

(3 Hours)

[Total Marks: 75]

Note:**Draw neat labeled diagrams wherever applicable.****I. Multiple choice questions.****20M**

1. Conjugation in a chromophore results in: **1M**
 - a. Shifting of absorption band to shorter wavelengths
 - b. No change in position of the absorption band
 - c. Disappearance of absorption band
 - d. Shifting of absorption band to longer wavelengths
2. For any compound to get analyzed by IR spectroscopy, the compound should have: _____ **1M**
 - a. Existence of dipole moment
 - b. Double bond
 - c. Triple bond
 - d. Benzene Ring
3. A mixture of compounds X, Y and Z was separated on 12 cm silica gel TLC plate. Solvent front was allowed to run up to 9 cm. If X, Y and Z travelled distances of 2cm, 7cm and 5cm, the order of polarity of X, Y and Z will be **1M**
 - a. $X > Y > Z$
 - b. $X < Y < Z$
 - c. $X > Z > Y$
 - d. $X = Y = Z$
4. Main characteristic of an isocratic method as compared to gradient elution method is **1M**
 - a. composition of mobile phase remains constant
 - b. pH of mobile phase is changed
 - c. proportion of aqueous solvent in mobile phase is increased
 - d. proportion of organic solvent in mobile phase is increased

5. Resins of ion exchange are formed by polymerization of styrene and _____ 1M
- Benzene
 - Chlorobenzene
 - Divinylbenzene
 - Toluene
6. In a Fluorimeter, the filter placed after the sample cell is called as 1M
- Secondary filter
 - Primary Filter
 - Interference Filter
 - Excitation filter
7. _____ is used as a source in Atomic absorption spectroscopy 1M
- UV lamp
 - Mercury Arc lamp
 - Hollow cathode lamp
 - Flame
8. R_f value in thin layer chromatography is 1M
- Less than zero
 - Between 1 to 10
 - Always more than 1000
 - Always less than 1 but more than 0
9. Name the terminology which involves increasing the temperature of a gas chromatograph column as a function of time 1M
- Isothermal run
 - Temperature programming
 - Isocratic elution
 - Gradient elution

10. Best technique which can be used for separation of different sizes of peptides from a mixture can be 1M
- a. Thin layer chromatography
 - b. Ion-exchange chromatography
 - c. Gel filtration chromatography
 - d. Affinity chromatography
11. A UV spectrum is a plot of? 1M
- a. Peak intensity versus wavenumber
 - b. Absorbance versus wavelength
 - c. Absorbance versus wavenumber
 - d. Peak intensity versus wavelength
12. In nephelo turbidimetry, the intensity of scattered light is measured at _____ angle 1M
- a. 60°
 - b. 180°
 - c. 90°
 - d. 30°
13. Name the technique in electrophoresis in which the stationary phase employed is in liquid state 1M
- a. Polyacrylamide Gel electrophoresis
 - b. Paper electrophoresis
 - c. Capillary electrophoresis
 - d. Cellulose acetate Gel electrophoresis
14. Which detector is used in Gas chromatography? 1M
- a. Electron capture detector
 - b. Bolometer
 - c. Photomultiplier
 - d. Pyroelectric detector

15. Recognizers used in Affinity chromatography are: 1M
- Specific type of molecules bound to stationary phase
 - Specific type of molecules to be included in the mobile phase
 - Multiple utility type of molecules bound to stationary phase
 - Multiple utility type of molecules to be included in the mobile phase
16. Which one of the following is an example of a monochromator used in UV-vis spectroscopy? 1M
- Interferometer
 - Filter
 - Prism
 - Light source
17. _____ colour flame is shown by sodium ions Flame photometry? 1M
- Blue
 - Green
 - Yellow
 - Red
18. Ultrasonication of HPLC mobile phase is performed to 1M
- Increase its resolving power
 - Increase its temperature
 - Remove dissolved gases
 - Remove entrapped ions
19. Which of the following is used as light source in fluorimetry? 1M
- Mercury vapor lamp
 - Incandescent wire
 - Xenon arc lamp
 - Deuterium discharge lamp

20. Atomic absorption spectroscopy is used for the detection of? 1M
- Organic compounds
 - Metals
 - Residual solvents
 - Non-metals

II. Long answer questions (Attempt any two out of three) 20M

- Define quenching. List types of quenching and explain any one in detail with example 5M
 - Write a detailed note on interferences in atomic absorption spectroscopy 5M
- Enlist and discuss various steps involved in separation by Thin Layer chromatography. Give one point of differentiation between isocratic and gradient elution. 5M
 - Give an account of column packings which can be used for Gel chromatography. Discuss applications of Gel chromatography 5M
- Enlist the various types of columns used in HPLC. Draw the diagram of rheodyne injector in 'Load' and 'Inject' position. 5M
 - Mixture of compounds A and B was separated on a 25 cm Normal phase silica gel Column Chromatogram obtained provided the following data 5M

	Retention time (mins)	Peak width at base (w) (mm)
Unretained	1.3	
Retained A	11.7	8
Retained B	17.1	10

Answer the following:

- Calculate the selectivity factor for this separation
- Calculate the capacity factor for A
- Comment on which compound is more polar and why.

III. Short answer questions (Attempt any seven out of nine) 35M

1. Explain the term quantum efficiency with reference to fluorescence spectroscopy. Specific absorbance of Paracetamol at its wavelength maxima is 723. 1 mL of an injection containing Paracetamol, when diluted to one liter for an analysis, gave an absorbance of 0.87 at λ_{\max} when measured in 2 cm cell. Calculate the amount of Paracetamol in mg/mL of the injection. 5M
 2. Discuss the basic modes of interaction of molecules with IR radiation. Enlist various components of an spectrophotometer. 5M
 3. With the help of suitable diagram, explain methodology involved in Radial Paper chromatography. Write the name of one paper used in the Paper chromatography. 5M
 4. Explain the working of electron capture detector in gas chromatography. Give any one advantage and one disadvantage of this detector. 5M
 5. Give the principle of ion-exchange chromatography. Classify ion-exchange resins with suitable example. 5M
 6. Give the block diagram of a double beam UV-Visible spectrophotometer. Write a detailed note on monochromators used in UV-Visible spectrophotometer. 5M
 7. Draw a labelled schematic diagram of an atomic absorption spectrophotometer and explain role of each of its component. Give any two applications of Atomic absorption spectroscopy technique. 5M
 8. What is electrophoretic mobility? Discuss in detail factors affecting the same 5M
 9. Enlist the bulk property detectors employed in HPLC. Discuss any one of them in detail. 5M
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N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks.

Q.I Multiple Choice Questions (Answer all)

20

1 The art of designing prototype using data obtained from pilot plant model is

- a) Scaling
- b) Act work
- c) Scale up
- d) Model design

2 Over lubrication of granules may result in

- a) Faster dissolution
- b) Faster Disintegration
- c) Delay in disintegration
- d) No effect on disintegration

3 According to SUPAC guidelines, Level 2 changes are those

- a) Which have significant impact on formulation quality and performance
- b) Which have no significant impact on formulation quality and performance
- c) Which are unlikely to have any detectable impact on formulation
- d) Which are unlikely to have any detectable impact on performance

4 Bloom strength determines the strength of

- a) Tablet
- b) Capsule
- c) Pellets
- d) Granules

5 Out of following functions of compression process, which one is optional

- a) Filling of empty die cavity
- b) Pre compression
- c) Compression
- d) Ejection of tablet

6 Technology transfer is brought about by

- a) Quality Assurance department to manufacturing unit
- b) Quality control department to manufacturing unit
- c) Research and development department to manufacturing unit
- d) Quality Assurance department to research and development department

7 BCIL facilitates

- a) Batch technology transfer
- b) Biological technology transfer
- c) Biotechnology transfer
- d) Bioenzyme technology transfer

8 ICH Q9 guidelines describe about

- a) Technology transfer
- b) Risk management
- c) Stability study
- d) Analytical method validation

9 Following is the regulatory agency of UK

- a) CDSCO
- b) FDA
- c) MHRA
- d) MHLW

10 Module 4 of NDA dossier as per CTD format includes

- a) Clinical study reports
- b) Quality overall summary
- c) Preclinical study reports
- d) Administrative information

11 The objective of Phase II clinical trial study is

- a) To assess safety of drug
- b) To assess efficacy of drug
- c) To assess bioavailability of drug
- d) To assess safety and efficacy of drug

12 In Clinical Research CRF implies

- a) Compliance report form
- b) Case report form
- c) Constitution report form
- d) Casualty report form

13 Following is the major part of toxicology study

- a) Determination of bioavailability of drug
- b) Determination of bioequivalence of drug
- c) Determination of therapeutic index of drug
- d) Determination of metabolism of drug

14 Following test is performed to indicate genotoxicity

- a) Draize test
- b) Ames test
- c) LAL test
- d) Endotoxin test

15 Variation within a batch belongs to which source of Quality variation

- a) Methods
- b) Machines
- c) Materials
- d) Personnel

16 ISO stands for

- a) International Organization for Standardization
- b) International Society Organization
- c) International Organization Schedules
- d) International Organization of Standards

17 The benefit of GLP is

- a) More time spent on re-work
- b) Reduces overall productivity
- c) Decreases reliability
- d) Increases right first time results

18 DTAB stands for

- a) Department of Technology Advisory Body
- b) Drug Technology Analysis Board
- c) Drug Technical Advisory Board
- d) Department of Technical Analysis Board

19 Which of the following is a function of CDSCO

- a) Reduce waste
- b) Import registration and licensing
- c) Control process
- d) Review of improvement

20 Which of the following provides guidelines and requirements for Clinical trials

- a) Schedule X
- b) Schedule M
- c) Schedule H
- d) Schedule Y

QII Answer the following (any Two)

20

- 1 Discuss Pilot plant scaleup consideration for Liquid oral dosage form. **10**
- 2 Describe the various specifications of starting input materials in technology transfer. **10**
- 3 Differentiate between IND and NDA. Describe in details contents and stages involved in NDA application **10**

QIII Answer the following (any Seven)

35

- 1 Discuss briefly SUPAC guidelines for IR formulation with respect to change of components & composition. **5**
- 2 Mention in brief the role and responsibilities of Receiving unit in technology transfer **5**
- 3 Write a note on technology transfer plan and report **5**
- 4 Write a note on bioequivalence studies **5**
- 5 What is QbD and discuss the key elements of QbD **5**
- 6 Explain the significance of Quality Management systems and write a note on TQM **5**
- 7 What is Six Sigma, give its key features and discuss any one methodology of six sigma **5**
- 8 Elaborate on the Indian approval procedure for New Drugs **5**
- 9 Discuss in detail the Common Technical Document **5**

(3 Hours)

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**Note: All questions are compulsory.
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QI Choose one correct answer and write it down. 20

i In the hospital _____ medical staff members remain available for 24 hours to attend to the patients.

- A Residential
- B Associate
- C Consulting
- D Honorary

ii In the hospital _____ is intramural service.

- A Medical camp
- B Outpatient department
- C Intensive care unit
- D Immunization program

iii In hospital pharmacy _____ reports to the administrator.

- A Chief pharmacist
- B Dispensing Pharmacist
- C Clinical Pharmacist
- D Store Pharmacist

iv A hospital pharmacy that services patients who have left the hospital or who are visiting doctors in a hospital outpatient clinic is known as _____.

- A Outpatient pharmacy
- B Center pharmacy
- C Pharmacy satellite
- D inpatient pharmacy

v Consumption of MAO inhibitors with cheese produces _____.

- A Hypotension
- B Drowsiness
- C Hypertensive crises
- D Heart failure

vi Adverse drug reaction due to secondary effects occurring on the administration of tricyclic antidepressants with chlorpromazine is _____.

- A Dryness of mouth
- B Increased salivation
- C Hyperacidity
- D Diarrhoea

vii Which of these is direct method of measuring medication adherence?

- A Patient questionnaire
- B Patient diary
- C Individual prescription order
- D Urine Analysis

viii _____ is a factor responsible for patient's noncompliance with therapy.

- A Multiple drug therapy
- B Clinical setting
- C Gender of patient
- D Marital status of patient

ix Which of the following is the part of hospital formulary?

- A Drug product listing
- B Dietary information
- C Billing information
- D Patients' information

x _____ is a written order by physician, dentist or health professional for medication to be dispensed for administration to a patient.

- A Prescription
- B Medication history
- C Prescribed medication order
- D Drug Formulary

xi _____ contains current news about devices and health industries.

- A Pharmaceutical news Index (PNI)
- B MICRODEX
- C MEDLINE
- D Drug abuse warning network

xii Internal teaching program involved in training of _____ in hospital.

- A Student Nurses
- B Cardiologist
- C Physician
- D Pulmonologist

xiii Budgeting is essential tool in the process of _____.

- A Planning
- B Distribution
- C Administration
- D Implementation

xiv The most accurate method for Therapeutic drug monitoring involves.

- A Measurement of medication concentrations in blood.
- B Measurement of drug efficacy
- C Measurement of drug metabolism
- D Measurement of renal secretion of drug

xv TDM is not required for drugs

- A Which is liable to interact
- B Whose metabolite might be toxic
- C Highly protein bound
- D With wide therapeutic window

xvi The cost of premises of drug store depends upon the _____.

- A Location
- B Design
- C Surrounding
- D Facilities

xvii Vaccines and other thermolabile drugs are required to be stored at cold stores at _____.

- A 30°C
- B 10°C
- C 15°C
- D 20°C

xviii Which Committee is essential to evaluate every proposed clinical research study in terms of its compliance with accepted ethical, legal and scientific standards?

- A FDA advisory committees
- B Institutional Review Committee
- C FDA Ethical committees
- D Institutional Ethical Committee

xix _____ refers to the cost involved in the reordering of stock of drugs.

- A Procurement cost
- B Carrying cost
- C Warehousing cost
- D Purchasing Cost

xx Which Test is performed for the detection of carbohydrates in urine?

- A Benzidine test.
- B Rothera's test
- C Dipstick test
- D Benedict's test

QII Answer the following (Any two out of three).

20

- i Define Community Pharmacy. Write a note on the Organisation and structure of the retail Pharmacy. Discuss legal requirements of drug store.
- ii Define Hospital Formulary and describe the contents of Hospital Formulary. Differentiate hospital formulary and drug list.
- ii Describe prescribed medication order, their types and the legal requirements for prescribed medication order.

QIII Answer the following (Any seven out of nine).

35

- i Classify adverse drug reactions with examples. Discuss various methods to detect adverse drug reactions.
- ii Define medication history interview. Explain medication interview form.
- iii Define coding, give its advantages and explain the methods of coding in community pharmacy.
- iv Describe various modes of communication with patients.
- v Describe the steps in patient counselling.
- vi Discuss in brief about medication chart review.
- vii What are OTC drugs? Give the advantages and disadvantages of OTC sale.
- viii Discuss the roles of Hospital Pharmacist in investigational Drug Studies.
- ix Write a note on Haematology and their Clinical implications.

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- N.B.:**
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 2. Figures to right indicate full marks.
 3. Draw neat labelled diagrams wherever necessary.

- Q.I Multiple Choice Questions. Write the correct option. (Answer all) 20**
- 1 Which of the following is a system comprising of a rate-controlling polymer matrix throughout which a drug is dissolved or dispersed? **1**
 - a) Reservoir system
 - b) Micro-reservoir system
 - c) Monolithic system
 - d) Sandwich system
 - 2 The dose achieving the steady-state plasma concentration immediately is called as: **1**
 - a) Maintenance dose
 - b) Loading dose
 - c) Retention dose
 - d) Total dose
 - 3 The mechanism by which Polyorthoesters release the drug is **1**
 - a) swelling
 - b) surface erosion
 - c) dissolution
 - d) diffusion
 - 4 A temperature responsive polymer is **1**
 - a) polyethylene glycol
 - b) polyglycolic acid
 - c) acrylic acid
 - d) polyisopropylacrylamide
 - 5 Coacervation Phase Separation can be brought about by **1**
 - a) Temperature change
 - b) Pressure change
 - c) Humidity change
 - d) Adiabatic change
 - 6 Reason for microencapsulation of peppermint oil is **1**
 - a) Sustained release
 - b) Conversion into solid
 - c) Gastric protection
 - d) Dose reduction
 - 7 Drug candidate for buccal mucoadhesive system shall have **1**
 - a) High permeability value
 - b) Low permeability value
 - c) High molecular weight
 - d) Bitter taste
 - 8 Water soluble drug passes across the buccal mucosa through **1**
 - a) transdermal pathway
 - b) intercellular pathway
 - c) intracellular pathway
 - d) precellular pathway

- 9 Osmotic drug delivery systems have a membrane that is **1**
a) soluble at intestinal pH
b) impermeable to GI fluids
c) permeable to water
d) swellable
- 10 Copper ions are released from **1**
a) first generation IUDs
b) second generation IUDs
c) third generation IUDs
d) fourth generation IUDs
- 11 An appendageal route does not include **1**
a) hair follicles
b) sebaceous glands
c) stratum corneum
d) sweat glands
- 12 Which of the following is an advantage of transdermal route? **1**
a) Favours absorption of ionized drug
b) Commonly used to deliver macromolecules like proteins and peptides
c) Suitable for only hydrophilic drugs
d) Bypasses first pass metabolism
- 13 Formulating a gastroretentive system of which of the following drugs will be impractical? **1**
a) Captopril – unstable in the small intestine
b) Ranitidine HCl – absorbed from the stomach
c) Misoprostol – locally acting in stomach
d) Penicillin G – unstable in gastric acid
- 14 Which of the following medium should be preferred to carry out the floating time test? **1**
a) Simulated intestinal fluid
b) 0.1 N HCl
c) Distilled water
d) Phosphate buffer pH 7.4
- 15 Mucociliary clearance is **1**
a) caused by non ciliated cells
b) clearance of mucus and entrapped substances into GIT
c) not affected by disease state
d) a destructive function of the nasal mucosa
- 16 If particles greater the one micron are inhaled **1**
a) deposition occurs in the pulmonary region
b) deposition mechanism is interception
c) deposition occurs in upper bronchio-tracheal region
d) deposition mechanism is diffusion
- 17 Advantages of liposomes include **1**
a) Drug leakage
b) Dose reduction
c) Complicated production method
d) Instability

- 18 In the production of monoclonal antibodies, after antigen injection, _____ of animal is removed. **1**
 a) Spleen
 b) liver
 c) Kidney
 d) pancreas
- 19 An EVA ring impregnated with titanium dioxide is added to the Ocusert. What is its purpose? **1**
 a) It controls the rate of drug release
 b) It helps in prolonged retention
 c) It helps in absorption of lachrymal fluid
 d) Provides better visibility so that there is ease of handling and insertion
- 20 Which of the following is a non-erodible ocular insert? **1**
 a) Contact lens
 b) Lacrisert
 c) Minidisc
 d) Soluble ocular drug insert

QII Answer any Two 20

- 1 Describe in detail controlled release formulations based on diffusion mechanism. **10**
- 2 Classify the microcapsules on the basis of their structures. Explain the concept of core and coat. Describe any one large scale method of their production. **10**
- 3 Enlist the advantages and limitations of ocular inserts. Classify them and explain ANY ONE erodible insert in detail. **10**

QIII Answer any Seven 35

- 1 Differentiate between sustained release and controlled release systems. Enumerate the pros and cons of controlled drug delivery. **5**
- 2 Explain the applications of polymers of natural and semi-synthetic origin in controlling drug release. **5**
- 3 Discuss transmucosal permeability. **5**
- 4 Enlist the evaluation parameters for the evaluation of pulmonary drug delivery systems. Describe the use of the Cascade Impactor. **5**
- 5 Briefly describe the various types of Intrauterine devices. **5**
- 6 Explain any one approach for formulation of a transdermal drug delivery system. **5**
- 7 Discuss effervescent floating drug delivery systems. **5**
- 8 Describe any one method for preparation of Nanoparticles. **5**
- 9 Write a note on Lacrisert. **5**