

Fourth Prof. A/2015
Examination: Doctor of Pharmacy (Pharm.D.)

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Subject: Pharmaceutics-VII (Biopharmaceutics)

PAPER: 4

TIME ALLOWED: 3 hrs.

MAX. MARKS: 100

Q. 1	a)	Define the following terminologies: I) Pharmaceutical equivalent II) Population Pharmacokinetics III) Mammillary model IV) Area under the first moment of curve V) Disposition Kinetics	10 Marks
	b)		10 Marks
Q. 2	a)	Describe the volume of distribution.	10 Marks
	b)	Discuss the types of proteins involved in drug protein binding. Explain clinical significance of plasma protein binding.	10 Marks
Q. 3	a)	What is the difference between Phase I and Phase II reactions? Describe phase II biotransformation reactions with at least one example.	14 Marks
	b)		6 Marks
Q. 4	a)	What are the parameters required for determination of one compartment open model after oral administration?	8 Marks
	b)		12 Marks
Q. 5	a)	Role of Biopharmaceutics in dosage form design?	15 Marks
	b)	Define bioavailability. Discuss different rate limiting steps in drug absorption.	5 Marks
Q. 6	a)	What is the biological half life? Describe the significance and the factors affecting half life.	10 Marks
	b)		10 Marks
Q. 7		Explain following terms briefly: I) Trapezoidal method II) Body clearance III) Bioavailability measurement using blood data	5+6+9 Marks



Fourth Prof. A/2016
Examination: Doctor of Pharmacy (Pharm.D.)

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Subject: Pharmaceutics-VII (Biopharmaceutics)

PAPER: 4

TIME ALLOWED: 3 hrs. MAX. MARKS: 100

			5 Marks
Q1	a)	Define the following terms:) Marks
		i) Absolute biognailability ii) Bioequivalent products	
		iii) Closed compartment iv) Steady state concentration	
		v) Pharmaceutical equivalents	1516
	b)	Discuss the importance of physicochemical nature of drugs in drug	15 Marks
	-	absorption through gastrointestinal tract.	
		AND CONTROL OF THE CO	4+4 Marks
Q2	a)	What is the sampling compartment for measuring drug concentration? Why	4+4 Marks
	1110	drug concentration cannot be measured at the receptor site?	12 Marks
	b)	Describe the measurement of bioavailability using the urine data.	12 Marks
			12 Marks
Q3	a)	Describe, with illustration the method used to calculate the rate for	12 Iviaiks
		distribution in two compartment open model after I/V administration.	8 Marks
	b)	What are compartment models? Write down the Pharmacokinetic	o wans
		parameters of non-compartmental analysis.	
		William Annual IV infusion? Describe the	15 Marks
Q4	a)	Which drug types are given through I/V infusion? Describe the	
		Pharmacokinetics parameters necessary for determination of I/V infusion?	5 Marks
	b)		
		drug administration.	
O.F	- 1	What is apparent volume of distribution? Discuss it significance.	6 Marks
Q5	a)	to the determination of one	14 Marks
	b)	compartment open model after oral administration?	
		compartment open model after of a desirable	
Q6	a)	Explain which proteins are available in body for drug binding. Describe the	6+4 Marks
Qu	aj	significance of protein binding.	
	b)		10 Marks
	Uj	II biotransformation reactions with at least one example.	
		II VIOLINIO VIII VIII VIII VIII VIII VIII VIII	
Q7		Write short notes on the following:	6+6+8
Α,		i) Mammillary and Catenary Models ii) Renal Clearance	Marks
		iii) Pharmacokinetics applications in age-based dose adjustment	



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Subject: Pharmaceutics-VII (Biopharmaceutics)

PAPER: 4

TIME ALLOWED: 3 hrs. MAX. MARKS: 100

Q1	a)	Define the following terms: i) Persistence factor. ii) Drug disposition. iii) Therapeutic equivalents. iv) Bioequivalence.	5 Marks
	b)	 v) Mammillary model. What is Bioavailability? Describe briefly different Pharmaceutical factors affecting the bioavailability of drugs. 	15 Marks
Q2	a)	Describe the measurement of bioavailability using the blood data.	8 Marks
	b)	How is the absorption rate constant determined in two compartment open model after oral administration? Demonstrate with illustration.	12 Marks
Q3	a)	What is therapeutic drug monitoring? Describe the process of Therapeutic drug monitoring.	2+6 Marks
	b)	What is Biopharmaceutics? How does Biopharmaceutics affect the dosage form design?	12 Marks
Q4	a)	What is the sequence of biotransformation reactions? What are the changes brought about in drug molecules during Phase I and II reactions?	3+3 Marks
	b)	What is the first pass effect? Describe Phase I biotransformation reactions with at least one example.	4+10 Marks
Q5	a)	Explain the difference between drug clearance and drug excretion.	6 Marks
	b)	Describe protein binding. Describe the kinetics of protein binding.	14 Marks
Q6	a)	Which categories of drugs are given through I/V infusion? Describe the Pharmacokinetics parameters to determine I/V infusion?	3+12 Marks
	b)	Describe volume of distribution. Why is it is called as "apparent?	5 Marks
Q7		Write short notes on the following:	6+8+6
ν,		i) Trapezoidal method iii) Hepatic clearance	Marks



Fourth Prof: A/2017 Examination: Doctor of Pharmacy (Pharm.D.) Roll No. ...

Subject: Pharmaceutics-VII (Biopharmaceutics)

PAPER: 4

TIME ALLOWED: 3 hrs.

MAX. MARKS: 100

		AND BY AND		
Q1	a)	Define the following		5 Marks
		 i) Therapeutic alternatives ii) 	Bioequivalence	
		iii) Open compartment iv) Mamillary model	
		v) Pharmaceutical substitution		
	b)	Describe what types of physicochemical fa	ctors are considered in dosage	15 Marks
		form design.	and the angle of the company of the	
Q2	a)	Discuss how does the Noyes-Whitney equa	tion explain factors for	08 Marks
		dissolution.		
	b)	Describe the measurement of bioavailabilit	y using urine data.	12 Marks
Q3	a)	Describe, with illustration role of residual r	nethod in calculation of	12 Marks
		distribution rate in two compartment open	model after I/V route.	
	b)	Describe the proteins available for binding		5+3 Marks
		significance of protein binding?.		
Q4	a)	Discuss apparent volume of distribution. W	hy is it called as apparent?	4+2+2
		Discuss the significance of volume of distri		Marks
	b)	Describe the calculation of parameters for o		12 Marks
		after oral administration?		
Q5	a)	Which are the categories of drugs given thr	ough I/V infusion? Describe the	12 Marks
		Pharmacokinetics parameters required for o	letermination of I/V infusion?	
	b)	Describe the factors affecting blood drug	concentration during multi-dose	08 Marks
		drug administration.		
Q6	a)	Describe non-linear pharmacokinetics		10 Marks
	b)	£	II biotransformation reactions	2+8 Marks
		with at least one example.		
Q7		Write short notes on the following:		6+5+9
			ose adjustment in renal diseases	Marks
		iii) Conditions requiring therapeutic drug n	nonitoring	
			9 17 17	



Fourth Prof: 2nd Annual - 2017 Examination: Doctor of Pharmacy (Pharm.D.) Roll No.

Subject: Pharmaceutics-VII (Biopharmaceutics)

PAPER: 4

TIME ALLOWED: 3 hrs. MAX. MARKS: 100

Q1	a)	Define the following: i) Therapeutic equivalents ii) Closed compartment iii) Pharmaceutical alternatives iv) Catenary model v) Pharmacokinetics	5 Marks
	b)	Describe how does biopharmaceutics effect design of dosage forms	15 Marks
Q2	a) b)	Discuss how do dissolution requirements meet with USP specifications? Discuss design and evaluation of bioequivalence studies.	8 Marks 12 Marks
Q3	a) b)	Describe the process of therapeutic drug monitoring. How is the distribution rate constant determined in two compartment oper model after oral administration? Demonstrate with illustration.	8 Marks en 12 Marks
Q4	a)	What is the significance of I/V infusion? How are steady sta concentration (Css), Pre-Css, Post-Css, Elimination rate and Half life a computed for I/V infusion?	
	b)	Briefly describe protein binding. What is the significance of proteinding	in 3+2 Marks
Q5	a) b)	Explain the difference between drug clearance and drug excretion. What is non-linear pharmacokinetics? How does it differ from oth kinetic orders? What is its impact on Pharmacokinetics.	8 Marks er 4+4+4 Marks
Q6	a)	What are the roles of biotransformation? What are the changes brought about in drug molecules during Phase I and II reactions?	3+3 Marks
	b)	What is the extraction ratio? What is its importance? Describe the factor affecting biotransformation.	s 3+3+8 Marks
Q7		Write short notes on the following: i) Dose consideration in hepatic diseases ii) IVIVC iii) Flip-flop model	5+10+5 Marks

Fourth Prof: Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics) (New Course)

PAPER: 4 (Part - II)

Roll No.	 	 	•••	 ••••	:
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TIME ALLOWED: 2 Hrs. & 30 min. MAX. MARKS: 80

Attempt this Paper on Separate Answer Sheet provided.

Attempt any 4 questions. Each question carry equal marks.

	Q1	a)	Describe how does biopharmaceutics affect design of dosage forms.	15 Marks
	Q1	b)	What are different patient-related factors which influence drug absorption?	5 Marks
	1,	,		-
	Q2	a)	Describe the process of therapeutic drug monitoring.	8 Marks
	~-	b)	Illustrate and give steps to determine the distribution rate constant in two compartment open model after oral administration?	12 Marks
	Q3	a)	How are steady state concentration (C _{ss}), Pre-C _{ss} , Post-C _{ss} , Elimination rate and Half-life are computed for I/V infusion after one compartment model?	10 Marks
		b)	Describe different designs of Dosage Regimens?	10 Marks
	Q4	a)	Explain the difference between drug clearance and drug excretion.	8 Marks
V	Q4	b)	What is non-linear pharmacokinetics? How does it differ from other kinetic orders? What is its impact on Pharmacokinetics?	4+4+4 Marks
	Q5	a)	Define IVIVC. Describe its significance.	2+6 Marks
	Q5	b)	a stal approach? Describe trapezoidal method for	2+6+4 Marks
	Q6		Write short notes on the following:	8+8+4
	Q0		i) Factors influencing drug variability ii) pH-partition theory iii) Flip-flop model	Marks



Roll No.

Fourth Prof: Annual – 2018
Examination: Doctor of Pharmacy (Pharm.D.)

Subject: Pharmaceutics-V (Biopharmaceutics &

Pharmacokinetics) (New Course)

PAPER: 4 Part - I (Compulsory)

TIME ALLOWED: 30 min. MAX. MARKS: 20

Attempt this Paper on this Question Sheet only.

Please encircle the correct statement. Each MCQ carries 1 Mark. This Paper will be collected back after expiry of time limit mentioned above.

1. Lag-time is the time needed for a drug to reach at:

(A. lower therapeutic blood level (B. measurable level in blood (C. maximum effect after intake (D. level to start pharmacological response

2. Protein binding causes transitorily:

(A. increased drug potency (B. elevated metabolism (C. drug inactivation (D. increased pharmacological effect

3. Change in rate of drug absorption changes values of pharmacokinetics parameter:

(A. Cmex (B. Tmex (C. area under the curve (D. half life

4. Change in extent of absorption alters the value of:

(A. area under the curve (B. T_{max} (C. rate of absorption (D. all A, B and C

5. Tissue or group of tissues, in compartmental approach is considered as:

(A. compartment I (B. central compartment (C. peripheral compartment (D. accessible compartment

- Drug products containing the same therapeutic moiety but different salts, dosage forms or strengths are:
 (A. pharmaceutical equivalents (B. pharmaceutical alternatives (C. therapeutic alternatives (D. therapeutic equivalents)
- Comparative areas under the curves (AUCs) after oral and I/V administration is called: (A. absolute bioavailability (B. bioequivalence (C. relative bioavailability (D. Bioavailability)

In equation, C_i = Be^{-βt}, β is:

(A. theoretical initial concentration (B. y-intercept (C. last concentration (D. slope of the curve

- Number of compartment is decided from the following portion of the plasma level time profile: (A. disposition curve (B. elimination curve (C. distribution curve (D. absorption curve
- 10. Method of residual in 2 compartment open model after I/V administration is used to calculate: (A. absorption rate (B. distribution rate (C. elimination rate (D. y-intercept of extrapolated curve)

11. Which of the following is NOT relevant for AUMC? AUMC is a:

(A. zero moment (B. parameter indicating absorption (C. non-compartmental parameter (D. statistical moment

- 12. The equation, $C_t = Ae^{-u.t} + B^{-\beta.t}$ calculates unknown concentration at any time in:
 - (A. I compartment model after IV administration (B. 2 compartment model after I/V administration

(C. 2 compartment model after E/V administration (D. 1 compartment model after E/V administration

- 13. Therapeutic drug monitoring is necessary in following situations EXCEPT when a drug has: (A. narrow therapeutic index (B. non-linear pharmacokinetics (C. concentration in blood, unrelated to clinical outcome (D. large individual variation in blood concentration)
- 14. The major parameter(s) in establishing a dosage regimen is/are:

(A. size of drug (dose) (B. administration frequency (τ) (C. C_{max} (D. both A and B

- 15. The aim of multiple dose is to achieve drug concentration which provides the following EXCEPT: (A. no drug accumulation (B. minimum fluctuations (C. increased bioavailability (D. maintained concentration)
- A drug showing poor solubility and poor permeability belongs to biopharmaceutical classification system:
 (A. Class I (B. Class II (C. Class III (D. Class IV)
- 17. In multiple dosing, higher accumulation of drug is expected if a drug has:

(A. smaller rate of elimination (B. longer half life (C. smaller clearance (D. all A, B, and C

- 18. Which drug is more soluble in intestine by forming a soluble salt at more alkaline pH? (A. Acidic (B. Neutral (C. Basic (D. Chelate
- 19. The amount of solid substance that goes into solution per unit time under standard conditions is: (A. dissolution (B. solubility (C. disintegration (D. miscibility
- 20. Method of residual in 2-compartment model after IV administration resolves plasma level curve into:
 (A. 1-linear phase (B. 2-linear phases (C. 1-linear and 1-nonlinear phase (D. 2-non-linear phase



Fourth Prof: 2nd Annual – 2018

Examination: Doctor of Pharmacy (Pharm.D.)

Roll No. ...

MAX. TIME: 2 Hrs. 30 Min. MAX. MARKS: 80

Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics) (New Course)

PAPER: 4 Part-II

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Attempt any FOUR questions. All questions carry equal Marks

Q1	a)	The state of the s	14 Marks
	b)		06 Marks
Q2	a)	The state of the s	12 Marks
	b)		5+3 Marks
Q3	a)		4+2+2 Marks
	b)		12 Marks
Q4	a)	Describe calculation of the Pharmacokinetics parameters required for determination of I/V infusion assuming one compartment model?	12 Marks
	b)		08 Marks
Q5	a)	Describe non-linear pharmacokinetics	10 Marks
	b)	Describe first pass effect? Explain Phase II biotransformation reactions with at least one example.	2+8 Marks
Q6		Write short notes on the following:	4+8+8
- CTURE		i) Mean residence time (MRT) ii) Level A correlation iii) Desage considerations in elderly and obese patients	Marks
	Q2 Q3 Q4	b) Q2 a) b) Q3 a) b) Q4 a) b) Q5 a) b)	form design. b) Discuss how does the Noyes-Whitney equation explain factors for dissolution. Q2 a) Illustration with steps the role of residual method for calculation of distribution rate constant in two compartment open model after I/V route. b) Describe the proteins available for binding of drugs. What is the significance of protein binding? Q3 a) Discuss apparent volume of distribution. Why is it called as apparent? Discuss the significance of volume of distribution. b) Describe the calculation of parameters for one compartment open model after oral administration? Q4 a) Describe calculation of the Pharmacokinetics parameters required for determination of I/V infusion assuming one compartment model? b) Describe Persistence Factor, Accumulation Factor and Loss factor during multiple dosing. Q5 a) Describe non-linear pharmacokinetics b) Describe first pass effect? Explain Phase II biotransformation reactions with at least one example. Q6 Write short notes on the following: i) Mean residence time (MRT) ii) Level A correlation



Fourth Prof: 2nd Annual – 2018
Examination: Doctor of Pharmacy (Pharm.D.)

Roll	No.	in F	ig.	•••••	
1	Roll	No.	in	Words.	

Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics) (New Course)

PAPER: 4 Part - I (Compulsory)

MAX. TIME: 30 Min. MAX. MARKS: 20

Signature of Supdt.:

Attempt this Paper on this Question Sheet only.

Please encircle the correct option. Division of marks is given in front of each question.

This Paper will be collected back after expiry of time limit mentioned above.

Q.1. Encircle the right answer cutting and overwriting is not allowed.

(1x20=20)

1. Tetracycline phosphate and tetracycline HCl are:

(A. therapeutic equivalents (B. therapeutic alternatives (C. pharmaceutical alternatives (D. pharmaceutical equivalents

2. Ratio of $AUMC_{\theta-\infty}$ to $AUC_{\theta-\infty}$ is:

(A. mean resident time (B. average concentration (C. relative bioavailability (D. persistent factor

3. Two independent compartments connected to a central compartment is a model called:

(A. open model (B. flip-flop model (C. catenary model (D. mammillary model

4. The following is NOT the feature of non-compartmental model. The non-compartmental models are: (A. assumption free (B. require algebraic equations (C. applicable only to non-linear PK (D. not requiring curve litting)

5. The theoretical initial drug concentration in 1-compartment model after I/V administration is equal to: (A. concentration at last time (B. y-intercept (C. zero (D. summation of y-intercepts, A and B

6. The compartment models have the features EXCEPT.

(A. assume concentration as statistical distribution (B. concentration time data is the expression of exponents (C. requires tedious computation (D. assume that data follow first order kinetics

7. The parameters required to proclaim bioequivalence between two dosage forms of a single drug are:

(A. AUC and t_{1/2} (B. C_{max} and K_{el} (C. C_{max} and Cl_T (D. AUC, C_{max} and T_{max}

8. Following is not applicable to blood drug concentration data following Michaelis-Menten's kinetics?

(A. Equations for the linear Pharmacokinetics (B. Concept of compartment model (C. Enzyme kinetics theory (D. Maximal rate of elimination

 A drug showing good solubility and poor permeability belongs to Biopharmaceutical Classification System: (A. Class I (B. Class II (C. Class III (D. Class IV)

10. Flip flop kinetics is observed when:

(A. $K_a > K_{el}$ (B. $K_{el} > K_a$ (C. $K_a = K_{el}$ D.) None of A, B and C

11. According to pH-partition theory, the following drug is more absorbable:

(A. ionized (B. unionized (C. hydrophilic (D. highly charged

12. Protein binding affects:

(A. lag time (B. absorption (C. volume of distribution (D. All A, B and C

13. In the equation, Y=b+mx, m represents:

(A. concentration or parameter on y-axis (B. slope of the curve (C. y-intercept (D. time

14. Which of the drugs mostly binds to albumin?

(A. basic (B. anionic (C. acidic (D. nonionic

15. The two phases of decline elimination on Michaelis Menten kinetics plot correspond to:

(A. first order-zero order (B. zero order-zero order (C. first order-first order (D. zero order-first order

16. The total drug excreted in urine is the amounts:

(A. filtered + secreted - reabsorbed (B. filtered + secreted + reabsorbed (C. filtered - secreted + reabsorbed (D. filtered - secreted - reabsorbed

17. The systemic absorption of a drug, given via intravascular route is:

(A. 1% (B. 100% (C. 50% (D. 75%

348. For very poor aqueous soluble drug, the rate limiting step is:

(A. dissolution (B. rate of dissolution (C. rate of absorption (D. both A and B

19. The time a drug takes to reach minimum effective concentration is:

(A. lag time (B. time to reach steady state concentration (C. onset time of action (D. time for duration of action

20. Volume of distribution is a parameter for:

(A. distribution (B. metabolism (C. absorption (D. excretion

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Fourth Prof: 2nd Annual – 2018 Examination: Doctor of Pharmacy (Pharm.D.)

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Subject: Pharmaceutics-VII (Biopharmaceutics) (Old Course)

MAX. TIME: 3 Hrs. MAX. MARKS: 100

PAPER: 4

III) Loss factor IV) Steady state concentration	
V) Area under the first moment curve (AUMC) What is relative bioavailability? Briefly describe how bioavailability of a drug is determined using urine data.	0 Marks
Q. 2 a) Define dissolution. Describe how dissolution requirements meet with the USP-NF specifications?	10 Marks
	10 Marks
	3+2+9 Marks
	6 Marks
Q. 4 a) What is apparent volume of distribution? Describe significance of the volume of distribution	12 Marks
b) Discuss the pharmacokinetic changes occurred during hepatic impairments and the dose adjustment in hepatic impairment.	8 Marks
Q. 5 a) Describe the open and closed compartment models. Which compartment model is logical in pharmacokinetics?	6 Marks
	14 Marks
	10 Marks
 b) Discuss pharmacokinetics of intravenous infusion and calculate elimination rate constant of IV infusion. 	10 Marks
Q. 7 Write note on the following:	8+4+8
Flip-flop model II) Trapezoidal method Mammillary and catenary models	Marks

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual–2019

Roll No. in Words.

Signature of Supdt.:

Roll No. in Fig.

Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics)

Paper: 4 Part - I (Compulsory)

(New Course)

Time: 30 Min. Marks: 20

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.

Division of marks is given in front of each question.

This Paper will be collected back after expiry of time limit mentioned above.

(20x1=20)

Q.1. Encircle the correct option.

1. To be soluble, a drug must be: (A. unionized (B. with similar pH to environment (C. lipophilic (D. ionized

2. The difference between the times for a drug to reach MEC and then decline back to MEC is:

(A. onset of action (B. action duration (C. intensity of action (D. therapeutic window

3. Therapeutic drug monitoring is applicable when a relationship exists between drug concentration in: (A. receptor and drug action (B. receptor and toxic effects (C. tissue and toxic effects (D. blood and adverse

4. Different classes of drugs but with similar indications are:

(A. pharmaceutical equivalent (B. pharmaceutical alternative (C. therapeutic alternative (D. therapeutic

5. The following statement is true for non-compartmental pharmacokinetic approach, it: (A. does not require non-linear regression (B. requires detailed description of disposition (C. is sensitive to sampling intervals (D. estimates distribution rate constants

6. The following statement is NOT true for compartmental pharmacokinetic approach, it is: (A. based on first order kinetics (B. majorly assumption based (C. solved by simple algebraic equations

(D. equally applicable to linear and non-linear pharmacokinetics

Individualization of dose regimen is implemented for drugs EXCEPT that:

(A. have narrow therapeutic window (B. follow non-linear pharmacokinetics (C. exhibit relationship between plasma concentration and clinical effect (D. have narrow inter- and intra- subject variability

8. Linear pharmacokinetics has the characteristics, EXCEPT:

(A. it follows 1st order kinetics (B. increased dose corresponds to increased peak concentration (C. increased dose causes proportionally increased area under the curve (D. elimination deviates the exponential decline

9. In calculating AUC for model, C, = Ae hat + Be-ft, the first concentration in plasma is equivalent to:

(A. zero (B. y-intercept (C. concentration at YI on plasma time cure (D. concentration at Y2 on plasma time cure 10. Change in rate of absorption alters the value of:

(A. AUC (B. Tmax) (C. Cmax (D. all A, B and C

11. In IVIVC, the level B correlation:

(A. is point to point (B. reflects biowaiver (C. drug dissolution reflects absorption (D. uses mean from entire data

12. Tissue or group of tissues, in compartmental approach is considered as:

(A. compartment I (B. central compartment (C. peripheral compartment (D. accessible compartment

13. Number of compartments is decided from the following portion of the plasma level time profile:

(A. disposition curve (B. elimination curve (C. distribution curve (D. absorption curve

14. Method of residual in 2 compartment open model after I/V administration is used to calculate: (A. absorption rate (B. distribution rate (C. elimination rate (D. absorption half life

15. AUC is NOT:

(A. non-compartmental parameter (B. absorption parameter (C. first moment (D. calculated by trapezoidal rule

16. A drug showing poor solubility and high permeability belongs to biopharmaceutical classification system: (A. Class I (B. Class II (C. Class III (D. Class IV

17. The amount of solid substance that goes into solution per unit time under standard conditions is:

(A. dissolution (B. salubility (C. disintegration (D. miscibility

18. Method of residual in 2-compartment model after IV administration resolves plasma level curve into: (A. I linear phase (B. 2 linear phases (C. I linear and I nonlinear phase (D. 2 non-linear phases

19. In IV infusion, increase in blood concentration does NOT depend on:

(A. half-life (B. Css value (C. absorption rate (D. elimination rate

20. Half-life depends on:

(A. clearance (B. volume of distribution (C. peak concentration (D. Both A and B

Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual-2019

Roll No.

Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics) (New Course)

Paper: 4 Part - II

III) Non-linear Pharmacokinetics

Time: 2 Hrs. 30 Min. Marks: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any FOUR questions. Each question carries equal marks.

Q 2 a) Describe how do pharmaceutical factors affect drug bioavailability? 14 Marks b) What is the sampling compartment from where drug concentration is 3+3 Marks measured most frequently? Give the reasons why concentration is not measured from the receptor compartment? Q 3 a) Describe the determination of bioavailability using urine data. 8 Marks b) Illustrate the determination of absorption rate in one open compartment 12 Marks model after oral administration. Q 4 a) What categories of drugs are given though IV infusion? Describe the 2+10 Marks calculation of steady state concentration (Css), Pre-Css, Post-Css, Elimination rate and Half life for IV infusion after one compartment model. b) What is a persistence factor? Compute the persistence factor for a drug 2+6 Marks with half life of 4 h for a dose administered at: (I) every 8 h, and (II) every 12 h. Describe the process of therapeutic drug monitoring. 8 Marks b) Discuss methods of dose adjustment based on drug clearance and 12 Marks Elimination rate in renal disease. Q 6 a) What is IVIVC? Describe the significance of IVIVC. 2+6 Marks Briefly describe the basis of non-compartmental approach? Describe 2+6+4 Marks trapezoidal method for area under the curve. Give formula for extrapolated AUMC (AUMC1-x). Q. 7 Write short notes on the following: 8+4+8 Drug clearance and excretion Marks II) Multi peak phenomenon



Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual-2019

Roll No.

Subject: Pharmaceutics-VII (Biopharmaceutics) (Old Course)

Paper: 4

Time: 3 Hrs. Marks: 100

Note: Attempt any FIVE questions. Each question carries equal marks.

Q. 1	a)	Pharmacokinetics II) Relative bioavailability III) Mamillary model IV) Mean residence time	5 Marks						
	b)	V) Dissolution Describe how the bioavailability of a drug is determined using blood data.	15 Marks						
Q. 2	a)	6 Marks							
	 limiting steps in drug absorption. Describe the physicochemical characteristics of drug affecting its absorption. 								
Q. 3	a)	Discuss calculation of pharmacokinetics parameters of a drug after its intravenous infusion.	12 Marks						
	b)	Discuss the parameters of multiple dose regimens.	8 Marks						
Q. 4	a)	Briefly describe the computation of pharmacokinetic parameters for	8 Marks						
	b)	one compartment open model after IV bolus administration. Demonstrate, with illustration the calculation of absorption rate constant for oral one compartment open model.	12 Marks						
Q. 5	a)	I - National Company (1997) 1997	08 Marks						
	b)	drug excretion? Define biotransformation. Describe phase II biotransformation reactions with at least one example.	12 Marks						
Q. 6	a) b)								
Q. 7		Write brief notes on the following: I) Therapeutic monitoring II) First pass effect III) Volume of distribution	8+4+8 Marks						

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Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics)

Paper: 4 Part – I (Compulsory)

(New Course)

Time: 30 Min. Marks: 20

ATTEMPT THIS PAPER ON THIS QUESTION SHEET ONLY.

Division of marks is given in front of each question.

This Paper will be collected back after expiry of time limit mentioned above.

Encircle the correct option. Q.1.

(20x1=20)

Roll No. in Fig.

Roll No. in Words.

Signature of Supdt.:

1. Aging has been associated with the increased:

(a) extracellular fluid volume (b) hepatic blood flow (c) subcutaneous fat (d) size of lung's alveolar ducts

2. With reference to the renal function and pharmacokinetics, in geriatrics the:

(a) serum creatinine remains normal due to decreased muscle mass (b) Glomerular function always declined (c) tubular secretions remain unchanged (d) 1.5 mg/dl serum creatine reflects normal renal function

3. An appropriate drug dosing strategy for obese patients in computed based on the:

(a) normal methods (b) total body water for loading dose (c) total body water for maintenance dose

(d) modified weight combined with TDM

4. Two compartments, connected independently to the central compartment make a:

(a) Caternary model (b) flip-flop model (c) closed model (d) mammillary model

5. The following drug is more soluble in the intestine, forming a soluble salt at more alkaline pH:

(a) acidic (b) neutral (c) basic (d) chelate

6. The pharmacokinetic process affected the most, by plasma or tissue protein binding is:

(a) absorption (b) distribution (c) elimination (d) metabilism

7. Increase in the free drug concentration causes increase in volume of distribution which is:

(a) maximum (b) permanent (c) transient (d) rapid

8. The fat-soluble vitamins are absorbed by:

(a) active transport (b) endocytosis (c) porte transport (d) facilitated diffusion

9. For systemic absorption, the unionized drug must be:

(a) hydrophilic (b) fast dissolving (c) lipophilic (d) neutral

10. The volume of distribution relates:

(a) drug in body to drug in plasma (b) drug dose to plasma drug (c) drug concentration to toxicity (d) dose to pharmacodynamics

11. A biphasic decline in oral route of administration indicates:

(a) absorption and distribution (b) absorption and elimination (c) disposition (d) absorption and elimination

12. The AUC gives an idea about:

(a) absorption rate (b) absorption extent (c) subtherapeutic concentration (d) drug distribution

13. The BCS Class II drugs have:

(a) poor solubility (b) high solubility (c) lower permeability (d) both a and c

14. The bioequivalence parameters are:

(a) C_{max} and K_{el} (b) C_{max} and Cl_{T} (c) AUC, C_{max} and T_{max} (d) AUC and $t_{1/2}$

15. The systemic drug absorption after oral administration is usually:

(a) unmeasurable (b) less than 100% (c) equals 100% (d) exceeds 100%

16. The time between drug administration and absorption is:

(a) onset time (b) lag time (c) peak time (d) mean residence time

17. The initial concentration after IV route in saturation kinetics is measured from extrapolated line at the:

(a) top left (b) bottom right (c) curved position (d) y-intercept of residual curve

18. Dose adjustment does NOT based on:

(a) clearance (b) half life (c) elimination rate (d) area under the curve

19. Dose given to facilitate achieving steady state earlier is the:

(a) loading dose (b) maintenance dose (c) steady state dose (d) minimum effective dose

20. The disposition phase on saturation kinetic plot corresponds the:

(a) first order-zero order (b) zero order-first order (c) zero order-zero order (d) first order-first order



Doctor of Pharmacy (Pharm.D.) Fourth Prof: Annual-2021

Subject: Pharmaceutics-V (Biopharmaceutics & Pharmacokinetics) (New Course)

Paper: 4 Part - II

Time: 2 Hrs. 30 Min. Marks: 80

ATTEMPT THIS (SUBJECTIVE) ON THE SEPARATE ANSWER SHEET PROVIDED

Note: Attempt any FOUR questions. Each question carries equal marks.

	Describe the drug physicochemical characteristics that are taken into	12 Marks		
Q.2. a) b)	consideration during drug product design How the drug binds with proteins. Discuss proteins involved in the binding of the drugs?	8 Marks		
Q.3. a)	the standard of candidate drugs for Therapeutic Drug	8 Marks		
(b)	Monitoring? Layout a procedure to determine the distribution rate constant in two compartment open model after IV administration?			
Q.4. a)	Which drugs are given through the IV infusion? How the pharmacokinetic parameters are computed for the I/V infusion after one compartment	10 Marks		
h	model? Describe different designs of dosage regimens?	10 Marks		
	Explain the difference between drug clearance, drug metabolism and drug	8 Marks		
	excretion. Describe the impact of saturation in the disposition of the drugs	12 Marks		
	Give the mathematical expressions for maximum and minimum	12 Marks		
Q.o. a	concentration of any dose during multiple dosing. What is statistical moment theory? How the area under the first moment of plasma level time curve is measured?.	2+6 Marks		
Q.7.	Write short notes on the following: i) Phase II metabolic reactions ii) pH-partition theory iii) Dose considerations in elderly patients	8+7+5 Marks		