Question Paper

Exam Date & Time: 23-May-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Biopharmaceutics and Pharmacokinetics (Theory) [PCE-BP604T -S1]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Drugs that bind to extravascular tissues show ---------- (1)

- Small apparent volume of distribution
- Large apparent volume of distribution
- Volume of distribution equal to real volume of distribution
- Volume of distribution depends on the nature of API

2) ---------- conjugation reaction is used to evaluate hepatic function. (1)

- Glucuronic acid
- Sulphate
- Glycine
- Glutathione

3) What is the mechanism of drug excretion for skin excretion? (1)

- Ionic transport
- Pore transport
- Active process
- Passive process

4) Which of the following will not be a parameter that should be examined for urinary excretion data? (1)

- $(dX_u/dt)_{max}$
- $(t_u)_{max}$
- X_u
- C_{max}

5) Which of the in vitro-in vivo correlation levels show highest category of correlation? (1)

- Level D
- Level B
- Level A
- Level C

6) If period 1 drug product and/or its metabolites induce physiological changes in the animal _____ method is preferred for bioequivalence studies. (1)

- Cross over design
- Partial replicate cross over design
- Parallel design
- Full replicate cross over design

7) Extrapolation of animal study data of pharmacokinetics of drug to humans is possible by (1)

- Catenary model
- Mammillary model
- Physiologic model
- Compartment model

8) Following pharmacokinetic parameter is calculated from the ratio of AUMC to AUC in statistical moments theory (1)

- Mean elimination time
- Mean distribution time
- Mean residence time
- Mean metabolism time

9) What kinetics of drug release is mainly followed when it is administered as Intravenous infusion? (1)

- Zero order
- First order
- Second order
- Mixed order

10) Highly perfused tissues and organs in compartment pharmacokinetic model are included into (1)

- First compartment
- Second compartment
- Third compartment
- Fourth compartment

11) All peripheral compartments are well connected to central compartment in (1)

- Catenary model
- Mammillary model
- Physiologic model
- Noncompartmental analysis

12) In IV bolus administration of drug following two compartment open model, the Initial faster decrease in the drug levels is mainly due to (1)

- Absorption and Distribution

Absorption and Elimination
Distribution and Elimination
Absorption and Excretion

13) Duration required to attain steady state drug levels following multiple administrations with half-life as the dosing interval: (1)

One half-life
Two half-lives
Three half-lives
Five half-lives

14) When the dosing interval is increased and the dose is unchanged in multiple dosing, Cmax, Cminand Cav (1)

Decrease
Increase
Increase and then decrease
Decrease and then increase

15) Following kinetics is observed in nonlinear pharmacokinetics at very low concentration or dose of drug (1)

Zero order kinetics
First order kinetics
Second order kinetics
None of the above

16) When tubular reabsorption of the drug becomes capacity limited renal clearance (1)

Decreases
Increases
Remain constant
Increase and then decrease

17) Mechanism of drug absorption that can cause nonlinearity (1)

Passive diffusion
Pore transport
Active transport
Convective transport

18) Zero order kinetics in the rate of change of drug concentration in nonlinear pharmacokinetics is attained when (1)

Km value is very high than concentration of drug

Km value is very less than concentration of drug
Km value and concentration of drug are equal
All of the above

19) Nonlinear pharmacokinetics of a drug follows (1)

First and second order kinetics
Zero and second order kinetics
Zero and first order kinetics
Zero, first and second order kinetics

20) Apparent volume of distribution _____ when tissue binding of drug gets saturated (1)

Increases
Decreases
Remain constant
Increase and then decrease

II Long Answers

Answer all the questions.

1) Discuss kinetics of Protein-Drug binding. (10)

2) Explain the pharmacokinetics of drug in blood upon extravascular administration of drug if it follows one compartment open model (10)

III Short Answers

Answer all the questions.

1) Write a short note on drug absorption by Passive diffusion. (5)

2) Briefly explain the features of phase I bio-transformation reactions. (5)

3) Describe rotating paddle dissolution apparatus. (5)

4) Describe the application of method of residuals in TWO compartment open model with IV bolus administration of the drug? (5)

5) Using suitable diagrams, explain the effects of dose size and dosing interval on the pharmacokinetic profile of drug in multiple dosing by oral administration? (5)

6) Discuss the sources of nonlinearity from drug absorption and drug distribution. (5)

7) Describe the kinetics of nonlinear pharmacokinetics using Michaelis Menton equation. (5)

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