Duration: 3 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	Options	
1	……..performed for newly developed bioanalytical methods or when additional analytes or metabolites are added for quantitation.	**a**	Partial validation
		b	Full validation
		c	Cross validation
		d	Concurrent validation
2	One of the common technique for sample preparation for bioanalysis is.	**a**	Solid phase extraction
		b	Sedimentation
		c	Distillation
		d	Filtration
3	The protein can be precipitated by addition of 10-20% ------.	**a**	Tri-chloroacetic acid
		b	Phenol
		c	Ethanol
		d	Ester
4	……the amount of drug from a formulation that reaches the systemic circulation	**a**	Relative Bioavailability
		b	Absolute Bioavailability
		c	Partial Bioavailability
		d	Full Bioavailability
5	A transport mechanism requiring energy is	**a**	Pore
		b	Passive
		c	Cellular
		d	Active

6	Most drugs are absorbed from the intestine due to	**a**	Large surface area
		b	Basic pH
		c	Greater degree of ionization
		d	Presence of unstirred layer
7	A disintegrant that decreases rate of absorption of a steroidal drug is	**a**	Avicel
		b	Veegum
		c	Starch Rx
		d	Microcrystalline cellulose
8	The rate at which drug reaches systemic circulation is determined by the slowest of the various steps involved in the sequence. This is known as……	**a**	Disintegration time
		b	Dissolution time
		c	Rate limiting step
		d	Gastric emptying time
9	Which tablets have longer Disintegration time?	**a**	Single coated tablets
		b	Sugar coated tablets
		c	Uncoated tablets
		d	Capsules
10	Which of the following best describes toxicokinetics?	**a**	The study of the toxic effects of chemicals on living organisms
		b	The study of the absorption, distribution, metabolism and excretion of toxic substances in the body
		c	The study of the interaction between toxic substances and cellular targets
		d	The study of the toxic effects of chemicals on the environment

11	Which of the following is NOT a phase of toxicokinetics?	**a**	Absorption
		b	Distribution
		c	Toxicity
		d	Excretion
12	The half life of a toxic substance refers to	**a**	The time required for the substance to be eliminated from the body
		b	The time required for the substance to reach its maximum concentration in the body
		c	The time required for the substance to be absorbed in the bloodstream
		d	The time required for the substance to cause toxic effects in the body
13	Culture freshly prepared from isolated tissue is known as _____	**a**	Organ Culture
		b	Primary culture
		c	Cell line
		d	Histotypic culture
14	Range of optimum glucose concentration present in the culture media is	**a**	5.5 to 55 mmol/lt
		b	55 to 75 mmol/lt
		c	75 to 105 mmol/lt
		d	105 to 150 mmol/lt
15	What are the main constituents of culture for animal cell growth?	**a**	Glucose and Glutamine
		b	Growth factors
		c	Cytokines
		d	Vitamins

16	What is the most important characteristic required for absorption of an orally administered drug?	**a**	Dissolution in hydrochloric acid
		b	Dissolution in alkaline conditions
		c	Formation of aggregates
		d	Passage through membranes
17	All of the following are advantages of buffered aspirin tablets, except	**a**	Increased ulcerogenic tendency
		b	Reduced gastric irritation
		c	Increased stability
		d	Enhanced absorption
18	Term bioavailability refers to	**a**	The fraction of an administered dose that reaches systemic circulation
		b	The elimination of toxic substances from the body
		c	The distribution of toxic substances within the body
		d	The rate at which toxic substances are absorbed into the blood stream
19	The comparison of bioavailability between two dosage forms.	**a**	Bioequivalence
		b	Biological
		c	Biopharmaceutics
		d	Bioavailability
20	Bioavailability of an intravenous drug is always 100% by definition because:	**a**	Bioavailability measures the amount of substance that reaches the bloodstream.
		b	Absolute bioavailability is 50%, for any drug taken intravenously
		c	Absolute bioavailability is a much more
		d	Absolute bioavailability is a much less

Q. II	**Attempt any TWO questions.**	**20**
1. a	Enlist different methods of extraction of drugs from plasma. Explain any one in detail.	**5**
1. b	Explain the general principles of toxicokinetics.	**5**
2. a	How do drug dissolution, polymorphism, salt form, lipophilicity and particle size of a drug affect its absorption? Give suitable examples.	**5**
2. b	Write a note on various equipment used for conducting cell culture experiments.	**5**
3. a	What is the modified Noyes Whitney Equation? Explain how the various parameters affect the dissolution of the drug.	**5**
3. b	Discuss the design and evaluation of Bioequivalence studies.	**5**
Q. III	**Attempt any SEVEN questions**	**35**
1.	Explain the terms: a. Partial Validation b. Full Validation c. Cross Validation.	**5**
2.	Enlist dissolution rate testing apparatus official in the USP with an example of the dosage form to be evaluated in each of them.	**5**
3.	Write about toxicokinetics in the preclinical stage	**5**
4.	Describe procedure for cryoprotection.	**5**
5.	List the methods to determine bioavailability of a drug. Describe any two	**5**
6.	Discuss the application of animal cell culture to the field of pharmacy.	**5**
7.	Write a short note on application of toxicokinetics	**5**
8.	Explain diffusion layer model theories for performing dissolution studies.	**5**
9.	What do you understand by the term Bioanalytical method validation? How will you conduct Accuracy, Precision, matrix effect, and Freeze thaw-stability.	**5**

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