

Time: 3 Hours

Max. Marks: 75

Note:

1. Draw net labeled diagrams wherever applicable

I. Multiple choice questions 20M

1. The following quantitation methods in UV - Visible spectroscopy need a reference standard except 1M

- a. Standard curve method
- b. Single point standardization
- c. Double point standardization
- d. Use of standard absorptivity

2. Molar absorptivity is expressed as? 1M

- a. Gram/100 ml
- b. Gram/litre
- c. Moles/ml
- d. Moles/litre

3. Which one of the following is an example of wavelength selector in uv-visible spectroscopy? 1M

- a. Detector
- b. Monochromator
- c. Light source
- d. Amplifier

4. Paracetamol and Ibuprofen combination can be analyzed by using the following method?

- a. Difference spectroscopy
- b. Simultaneous equation
- c. Calibration graph method
- d. Use of standard absorptivity value

5. IR spectrum is a plot of? 1M
- a. % Transmittance versus wavenumber
 - b. Absorbance versus wavelength
 - c. Peak area versus retention time
 - d. Absorbance versus concentration
6. Stretching vibration is associated with? 1M
- a. Change in bond rotation
 - b. Change in bond angle
 - c. Change in bond length
 - d. Change in chemical composition
7. Which of the following is used in preparation of solid sample for IR spectroscopy? 1M
- a. Potassium carbonate
 - b. Potassium bromide
 - c. Potassium hydroxide
 - d. Potassium nitrate
8. In flame photometry, as the energy gap between excited and unexcited metal atoms increases, the proportion of atoms in the ground state 1M
- a. Increases
 - b. Decreases
 - c. Remains unaffected
 - d. Increases or decreases
9. Atomic absorption spectroscopy involves? 1M
- a. Measurement of concentration of elements
 - b. Measurement of concentration of molecules
 - c. Measurement of molecular mass
 - d. Measurement of degree of crystallinity

10. Nephelometry is based on? 1M
- a. Light scattering
 - b. Light transmission
 - c. Light absorption
 - d. Light reflection
11. The term _____ is independent of the flow rate of mobile phase in column chromatography 1M
- a. HETP
 - b. Mass transfer
 - c. Longitudinal diffusion
 - d. Eddy diffusion
12. In paper chromatography, separation is based on the principle of _____ phenomenon 1M
- a. Partition
 - b. Adsorption
 - c. Size Exclusion
 - d. Ion exchange
13. In electrophoresis, as the ionic strength of the buffer is decreased, 1M
- a. rate of migration of charged particle decreases
 - b. rate of migration of the charged particle increases
 - c. No change in the migration rate of the charge particle
 - d. Particle becomes immobile
14. In Gas chromatography, derivatization of a sample is carried out to: 1M
- a. increase polarity of the analytes
 - b. increase volatility of the analytes
 - c. decrease solubility
 - d. Decrease detector response

15. Parameter used for the qualitative analysis by HPLC is 1M
- a. Retention time
 - b. Peak height
 - c. Peak Area
 - d. Width at the base
16. Selectivity Factor in column chromatography is associated with 1M
- a. Ability of the column to hold the sample component of a mixture
 - b. Ability of the column to efficiently separate components of a mixture
 - c. Presence of an asymmetric peak in the chromatogram
 - d. Selection of polarity of the mobile phase used for separation
17. A mixture of compounds X, Y, Z and M after separation by RP HPLC using mobile phase methanol : water (50:50) showed retention times of 2.5min, 2.8min, 12 min and 15 min respectively. Following is the most non polar component 1M
- a. X
 - b. Y
 - c. Z
 - d. M
18. Resin of ion exchange are formed by polymerization of styrene and _____ 1M
- a. Benzene
 - b. Chlorobenzene
 - c. Divinylbenzene
 - d. Bromobenzene

19. Separation based on molecular size occurs in _____ chromatographic technique 1M
- a. Ion-exchange
 - b. Gel
 - c. Affinity
 - d. Gas
20. The chromatographic method of separating biological mixtures based on specific biological interactions is? 1M
- a. Gel
 - b. TLC
 - c. Affinity
 - d. Ion exchange

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

1. a. State Beer Lambert's law. Give its derivation. 5M
- b. Explain the principle for IR spectroscopy. Give any two applications for IR spectroscopy 5M
2. a. Explain the term Radial Chromatography with a suitable diagram. Give one spraying agent used in paper chromatography. 5M
- b. Classify the different types of ion exchange resins. Give suitable examples for each type. 5M
3. a. Enlist any four detectors used in Gas chromatography. Explain any one detector in detail. Support your answer with a suitable diagram 5M
- b. An analyte X when passed through column A of length 12 cm showed a retention time of 7 mins with peak width of 0.54 mins at half the peak height. The same analyte X when subjected to chromatographic analysis on column B of length a 25cm, eluted out at a retention time of 12 mins and had a peak width of 0.72 mins at the base. Which column is more efficient for the separation of analyte X and why ? 5M

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

1. Enlist the methods for multicomponent analysis in UV - Visible spectroscopy. 5M
If a $12\mu\text{g/ml}$ solution of molecule $\text{C}_8\text{H}_9\text{NO}_2$ gives an absorbance of 0.86 at its λ_{max} in a 1cm cell, what is its molar absorptivity?
2. Explain the terms: i. Fluorescence ii. Phosphorescence. 5M
Enlist any four factors affecting fluorescence intensity.
3. Write two points of distinction between atomic absorption spectroscopy and flame photometry. Explain principle of atomic absorption spectroscopy. 5M
4. Enlist the detectors used in uv-visible spectroscopy. Write a detailed note on any one of them. 5M
5. Give the principle of separation of compounds using thin layer chromatography. Give a detailed account of the methods used for detection of separated compounds in thin layer chromatography 5M
6. Discuss guard column in HPLC. Explain the term isocratic elution and give one advantage and disadvantage of the Isocratic elution. 5M
7. Write a note on paper electrophoresis. Give any two applications of paper electrophoresis. 5M
8. Explain the term headspace analysis. Give its application. Enlist the carrier gases used in gas chromatography 5M
9. Write a note on stationary phase and mobile phase employed in affinity chromatography 5M

Duration: 3 Hours

Total marks: 75

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks.

Q.I Multiple Choice Questions (Answer all) 20

1 Which of the following is not scale up process 1

- a) Laboratory to pilot scale
- b) Pilot to industrial scale
- c) Industry to pilot scale
- d) Laboratory to industrial scale

2 Rapid mixer granulators are used in 1

- a) Wet granulation
- b) Dry granulation
- c) Compression granulation
- d) Direct compression

**3 Changes in the technical grade of excipients, comes under 1
_____ as per SUPAC guidelines**

- a) Level 1
- b) Level 2
- c) Level 3
- d) Level 4

4 A group of Technologies that are used as base upon which other technologies or processes are developed is 1

- a) PAT Technology
- b) QBD Technology
- c) Platform Technology
- d) Platinum Technology

5 Slugging is used for 1

- a) Ingredients which can be directly compresses
- b) Ingredients which cannot be directly compressed
- c) Ingredients which are stable to heat and moisture
- d) Ingredients with excellent flow property

6 Technology transfer guidelines issued by 1

- a) MHRA
- b) WHO
- c) FDA
- d) CSCO

7 BMR stands for 1

- a) Batch Manufacturing Record
- b) Batch Marketing Record
- c) Batch Marketing Report
- d) Batch Manufacturing Report

8 Following ICH guideline mentions about product development 1

- a) Q4
- b) Q8
- c) Q9
- d) Q10

9 NRDC implies 1

- a) National Revenue Development Council
- b) National Research Development Council
- c) National Research Design Council
- d) National Revenue Design Council

10 Module 3 of NDA dossier as per CTD format includes 1

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

11 The objective of Phase III clinical trial study is 1

- 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 Safety Pharmacology studies are part of 1

- a) Clinical study
- b) Preclinical study
- c) Bioequivalence study
- d) Bioavailability study

13 In Clinical Research CRF implies 1

- a) Clinical Report Form
- b) Case Report form
- c) Compliance report form
- d) Candidate report form

14 Institutional Ethics Committee approves 1

- a) Protocol involving study on animals
- b) Protocol involving study on cell lines
- c) Protocol involving study on humans
- d) Protocol involving study on pathogens

15 In QbD the term CQA stands for 1

- a) Critical Quantitative Attainment
- b) Cumulative Quality Attributes
- c) Critical Quality Attributes
- d) Cumulative Quantitative Attributes

16 Which of the following parameters relates to the “Six sigma approach” 1

- a) Errors
- b) Cost
- c) Safety
- d) Defects

17 _____ is a series of certification for international environmental management standards 1

- a) ISO 9000
- b) ISO 14000
- c) ISO 27000
- d) ISO 13000

18 In CTD which of the following Modules is region specific 1

- a) Module 1
- b) Module 2
- c) Module 3
- d) Module 4

19 DCGI stands for 1

- a) Deputy Commissioner General of India
- b) Drug Controller General of India
- c) Drug Commissioner General of India
- d) Deputy Controller General of India

20 Which one of the following is the first document of submissions made in approval of a new drug 1

- a) Post marketing surveillance data
- b) Bioequivalence studies
- c) Chemistry, manufacturing and controls
- d) Onsite visit of facility

QII Answer the following (any two) 20

- 1 Give the detailed account of Pilot plant scale up of Tablet. 10
- 2 Describe in details the goals and phases of technology transfer 10
- 3 Differentiate between NDA and ANDA. Describe in details contents of ANDA 10

QIII Answer the following (any seven) 35

- 1 Explain the SUPAC guidelines for the change of manufacture site for immediate release products. 5
- 2 Mention in brief the role and responsibilities of Sending unit in technology transfer 5
- 3 Enlist different technology transfer agencies in India and describe objectives and functions of any one agency 5
- 4 Describe in brief the scope and contents of Investigator's brochure 5
- 5 Elaborate on the elements of QbD as a part of QMS 5
- 6 Explain the objective and principles of GLP 5
- 7 Define OOS and explain methods to handle or investigate an OOS 5
- 8 What is CDSCO and explain in brief its organization and responsibilities. 5
- 9 Discuss the importance of Certificate of Pharmaceutical Product 5

X-----X-----X

Duration: 3 Hours

Total marks: 75

- N.B.:** 1. All questions are compulsory
2. Figures to the right indicate full marks.

Question No.	Question	Max. Marks
Q.I	Multiple Choice Questions (Answer all of the following):	20
1	The physicochemical factor to be considered in selection of a drug candidate to be formulated as a sustained release drug delivery system is:	1
	a) partition coefficient	
	b) half-life	
	c) absorption	
	d) distribution	
2	The following equation under sink condition depicts the importance of drug solubility in the context of drug release from solute particles:	1
	a) Higuchi equation	
	b) Noyes-Whitney equation	
	c) Fick's law	
	d) Dalton's law	
3	A polymer used in dissolution controlled release formulations is	1
	a) Ethylcellulose	
	b) Polyethylene	
	c) Polyvinyl pyrrolidone	
	d) Polyurethane	
4	A feature of synthetic polymers is	1
	a) Polymer properties cannot be controlled	
	b) Large scale production is difficult	
	c) Low immunogenicity	
	d) Degradation rate can be controlled	
5	Following is the method used for preparation of microcapsules:	1
	a) Multiorifice centrifugal technique	
	b) Shaking method	
	c) Reverse Phase evaporation	
	d) Freeze drying method	
6	Bitter taste of the drug can be avoided by forming	1
	a) Microcapsules	
	b) Niosomes	
	c) Liposomes	
	d) Aquasomes	

- 7 The most common route for drug permeation through the buccal mucosa is by _____ pathway **1**
- Carrier mediated
 - Intracellular
 - Pre-cellular
 - Pinocytosis
- 8 Chitosan is a _____ mucoadhesive polymer. **1**
- Cationic
 - Anionic
 - Synthetic
 - Non-ionic
- 9 Osmotic drug delivery systems have the following characteristic: **1**
- have a membrane that is soluble at intestinal pH
 - the membrane is impermeable to GI fluids
 - the membrane is permeable to water
 - the membrane must swell
- 10 Copper-T is a following type of implant: **1**
- Intra-uterine
 - Buccal
 - Osmotic-pump based
 - Ocular
- 11 An advantage of the transdermal route is: **1**
- used only for hydrophilic drugs
 - prevents first pass metabolism
 - used for drugs with high doses
 - produces high levels of drug in plasma
- 12 A backing used for transdermal patches is **1**
- Methyl cellulose
 - Polyacrylate
 - Polyisobutylene
 - Polyethylene terephthalate
- 13 Factors affecting floating of a GRDDS include all, except **1**
- Size
 - Posture
 - Buoyancy
 - Volume of fluid
- 14 Alginate beads for gastroretention are prepared using **1**
- alginate acid and calcium sulphate
 - magnesium sulphate and sodium alginate
 - alginate acid and sodium chloride
 - sodium alginate and calcium chloride

- 15 Pulmonary drug delivery system based on use of piezoelectric crystal is characteristic of one of the following: **1**
- Ultrasonic nebulizer
 - Jet nebulizer
 - Aerosol
 - MDI
- 16 Oropharynx is a part of **1**
- Left Lung
 - Nasal Region
 - Right lung
 - Tracheal Region
- 17 Which scientist gave the concept of “The Magic Bullet”? **1**
- Paul Ehrlich
 - Arthur Noyes
 - Willis Whitney
 - Gordon Amidon
- 18 Lecithins are also called: **1**
- Phosphatidyl serine
 - Phosphatidyl choline
 - Phosphatidyl inositol
 - Phosphatidyl ethanolamine
- 19 In Ocusert the two outer layers of EVA enclosing the inner core of drug gelled with polymer plays the following role: **1**
- helps in handling and inserting the system
 - acts as drug reservoir
 - acts as a rate controlling membrane
 - helps in absorption of lachrymal fluid
- 20 The polymer used to construct a Soluble Ocular Drug Insert is designated as: **1**
- PVA
 - HPMC
 - CAP
 - ABE
- QII Answer any Two questions of the following: 20**
- 1 Elaborate in detail on the physicochemical properties of API related to design of controlled release formulations. **10**
 - 2 State the various advantages and applications of microencapsulation. Explain fluidized bed coating process for microencapsulation. **10**
 - 3 Provide the rationale for design of ocular inserts. Elaborate in detail on Ocusert. **10**

- QIII Answer any Seven questions of the following: 35**
- 1** Give a brief account of controlled release formulations based on the principle of ion-exchange. **5**
 - 2** Write a note on the types of polymers used for controlled release drug delivery systems. **5**
 - 3** Enlist various tests for evaluation of the mucoadhesive strength of a mucoadhesive drug delivery system. Write in detail about any two of them. **5**
 - 4** Discuss the formulation of Dry Powder Inhalers. **5**
 - 5** Briefly describe the various medicated and non-medicated intra-uterine devices. **5**
 - 6** Describe the membrane permeation controlled systems for transdermal delivery of drugs. **5**
 - 7** Explain the need to modulate gastric residence time of drugs. Elaborate on the various approaches to do so. **5**
 - 8** Elaborate on the solvent evaporation method for preparation of liposomes. **5**
 - 9** Write a short note on New Ophthalmic Delivery system. **5**

(Time: 3 Hours)

(Total Marks: 75)

- Note :
- i) All questions are compulsory.
 - ii) Figures to the right indicate full Marks.

Q.I Choose the correct Answer and write it down 20

i Which department in a hospital is responsible for managing patient admissions and ensuring proper utilization of beds?

- Alternative 1 Radiology Department
- Alternative 2 Dietary Services
- Alternative 3 Medical Records Department
- Alternative 4 Human Resources Department

ii Community pharmacists often play a key role in identifying and preventing drug interactions and adverse effects. What is this practice known as?

- Alternative 1 Pharmacoeconomics
- Alternative 2 Medication reconciliation
- Alternative 3 Medication therapy management
- Alternative 4 Drug compounding

iii What document serves as a written prescription for a patient's inpatient medications and includes the drug, dose, frequency, and route of administration?

- Alternative 1 Patient insurance card
- Alternative 2 Medication discharge plan
- Alternative 3 Medication order or chart
- Alternative 4 Physician's license

iv Grapefruit juice is known to interact with various medications, especially those metabolized by the liver. What is the mechanism of this interaction?

- Alternative 1 It enhances drug metabolism
- Alternative 2 It inhibits drug metabolism
- Alternative 3 It has no impact on drug metabolism
- Alternative 4 It reduces drug-protein binding

v Why is it crucial for healthcare professionals to consider drug-drug interactions during patient care?

- Alternative 1 To minimize the cost of medications for patients
- Alternative 2 To avoid adverse effects and ensure optimal therapy
- Alternative 3 To determine which drugs are most effective
- Alternative 4 To improve the taste of oral medications

- vi** Which of the following is an example of an idiosyncratic adverse drug reaction?
- Alternative 1 Nausea and vomiting after chemotherapy
Alternative 2 Allergic skin rash after taking an antibiotic
Alternative 3 Drowsiness as a result of an antihistamine
Alternative 4 Gastric irritation due to non-steroidal anti-inflammatory drugs
- vii** When was the International level convention held to exercise control on the use of narcotics?
- Alternative 1 1930
Alternative 2 1919
Alternative 3 1940
Alternative 4 1945
- viii** In hospitals where a catalogue has been published, what type of requisition form is recommended?
- Alternative 1 Pre-printed requisition form
Alternative 2 Handwritten requisition form
Alternative 3 Online requisition form
Alternative 4 Special requisition form
- ix** Which of the following is a manual containing clinically oriented summaries of pharmacological information about some of the selected drugs?
- Alternative 1 Drug formulary
Alternative 2 Drug list
Alternative 3 Loose leaf formulary
Alternative 4 Ancillary formulary
- x** Prescriptions and _____ are the principal ways through which the prescribers and the pharmacists communicate with each other concerning the desired treatment regimen for a patient.
- Alternative 1 Medication orders
Alternative 2 Dosage instructions
Alternative 3 Treatment plans
Alternative 4 Medication recommendations
- xi** _____ is the process in which the professionals in different departments report to each other regarding the care provided to the patients.
- Alternative 1 Cross-functional collaboration
Alternative 2 Patient care coordination
Alternative 3 Multidisciplinary information sharing
Alternative 4 Interdepartmental communication

xii _____ contains current news about devices and health industries.

- Alternative 1 Pharmaceutical News Index (PNI)
- Alternative 2 MICRODEX
- Alternative 3 MEDLINE
- Alternative 4 Drug abuse warning network

xiii Preparation of budget is _____ which calls for the compilation of all relevant facts and figures.

- Alternative 1 Forecasting
- Alternative 2 Planning
- Alternative 3 Organizing
- Alternative 4 Preparing Questions

xiv Usually at least _____ ward round is conducted every day to review the progress of each patient.

- Alternative 1 One
- Alternative 2 Two
- Alternative 3 Five
- Alternative 4 Seven

xv TDM is very essential for those drugs with _____ therapeutic index.

- Alternative 1 Wide
- Alternative 2 Narrow
- Alternative 3 Large
- Alternative 4 Small

xvi OTC drugs are _____.

- Alternative 1 Ethical Drugs
- Alternative 2 Prescription Drugs
- Alternative 3 Non-Prescription Drugs
- Alternative 4 Ethical & Prescription Drug

xvii F S N in the layout of the drug store stands for _____ .

- Alternative 1 Fast moving, slow moving, non-moving material
- Alternative 2 First, Six, Nine
- Alternative 3 Fast moving, storing, net quantity
- Alternative 4 Fast Moving, Slow Moving, New material

xviii VED analysis stands for _____ .

- Alternative 1 Very essential deal
- Alternative 2 Vital essential desirable
- Alternative 3 Very essential desirable
- Alternative 4 Vital essential deal

- xix** A ledger or bin card has ____ codes.
- Alternative 1 1
Alternative 2 2
Alternative 3 3
Alternative 4 4

- xx** Westergren and Wintrob are the methods for the determination of _____.
- Alternative 1 Anaemia
Alternative 2 Hb
Alternative 3 ESR
Alternative 4 Blood sugar

Q.II Answer the following (Any two out of three) 20

- i Draw a well-labelled layout of the community Pharmacy. Discuss legal requirements and maintenance of various records for Community Pharmacy.
- ii Define the Hospital Formulary, and describe the objectives and contents of the Hospital Formulary.
- ii Describe in brief the policies of the Pharmacy and Therapeutic Committee in in-patient and out-patient prescription.

Q.III Answer the following (Any seven out of nine) 35

- i Discuss various mechanisms of drug interactions altering the absorption of drugs with suitable examples.
- ii Describe the dispensing of controlled drugs.
- iii Explain the interview process in the medication history interview.
- iv Describe the drug information services.
- v Describe various modes of communication with patients.
- vi Elaborate budget preparation and its implementation.
- vii Describe Pharmacist Intervention in drug therapy monitoring.
- viii Explain in detail the Purchase procedure.
- ix Explain three distinct testing phases of urine analysis.
