts and multiplicities of various signals possible in $^1$H-NMR spectrum of *tert*-butyl propyl ether. 7

4. a) Describe principles of separation by the following techniques: 9

   i) Paper chromatography

   ii) Ion-exchange chromatography

   iii) Affinity chromatography.



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   b) Write a note on various detectors used in HPLC with their specific applications. 6

5. a) What is the principle of electrophoretic separations? Write an account on Isoelectric focusing method. 8

   b) Define a crystal. Give a detailed classification of crystals. 7

6. a) Write a detailed account on various types of ionization techniques used in mass spectrometry. 10

   b) Define an isotope peak. Give its significance with an example. 5

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Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (Sem.–1)

DRUG DELIVERY SYSTEM

Subject Code : MPH-102T

M.Code : 74658

Date of Examination: 14-01-2023

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a. Explain the physicochemical and biological approaches for sustained release formulation.

   b. What are the factors effecting controlled release formulations?

2. a. Explain the properties and application of polymers.

   b. What is the contribution of personalized medicine in pharmacogenetics?

3. Explain 3D printing of personalized medicine?

4. Write short note on :

   a. Rate controlled drug delivery system

   b. GRDDS

5. Give formulation and evaluation of :

   a. Transdermal drug delivery system

   b. Macromolecules

6. Write short note on :

   a. Trandermal delivery of Vaccine

   b. Ocular delivery.

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Roll No. [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (Sem.–1)

MODERN PHARMACEUTICS

Subject Code : MPH-103T

M.Code : 74659

Date of Examination: 12-01-2023

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Discuss in detail the pre-formulation studies conducted for pharmaceutical emulsions.

   b) Give an account on different statistical design involved in optimization of pharmaceutical dosage forms.

2. a) Discuss similarity factors and its role in drug release kinetics.

   b) Write a short note on ANOVA test.

3. a) Discuss different forces involved in tablet compression.

   b) Explain different types of pharmaceutical validation along with the specific situations in which they are applied.

4. a) Explain sterilization process of LVPs and mention the limit of particulate matter in LVPs.

   b) What are flocculated and deflocculated suspensions? Discuss the evaluation parameters for suspensions.

5. a) Give an account on cGMP requirements for building layout of a coated tablets manufacturing unit.

   b) Discuss the role response surface methodology in formulation optimization.

6. a) Write a short note on stability testing of SMEDDS.

   b) What do you mean by dissolution? Discuss different parameters of dissolution which should be considered in dosage form development.

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Total No. of Questions : 06

Total No. of Pages : 02

**M.Pharmacy (Pharmaceutics) (Sem.–1)**

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

**Subject Code : MPH-101T**

**M.Code : 74657**

**Date of Examination : 10-01-2023**

**Time : 3 Hrs.**

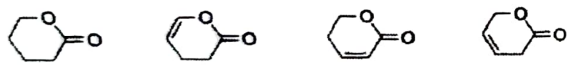
**Max. Marks : 75**

**INSTRUCTIONS TO CANDIDATES :**

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries EQUAL marks.**

1. a) What is Beer-Lambert law? Derive its equation. Describe various factors responsible for its deviation. 10

   b) Arrange the following compounds in increasing orders of their C=0 stretching frequency. Support your answer with relevant explanations. 5



2. a) What are the structural pre-requisites for an organic molecule to be fluorescent? Describe various factors affecting fluorescence,. 10

   b) What is the principle of RIA? Describe its working with the help of an example. 5

3. a) Define the terms Precessional frequency, Magnetic shielding, Magnetic anisotropy, and Chemical shift. 8

   b) Predict the chemical shifts and multiplicities of various signals possible in $^1$H-NMR spectrum of *tert*-butyl propyl ether. 7

4. a) Describe principles of separation by the following techniques: 9

   i) Paper chromatography

   ii) Ion-exchange chromatography

   iii) Affinity chromatography.



   b) Write a note on various detectors used in HPLC with their specific applications. 6

5. a) What is the principle of electrophoretic separations? Write an account on Isoelectric focusing method. 8

   b) Define a crystal. Give a detailed classification of crystals. 7

6. a) Write a detailed account on various types of ionization techniques used in mass spectrometry. 10

   b) Define an isotope peak. Give its significance with an example. 5

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No. of Questions : 06

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M.Pharmacy (Pharmaceutics)

DRUG DELIVERY SYSTEM (Sem.–1)

Subject Code : MPH-102T

M.Code : 74658

Date of Examination: 14-01-2023

e : 3 Hrs.

Max. Marks : 75

TRUCTIONS TO CANDIDATES :

Attempt any FIVE questions out of SIX questions.

Each question carries FIFTEEN marks.

a. Explain the physicochemical and biological approaches for sustained release formulation.

b. What are the factors effecting controlled release formulations?

a. Explain the properties and application of polymers.

b. What is the contribution of personalized medicine in pharmacogenetics?

Explain 3D printing of personalized medicine?

Write short note on :

a. Rate controlled drug delivery system

b. GRDDS

5. Give formulation and evaluation of :

a. Transdermal drug delivery system

b. Macromolecules

6. Write short note on :

a. Trandermal delivery of Vaccine

b. Ocular delivery.

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No.

No. of Questions : 06

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M.Pharmacy (Pharmaceutics) (Sem.–1)

DRUG DELIVERY SYSTEM

Subject Code : MPH-102T

M.Code : 74658

Date of Examination: 14-01-2023

me : 3 Hrs.

Max. Marks : 75

STRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a. Explain the physicochemical and biological approaches for sustained release formulation.

   b. What are the factors effecting controlled release formulations?

2. a. Explain the properties and application of polymers.

   b. What is the contribution of personalized medicine in pharmacogenetics?

3. Explain 3D printing of personalized medicine?

4. Write short note on :

   a. Rate controlled drug delivery system

   b. GRDDS

5. Give formulation and evaluation of :

   a. Transdermal drug delivery system

   b. Macromolecules

6. Write short note on :

   a. Trandermal delivery of Vaccine

   b. Ocular delivery.

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DEC-2022

Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

**M.Pharmacy (Pharmaceutics) (Sem.–1)**

**MODERN PHARMACEUTICS**

**Subject Code : MPH-103T**

**M.Code : 74659**

**Date of Examination: 12-01-2023**

**Time : 3 Hrs.**

**Max. Marks: 75**

**INSTRUCTIONS TO CANDIDATES :**

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

1. a) Discuss in detail the pre-formulation studies conducted for pharmaceutical emulsions.

   b) Give an account on different statistical design involved in optimization of pharmaceutical dosage forms.

2. a) Discuss similarity factors and its role in drug release kinetics.

   b) Write a short note on ANOVA test.

3. a) Discuss different forces involved in tablet compression.

   b) Explain different types of pharmaceutical validation along with the specific situations in which they are applied.

4. a) Explain sterilization process of LVPs and mention the limit of particulate matter in LVPs.

   b) What are flocculated and deflocculated suspensions? Discuss the evaluation parameters for suspensions.

5. a) Give an account on cGMP requirements for building layout of a coated tablets manufacturing unit.

   b) Discuss the role response surface methodology in formulation optimization.

6. a) Write a short note on stability testing of SMEDDS.

   b) What do you mean by dissolution? Discuss different parameters of dissolution which should be considered in dosage form development.

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Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code : MPH-101T

M.Code : 74657

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries EQUAL marks.

Q1. a. Describe the principle, instrumentation and applications of atomic absorption spectroscopy. 10

b. Describe the principle and applications of IR spectroscopy. 5

Q2. a. Write a detailed account on $^{13}C$ NMR. 10

b. How to differentiate between $^{1}H$ NMR peak of OH and CH? 5

Q3. Describe the principle, theory and instrumentation of Mass spectrometer. 15

Q4. Write a detailed account on HPLC. 15

Q5. Write a detailed account on X-Ray crystallography. 15

Q6. Write a detailed account on RIA.

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Roll No.

Total No. of Questions : 06 Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)

# REGULATORY AFFAIRS

Subject Code : MPH-104T

M.Code : 74660

Time : 3 Hrs. Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. Give detailed account on documentation in pharmaceutical industries with suitable examples. 15

2. Write short notes on :

   a. ANDA 5

   b. NDA 5

   c. Scale up process after approval 5

3. Discuss various aspects of CRO in detail with suitable examples. 15

4. Briefly discuss the following :

   a. Hatch-Waxman act and amendments 7

   b. Regulatory requirements of EU 8

5. Write short notes on:

   a. *In-vitro* product performance 5

   b. Generic drugs 5

   c. IND 5

6. a. Write clinical trial protocol for new anti-cancer drug. 9

   b. Elaborate on the role and responsibilities of institutional review boards / independent ethics committee in clinical trials. 6

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Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code : MPH-101T

M.Code : 74657

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries EQUAL marks.

1. What is the Principle, instrumentation and applications of U.V visible spectroscopy? (15)

2. Write a note on Proton NMR. How it is different from the usual NMR process? (15)

3. a) What is Mass fragmentation? Discuss its rules. (10)

   b) Discuss the isotropic peaks in mass spectroscopy. (5)

4. a) Explain the principle, apparatus and instrumentation of HPLC. (10)

   b) Discuss the major applications of column chromatography. (5)

5. a) Write a note on X-Ray diffraction methods. (10)

   b) Discuss Bragg's I.aw. (5)

6. Write a note on the following : (7)

   a) ELISA (8)

   b) Isoelectric focusing electrophoresis

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May-2019

Roll No. _____ Total No. of Pages : 02

Total No. of Questions : 06

M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)

# MODERN PHARMACEUTICS

Subject Code : MPH-103T

M.Code : 74659

Time : 3 Hrs. Max. Marks: 75

**INSTRUCTIONS TO CANDIDATES :**

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. (a) What is cGMP? Discuss briefly its significance. (5)

   (b) Discuss in detail the effect of friction and distribution of forces during tablet compression. (5)

   (c) Detail the WHO guidelines for calibration and validation of equipments. (5)

2. (a) Differentiate between suspensions and emulsions. Discuss the stability problems of Suspensions (7.5)

   (b) Write a note on :

   i. IQ and OQ (2.5)

   ii. SMEDDS (2.5)

   iii. ANOVA (2.5)

3. (a) Discuss in detail the validation and calibration of master plan. (7.5)

   (b) Discuss the various Dissolution and Diffusion parameters. (7.5)

4. (a) Discuss importance and types of contour plots. (5)

   (b) Discuss the various parameters to be studied for validation of specific dosage form. (5)

   (c) Why do we need to conduct stability testing? (5)

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5. Write short notes (any three) : (3×5=15)

   (a) Response surface methods.

   (b) IQ, OQ and PQ.

   (c) Large volume parental.

   (d) Sales forecasting in production management.

   (e) Chi square test.

6. (a) What is validation protocol? Describe contents of validation protocol. (5)

   (b) Describe the formulation considerations of small volume parentrals. (5)

   (c) Discuss in detail material management and handling in Pharma Industry. (5)

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al No. of Questions : 06

Total No. of Pages : 02

**M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)**

**DRUG DELIVERY SYSTEM**

**Subject Code : MPH-102T**

**M.Code : 74658**

ime : 3 Hrs.

**Max. Marks : 75**

**NSTRUCTIONS TO CANDIDATES :**

1. **Attempt any FIVE questions out of SIX questions.**
2. **Each question carries FIFTEEN marks.**

1. a) What is smart / intelligent polymer? Discuss polymers as integral component of Pharmaceutical dosage forms.

   b) Write a short note on mucosal transdermal delivery of vaccines.

   c) Explain the mechanism of drug delivery from sustained release/controlled release formulation.

2. a) Give the principle which affect skin also discuss the factors of drug absorption.

   b) Explain in detail dosage forms for personalized medicine.

   c) Define vaccines. Discuss in detail single shot.

3. a) What do you understand by gastroretentive systems. Discuss it advantages and disadvantages.

   b) Discuss the evaluation of transdermal drug delivery system.

   c) Discuss Fick's first and second law of drug release with illustration.

4. a) Write a note on formulation strategies for protein and peptides based drugs.

   b) Discuss the principle of mechanically activated drug delivery system.

   c) Discuss the mechanism of drug release of SR/CR.

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5. a) Explain the barriers of drug permeation in ocular drug delivery systems(ODDS).

   b) Give classification and applications of biodegradable polymers.

   c) Write a short note on telepharmcy.

6. Write a note on **any three** :

   a) Bioelectronic medicines.

   b) Enzyme activated system.

   c) Evaluation of buccal drug delivery system.

   d) Barriers of protein delivery.

   e) Transdermal delivery of vaccines.

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Total No. of Questions : 06

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M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.–1)

REGULATORY AFFAIRS

Subject Code : MPH-104T

Paper ID : [74660]

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Write a note on Drug Master Files. (7.5)

   b) Distinguish between Generic drugs and Proprietary medicines. Write a note on development of generic versions of a drug. (7.5)

2. a) What is a CRO? Highlight the essential requirements for a CRO. (7.5)

   b) What is the purpose of maintaining drug distribution records? Write a note on ICH requirements pertaining to drug distribution records. (7.5)

3. a) What are combination products? Give examples. Highlight the regulatory requirements to be fulfilled for them. (7.5)

   b) Briefly discuss Master Formula Record and its importance. (7.5)

4. a) What is the constitution of Institutional Ethics Committee? Highlight the functions of Ethics Committee. (7.5)

   b) What is meant by HIPPA? Highlight its key features aimed at protecting sensitive patient data. (7.5)

5. a) What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial. (7.5)

   b) Mention the composition and functions of Institutional Review Board. (7.5)

(5×3=15)

6. Write short notes on :

   a) Pharmacovigilance

   b) e CTD

   c) Investigator Brochure

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Total No. of Questions : 06

Total No of Pages : 01

M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem.-1)

MODERN PHARMACEUTICS

Subject Code : MPH-103T

Paper ID : [74659]

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) What are SMEDDS? Mention the reasons for preparing them. Give a brief account of the preformulation studies conducted on them.

   b) Explain the response surface method used for formulation optimization.

2. a) What is validation and its necessity? Give an account of concurrent validation for tablet dosage form.

   b) Comment on the evaluation parameters for LVPs.

3. a) Comment on the cGMP requirements for building layout of a hard gelatin capsule manufacturing unit.

   b) Mention the key considerations and write briefly about sales forecasting in pharmaceutical industry.

4. a) Enumerate different approaches used for enhancing solubility of drugs. Briefly discuss any one method.

   b) Differentiate between plastic and elastic deformation of solid particles. Giving examples of such materials, explain their compaction behavior.

5. a) Enumerate dissolution variables and the parameters of dissolution. Explain f 1 and f 2 tests and their interpretation.

   b) What is the significance of Heckle Plot? Discuss the nature of Heckle Plot for substances of different nature.

6. Write short notes on :

   a) Stability testing of suspensions.

   b) Chi square test.

   c) Inventory control.

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Roll No.

Total No. of Questions : 06

Total No. of Pages : 01

M. Pharma (Pharmaceutics) (2013 & Onwards) (Sem.–1)

# NOVEL DRUG DELIVERY SYSTEMS

Subject Code : PHCEU-135

Paper ID : [E1324]

Time : 3 Hrs.

Max. Marks : 80

INSTRUCTION TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries SIXTEEN marks.

1. What are the rate controlled drug delivery systems? Classify and discuss. (16)

2 Write notes on :

a) Difference between aquasomes and trasferosomes

b) Magnetically induced targetting techniques

c) Microemulsions

d) Difference between liposomes and solid lipid nano particle (4×4=16)

3 a) What are the various approaches that can be utilized for enhancing transdermal drug delivery?

b) Write a note on osmotic drug delivery system. (10+6=16)

4 a) Define bioadhesion and discuss the mechanism of bioadhesion. How the characterization of mucoadhesive formulations is carried out?

b) Write a note on SEDDS. (10+6=16)

5 a) Discuss the role of isotonicity in the formulation of parenterals.

b) Write a note on compatibility of polymers with carrier. (8+8=16)

6 a) What is the importance of formulation considerations to improve ocular bioavailability?

b) Discuss in brief the application of zeta potential. (8+8=16)

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Total No. of Questions : 06

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M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem - 1)

DRUG DELIVERY SYSTEM

Subject Code : MPH-102T

Paper ID : [74658]

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1. a) Explain the mechanisms of drug release from controlled release dosage forms. Enumerate the different types of oral controlled release formulations.

   b) What is meant by personalized medication? Write a note on the different approached employed for this type of medication.

2. a) Enumerate different types of drug release activation systems used for controlled drug delivery. Explain mechanically activated systems.

   b) Discuss the mechanisms of muco adhesion and give examples of polymers used in such dosage forms.

3. a) Discuss the barriers for successful ocular drug delivery and the approaches used for overcoming them.

   b) Distinguish between matrix and reservoir TDDS. Enumerate the barriers for successful transdermal drug delivery.

4. a) Give an account of vaccine delivery systems.

   b) Explain the mechanisms for uptake of antigens.

5. a) What are the challenges for oral delivery of macromolecules. Briefly discuss the approaches employed for this purpose.

   b) Give a brief account of evaluation of TDDS.

6. Write short notes on :

   a) Hydrodynamically balanced drug delivery systems.

   b) Single shot vaccines.

   c) Evaluation of mucoadhesive systems.

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M.Pharmacy (Pharmaceutics) (2017 & Onwards) (Sem -1)

# MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code : MPH-101T

Paper ID : [74657]

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries EQUAL marks.

1. a. What are the limitations of Beer -Lambert law

b. What are the factors affecting vibrational frequency in IR? Comment on effect of H-bonding. (5)

c. Explain the principle of Flame emission spectroscopy. (5)

2. a. What are the factors affecting fluorescence. (5)

b. Comment on solvents used in NMR. (5)

c. Explain role of coupling constant in interpretation of $^1$H NMR spectrum. (5)

3. a. Give comparative statements of various ionization methods used in MASS spectrometry (9)

b. Briefly explain following in Mass spectrometry : (6)

Meta stable ion, Mc Lafferty rearrangements and Nitrogen rule

4. a. What is the principle of Ion exchange chromatography? (5)

b. Give block diagram of typical HPLC apparatus. (5)

c. Describe the pharmaceutical applications of GLC (5)

5. a. Describe polyacrylamide gel as electrophoretic matrices. (5)

b. What is isoelectric focusing? (5)

c. What is operative equation in X-ray diffraction? (5)

6. Explain the basic principle of ELISA. Describe various type of ELISAs used in estimation of enzyme activity and drugs in biological fluids. (15)



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