Duration: 32 hours **Total Marks: 75**

N.B.: 1. All questions are compulsory

2. Figures to right indicate full marks

Q. I Attempt all multiple-choice questions (MCQ) **20 Marks**

Sr. No.	Questions
1	This is important when more than one laboratory is involved in sample assay during the course of clinical trials and when multiple assay methods are used in sample assay for a single study. a) Partial validation b) Full validation c) Cross validation d) Concurrent validation
2	A spiking sample is referred to as a _____ in the protocol of the sample preparation method of metabolomics. b) Blank Sample c) Internal Standard Sample d) Quality Control Sample e) External standard sample
3	The order of binding of drugs to various plasma proteins is_____. b) Albumin < Acid Glycoprotein < Lipoproteins < Globulins c) Albumin > Globulins > Acid Glycoprotein > Lipoproteins d) Albumin < Globulins < Lipoproteins < Acid Glycoprotein e) Albumin > Acid Glycoprotein > Lipoproteins > Globulins
4	The stoichiometric ratio of the analyse in the organic phase compared to that in the aqueous phase is known as_____. b) Distribution ratio c) Partition coefficient d) Phase ratio e) Equilibrium
5	Passive diffusion is best expressed by b) Kick's first law c) Fick's second law of diffusion d) Rittinger's Law e) Fick's first law of diffusion

6 Permeation of drug through temporary openings formed by shedding of two neighbouring epithelial cells into the lumen is referred as

a Primary active transport

b Endocytosis

c Facilitated- or mediated-diffusion

d Persorption

7 For majority of drugs that bind to extravascular tissues, the order of binding is:

a) Lung > Muscles > Liver > Kidney
b) Muscles > Lung > Liver > Kidney
c) Liver > Kidney > Lung > Muscles
d) Kidney > Liver > Lung > Muscles

8 _____is defined as the transport of drugs through the junctions between the gastrointestinal epithelial cells.

a) Passive diffusion
b) Active transport
c) Paracellular transport
d) Facilitated diffusion

9 The bioavailability of a drug from various dosage forms decreases in the following order

a) Solutions > Emulsions > Suspensions > Capsules > Tablets > Coated Tablets > Enteric Coated Tablets > Sustained Release Products.
b) Solutions > Tablets > Suspensions > Capsules > Emulsions> Coated Tablets > Enteric Coated Tablets > Sustained Release Products
c) Solutions > Emulsions > Suspensions > Capsules > Tablets > Coated Tablets > Sustained Release Products.> Enteric Coated Tablets
d) Solutions > Suspensions > Emulsions> Tablets > Capsules > Coated > Emulsions Tablets > Enteric Coated Tablets > Sustained Release Products

10 The application of pharmacokinetic principles to the design, conduct and interpretation of drug safety evaluation studies is known as

a) Bioequivalence study
b) Bioavailability Study
c) Pharmacokinetic Study
d) Toxicokinetic study

11 The packing material used as stationary phase in SPE cartridge is

a) Normal phase material

b) Reverse phase material

c) cationic phase material

d) Ionic phase material

12 ------ is a nonofficial dissolution method

a) Flow-through cell
b) Paddle method
c) Rotating Basket method
d) Rotating Disk method

13 One of the following is a method used for cell culture contamination control.

a) Using antibiotics at high concentrations
b) Maintaining aseptic techniques
c) Regularly changing media without monitoring
d) Exposing cultures to room temperature frequently

14 The area of solid surface exposed to the dissolution medium is referred to as _____.

a) Absolute Surface Area
b) Effective Surface Area
c) Total Surface area
d) Micronized Surface Area

15 Which of the following tetrazolium salt is used in MTT assay?

a) (1-(4,5 Dimethyl thiazol-2-yl)-2,5-Diphenyltetrazolium Bromide)
b) (3-(4,5 Dimethyl thiazol-2-yl)-2,5-Diphenyltetrazolium Bromide)
c) (2-(4,5 Dimethyl thiazol-3-yl)-2,5-Diphenyltetrazolium Bromide)
d) (3-(4,5 Dimethyl thiazol-2-yl)-1,5-Diphenyltetrazolium Bromide)

16 According to Biopharmaceutics Classification System (BCS), Class IV drugs have

a) Low solubility /High permeability
b) Low solubility /Low permeability
c) High solubility /Low permeability
d) High solubility/High permeability

17 Cell cycle analysis in cell culture based experiments is done by using the following ____

a) Flow cytometry
b) UV-Spectrophotometer
c) Centrifugation
d) Passaging of cells

18 Tissue-drug binding generally involves _____ bonds.

a) Weak ionic
b) Strong covalent
c) Non-covalent
d) Weak coordinate

19 PAMPA stands for _____ assay.
a) parallel absorption membrane permeability
b) parallel adsorption membrane permeability
c) parallel artificial membrane permeability
d) parallel artificial membrane assay

20 The following theories are related to the dissolution phenomenon except_____.
a) Interfacial theory
b) Film theory
c) Rittinger's theory
d) Surface renewal theory

Q. II Attempt any TWO questions **20 Marks**

1. a	Enlist the methods used in sample preparation in bioanalytical method development. Describe solid phase extraction as a sample preparation method	**5 marks**
1. b	Explain the methods used for evaluation of toxicokinetic in preclinical studies. Indicate the importance of toxicokinetic studies.	**5 marks**
2. a	Discuss the pharmacotechnical factors affecting absorption of drugs. Support your answer with suitable examples.	**5 marks**
2. b	Explain the principle and protocol of MTT assay. Discuss the applications of the same.	**5 marks**
3. a	Carrier-mediated transport follows mixed order kinetics. Predict if this statement is true or false, Justify your answer using suitable examples.	**5 marks**
3. b	Discuss genetic biologics with suitable examples.	**5 marks**

Q. III Attempt any SEVEN questions **35 Marks**

1.	Illustrate two merits and demerits each of protein precipitation and liquid –liquid extraction techniques in bioanalysis. Predict the schematic workflow of plasma sample using protein precipitation.	**5 marks**

2.	Explain in detail a suitable dissolution apparatus used for release studies of ophthalmic products.	**5 marks**
3.	Discuss the significance of protein/tissue binding of drugs.	**5 marks**
4.	Describe the various equipment used for conducting cell culture experiments.	**5 marks**
5.	Define relative and absolute bioavailability. Explain various methods for assessing bioavailability.	**5 marks**
6.	Explain the process of cryopreservation in cell culture based experiments.	**5 marks**
7.	Explain merits and demerits of HLM and RLM in assays.	**5 marks**
8.	Explain diffusion layer model theories for performing dissolution studies.	**5 marks**
9.	Explain the term Bioanalytical method validation? How will you conduct linearity, precision, specificity, and freeze thaw-stability studies?	**5 marks**
