D. Ceutics

Q. P. Code : 96033

Semester Examination- FH2022 (Academic Year 2021-2022)
M. Pharm Sem II (Choice based R2019)
Subject: Advanced Biopharmaceutics and Pharmacokinetics

Total Marks: 80

Time: 3 hours

Q. 1 Attempt all multiple-choice questions (MCQ) **20M**

Sr No	Questions		Options
1	The movement of drug between one compartment and another (extravascular tissue) is called	a	Distribution
		b	Disposition
		c	Elimination
		d	Binding
2	Transfer of drug from plasma to tissue depends on	a	Size of tissue
		b	Weight of tissue
		c	Blood perfusion rate of tissue
		d	Gastric emptying rate
3	Absorption mechanism through rectal route is	a	Passive diffusion
		b	Endocytosis
		c	Facilitated diffusion
		d	Pore transport
4	Dissolution rate is the amount of solid substrate that goes into solution under	a	constant time under standard temperature, pH, solvent composition and constant surface area
		b	constant time
		c	constant time under standard Temperature
		d	constant time under standard temperature, pH, and pressure
5	Interfacial barrier model is also known as	a	Limited solvation theory
		b	Danckwert model
		c	Noyes–Whitney Relationship
		d	Hixon–Crowell Cube Root Law
6	Which of these drugs binds to B2 Globulin?	a	Steroids
		b	Carotenoids
		c	Vitamin A,D,E,K
		d	Ferrous ions
7	A bioequivalent product	a	has equivalent therapeutic index
		b	has equivalent excipients
		c	is therapeutically equivalent

		d	is chemically equivalent
8	What is the correct order of bioavailability of different dosage forms?	a	Emulsion > Solutions > Tablet > Capsules > SR Tablet
		b	Solutions > Emulsion > Capsules > Tablet > SR Tablet
		c	Emulsion > Solutions > Capsules > Tablet > SR Tablet
		d	Solutions > Emulsion > Tablet > Capsules > SR Tablet
9	Select the formula for the calculation of the loading dose of a drug while formulating prolonged release formulation.	a	[Concentration at steady state X Dosing interval] / Fraction bioavailable
		b	[Concentration at steady state X Elimination rate constant] / Fraction bioavailable
		c	[Concentration at steady state X Apparent volume of distribution] / Fraction bioavailable
		d	[Concentration at steady state X Systemic clearance] / Fraction bioavailable
10	What would be the appropriate drug release profile of a controlled release formulation comprising of both the loading and maintenance dose?	a	First order release
		b	Initial rapid release followed by first order release
		c	Zero order release
		d	Initial rapid release followed by zero order release
11	What involves the engulfment of small molecules or fluid?	a	Pinocytosis
		b	Exoocytosis
		c	Phagocytosis
		d	Pore transport
12	Select the equation that gives the rate of drug dissolution from a tablet	a	Handerson Hasselbatch equation
		b	Michelis Menten equation
		c	Noyes Whitney equation
		d	Fick's law
13	Which form has maximum solubility?	a	Hydrous
		b	Crystalline
		c	Monohydrate
		d	Anhydrous
14	The rate of absorption of a steroidal drug is decreased by the excipient	a	Avicel

		b	Microcrystalline cellulose
		c	Veegum
		d	Starch Rx
15	Under compartment modeling, Wegner-Nelson-Method involves	a	Determination of absorption rate constant (Ke) from %ARA Vs Concentration curve
		b	Determination of plasma half life
		c	Determination of absorption rate constant (Ka) from %ARA Vs time curve
		d	Determination of elimination rate constant (Ke) from % ARA Vs time curve
16	Which is not a parameter for measuring bioavailability using urinary excretion data	a	(dDu/dt)max
		b	t_{∞}
		c	Du_{∞}
		d	Cmax
17	For a ANDA product, which of the following is not done	a	comparison of extent of absorption with standard product
		b	comparison of rate of absorption with standard product
		c	efficacy studies
		d	dissolution test
18	Which of following drug shows non-linearity in hepatic elimination?	a	Carbamazepine
		b	Propranolol
		c	Penicillin
		d	Thiopental
19	Carbon tetrachloride and ethanol are individually toxic to the liver, but together they produce much more liver injury than the sum of their individual effects on the liver. This is commonly referred to as	a	Antagonism
		b	Synergism
		c	Summation
		d	Addition
20	Pharmacodynamic interactions affect	a	Plasma concentration and activity of a drug
		b	Metabolism of a drug and its distribution
		c	Activity of a drug and not plasma concentration
		d	Protein binding of a drug

Q 2. Attempt any one question: **12M**

i. Explain effect of any four drug related factors affecting its absorption, with suitable examples. 12M

ii. a.) Write a note on protein binding and its effect on Pharmacokinetics. 6M

b.) An intravenous bolus dose of 60 mg of a drug following one compartment kinetics has a half-life of 6 hours and volume of distribution of 24 litres. Calculate : 6M

1) Concentration at zero hours, elimination rate constant 1M
2) Clearance, AUC (zero to infinity) 1M
3) The percent dose remaining in the body after 20 hours 2M
4) Time required to eliminate 75% of the dose 2M

Q 3. Attempt any four questions : **48M**

i a.) Enlist the dissolution apparatus as per USP. Discuss USP dissolution apparatus type I. 6M

b.) What are the levels of IVIVC? Give its applications. 6M

ii. a.) What are the elements of a Bioequivalence study protocol? 6M

b) How are drugs classified according to the Biopharmaceutical Classification System? 6M

iii. a,) Describe the active transport processes of drug absorption. 6M

b.) How do manufacturing variables affect dissolution of a drug from its dosage form? 6M

iv. a.) Explain how non-linearity is observed in pharmacokinetics with respect to the processes of distribution and excretion with suitable examples. 6M

b.) Differentiate between parallel and crossover designs for bioequivalence studies. 6M

v. a) Explain how Biotechnological drugs exhibit their pharmacokinetics. 6M

b,) What are the considerations in development of targeted drug delivery systems? 6M
