

## VI SEMESTER B.TECH. (BIOTECHNOLOGY) END SEMESTER EXAMINATIONS, April/May 2018

SUBJECT: Biopharmaceutical Engineering [BIO 4010]

## **REVISED CREDIT SYSTEM**

Time: 3 Hours

MAX. MARKS: 50

## Instructions to Candidates:

✤ Answer ALL the questions.

✤ Missing data may be suitable assumed.

1A.	Briefly explain the following terms:											
	(a) Biopharmaceutics											
	(b) Clinical Pharmacokinetics											
	(c) Toxicokinetics											
1B.	Why is plasma or serum drug concentration, rather than blood concentration, used to monitor drug											
	concentration in the body?											
1C.	Discuss briefly the following terms:											
	(a) Active Transport	6										
	(b) Vesicular Transport											
	(c) lon pair formation											
2A.	Let $pK_a = 5$ for an acidic drug. Calculate the percentage of drug ionized at urinary pH 3											
2B	If the pH on one side of a cell membrane differs from the pH on the other side of the membrane, what											
	conclusions you make based on pH-partition hypothesis?											
	A pharmacist dissolved a few milligrams of a new antibiotic drug into exactly 100 mL of distilled											
	water and placed the solution in a refrigerator ( $5^{\circ}$ C). At various time intervals, the pharmacist removed											
	a 10-mL aliquot from the solution and measured the amount of drug contained in each aliquot. The											
	following data were obtained.											
20	$T_{im2}$ (hr) 0.5 1 2 4 6 8 12	2										
20.	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$											
	Anublouc ( $\mu$ g/IIIL)   84.5   81.2   74.5   01   48   55   8.7											
	(a) Is the decomposition of this antibiotic a first order or a zero order process?											
	(a) Is the decomposition of this antibiotic a first order of a zero order process:											
	(c) How many milligrams of antibiotics were in the original solution prenared by the pharmacist?											
	How many half-lives $(t_{1/2})$ would it take for 80 % of any initial concentration of a drug to decompose?											
2D.	Assume first-order kinetics	2										
	Penicillin has a Cl <sub>T</sub> of 15 mL/min. Calculate the elimination rate for penicillin when the plasma drug											
3A.	concentration, C p, is $2 \mu g/mL$											
20	70 kg female patient received 100 mg of drug x through IV Injection. A urine samples have been	4										
<u>э</u> р.	collected as follows:											

	Time Interval (hr)		0 -	l 1 - 2	2 2 -	4 4	-66	-99-	12					
	Amount of drug in	urine (m	g) 9.7	6.7	6.2	3.	.4 1.	5 0.6	63					
a) The half – life for drug X.														
b) Total elimination rate constant														
c) Renal elimination rate constant														
d) Fraction of drug excreted unchanged renally														
Studied	the pharmacokinetic	s of amr	rinone a	fter a s	ingle l	V bo	lus inje	ction (7	5 mg) in	14 he	althy a	dult		
male vo	olunteers. The pharm	acokinet	tics of t	his dru	g follo	owed	a two-	compart	ment op	en mo	del and	d fit		
the foll	owing equation: C <sub>p</sub> (1	ng/L) = 4	4.62e <sup>(-8.</sup>	$^{94t}$ +0.	54e <sup>(-0.</sup>	19t)								
<ul> <li>From these data, calculate:</li> <li>(a) The volume of the central compartment</li> </ul>													4	
(b) The	volume of distribution	on at stea	ady state	:										
(c) The	extrapolated volume	of distri	bution											
(d) The	volume of distribution	on by are	ea											
Plasma samples from a patient were collected after an oral bolus dose of 10 mg of a new														
benzodiazepine solution as follows:														
			~					-			• •	1		
T1	me (hr)	0.25 0	0.5   0.	75 1	2		4	6	10	14	20		_	
C	n contration (n a/mI)	2 95 4	5 4 2 7	75 0	QA 1	6 20	22.15	22.01	10.00	12.0	7.07		5	
	incentration(ing/inL)	2.65	5.45 7	13 9.	04 1	0.20	22.13	25.01	19.09	15.9	1.97			
From the data above:														
(a) Det	ermine the eliminatio	n consta	nt of the	drug.										
(b) Det	ermine k a by featheri	ng.		8										
Derive	the mathematical exp	pression (	to calcu	ate abs	orptic	n rate	e consta	nt when	the dru	ıg is gi	ven ora	ally	5	
using u	rinary date (Assume	drug is e	liminati	ng by f	irst or	der ai	nd follo	ws one	compart	ment <sup>1</sup>	nodel)	5		
Develop the mathematical expression to calculate drug concentration after nth dose when the drug is											the dru	g is	4	
Develo	p the mathematical e	expressio	in to car	given by multiple IV injections to a patient?										
Develo given b	p the mathematical e y multiple IV injection	expressio ons to a p	patient?	• • • • • • • • • • • • • • • • • • • •	0		manon						1.	
given b An adu	p the mathematical e y multiple IV injectio lt male patient (46 ye	expressions to a pression ars old, and the second s	patient? 81 kg) v	as giv	en ora	lly 25	0 mg o	f tetracy	cline hy	drochl	oride		-	
Develo given b An adu every 8	p the mathematical e y multiple IV injection It male patient (46 ye hours for 2 weeks. F	expressions to a pression to a pression of the second seco	patient? 81 kg) v literatur	vas giv e, tetra	en ora	lly 25 e hyd	0 mg o rochlor	f tetracy ide is at	cline hy out 75%	drochl 6 bioav	oride vailable	;		
Develo given b An adu every 8 and has	p the mathematical e y multiple IV injection It male patient (46 ye hours for 2 weeks. F an apparent volume	expressions to a pression to a pression of the second seco	patient? 81 kg) v literatur bution o	vas give e, tetra f 1.5 L	en ora cyclin /kg. Ti	lly 25 e hyd he eli	0 mg o rochlor minatio	f tetracy ide is at n half-li	cline hy oout 75% fe is abo	drochl 6 bioav	oride vailable hours. 7	The		
given b An adu every 8 and has absorpt	p the mathematical e y multiple IV injection It male patient (46 ye hours for 2 weeks. F an apparent volume ion rate constant is 0.	expression ons to a p ears old, a from the of distribution of distribution of hr <sup>-1</sup> . H	bit to can patient? 81 kg) v literatur bution o From thi	vas giv e, tetra f 1.5 L s infor	en ora cyclin /kg. T	lly 25 e hyd he eli n, calo	0 mg o rochlor minatio culate	f tetracy ide is at n half-li	cline hy out 75% fe is abo	drochl bioav	oride vailable hours. 7	The	4	
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The pharmacokinetics of this drug followedthe following equation: $C_p (mg/L) = 4.62e^{(-8.94t)} + 0.64e^{(-0.19t)}$ From these data, calculate:(a) The volume of the central compartment(b) The volume of distribution at steady state(c) The extrapolated volume of distribution(d) The volume of distribution by areaPlasma samples from a patient were collected after an obenzodiazepine solution as follows:Time (hr) $0.25$ $0.5$ $0.75$ $1$ $2$ Concentration(ng/mL) $2.85$ $5.43$ $7.75$ $9.84$ $16.20$ From the data above:(a) Determine the elimination constant of the drug.(b) Determine k a by feathering.Derive the mathematical expression to calculate absorption rateusing urinary date (Assume drug is eliminating by first order at Develop the mathematical expression to calculate drug conce	Time Interval (hr) $0 - 1$ $1 - 2$ $2 - 4$ $4 - 6$ $6$ Amount of drug in urine (mg) $9.7$ $6.7$ $6.2$ $3.4$ $1.$ a) The half – life for drug X.b) Total elimination rate constantc) Renal elimination rate constantd) Fraction of drug excreted unchanged renallyStudied the pharmacokinetics of amrinone after a single IV bolus injemale volunteers. 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The pharmacokinetics of this drug followed a two-compartthe following equation: $C_p$ (mg/L) = $4.62e^{(-8.941)} + 0.64e^{(-0.190)}$ From these data, calculate:(a) The volume of the central compartment(b) The volume of distribution at steady state(c) The extrapolated volume of distribution(d) The volume of distribution by areaPlasma samples from a patient were collected after an oral bolus dosbenzodiazepine solution as follows:Time (hr) $0.25$ $0.5$ $0.75$ $1$ $2$ $4$ $6$ Concentration(ng/mL) $2.85$ $5.43$ $7.75$ $9.84$ $16.20$ $22.15$ $23.01$ From the data above:(a) Determine the elimination constant of the drug.(b) Determine the alimination constant of the drug.(c) Determine the alimination constant of the drug.(d) Determine the alimination constant of the drug.(e) Determine the alimination constant of the drug.(f) Determine the alimination constant of the drug.(g) Determine the alimination expression to calculate absorption rate const	Time Interval (hr) $0 \cdot 1$ $1 \cdot 2$ $2 \cdot 4$ $4 \cdot 6$ $6 - 9$ $9 \cdot 12$ Amount of drug in urine (mg) $9.7$ $6.7$ $6.2$ $3.4$ $1.5$ $0.63$ a) The half – life for drug X.b) Total elimination rate constantc) Renal elimination rate constantd) Fraction of drug excreted unchanged renallyStudied the pharmacokinetics of amrinone after a single IV bolus injection (75 mg) inmale volunteers. The pharmacokinetics of this drug followed a two-compartment opthe following equation: $C_p$ (mg/L) = $4.62e^{(-8.94t)} + 0.64e^{(-0.19t)}$ From these data, calculate:(a) The volume of the central compartment(b) The volume of distribution at steady state(c) The extrapolated volume of distribution(d) The volume of distribution by areaPlasma samples from a patient were collected after an oral bolus dose of 10benzodiazepine solution as follows: $\boxed{\text{Time (hr)}}$ $0.25$ $0.5$ $0.75$ $1$ $2$ $4$ $6$ $10$ Concentration(ng/mL) $2.85$ $5.43$ $7.75$ $9.84$ $16.20$ $22.15$ $23.01$ $19.09$ From the data above:(a) Determine the elimination constant of the drug.(b) Determine the alimination expression to calculate absorption rate constant when the druusing urinary date (Assume drug is eliminating by first order and follows one compartDerive the mathematical expression to calculate drug concentration after nth dose	Time Interval (hr) $0 - 1$ $1 - 2$ $2 - 4$ $4 - 6$ $6 - 9$ $9 - 12$ Amount of drug in urine (mg) $9.7$ $6.7$ $6.2$ $3.4$ $1.5$ $0.63$ a) The half – life for drug X.b) Total elimination rate constantc) Renal elimination rate constantd) Fraction of drug excreted unchanged renallyStudied the pharmacokinetics of amrinone after a single IV bolus injection (75 mg) in 14 hemale volunteers. The pharmacokinetics of this drug followed a two-compartment open mothe following equation: $C_p$ (mg/L) = $4.62e^{(-8.94t)} + 0.64e^{(-0.19t)}$ From these data, calculate:(a) The volume of the central compartment(b) The volume of distribution at steady state(c) The extrapolated volume of distribution(d) The volume of distribution by areaPlasma samples from a patient were collected after an oral bolus dose of 10 mgbenzodiazepine solution as follows: $Iime (hr)$ $0.25$ $0.5$ $0.75$ $1$ $2$ $4$ $6$ $10$ $14$ Concentration(ng/mL) $2.85$ $5.43$ $7.75$ $9.84$ $16.20$ $22.15$ $23.01$ $19.09$ $13.9$ From the data above:(a) Determine k aby feathering.Derive the mathematical expression to calculate absorption rate constant when the drug is giusing urinary date (Assume drug is eliminating by first order and follows one compartment inDevelop the math	Time Interval (hr) $0 \cdot 1$ $1 \cdot 2$ $2 \cdot 4$ $4 \cdot 6$ $6 - 9$ $9 \cdot 12$ Amount of drug in urine (mg) $9.7$ $6.7$ $6.2$ $3.4$ $1.5$ $0.63$ a) The half – life for drug X.b) Total elimination rate constantc) Renal elimination rate constantd) Fraction of drug excreted unchanged renallyStudied the pharmacokinetics of amrinone after a single IV bolus injection (75 mg) in 14 healthy a male volunteers. The pharmacokinetics of this drug followed a two-compartment open model and the following equation: $C_p$ (mg/L) = $4.62e^{(-8.94i)} + 0.64e^{(-0.19i)}$ From these data, calculate:(a) The volume of the central compartment (b) The volume of distribution at steady state (c) The extrapolated volume of distribution (d) The volume of distribution by areaPlasma samples from a patient were collected after an oral bolus dose of 10 mg of a rebenzodiazepine solution as follows: $\overline{\text{Time (hr)}}$ $0.25$ $0.5$ $0.75$ $1$ $2$ $4$ $6$ $10$ $14$ $20$ Concentration(ng/mL) $2.85$ $5.43$ $7.75$ $9.84$ $16.20$ $22.15$ $23.01$ $19.09$ $13.9$ $7.97$ From the data above: (a) Determine k a by feathering.Determine k a sy feathering.Determine k and follows one compartment model)Derive the mathematical expression to calculate absorption rate constant when the drug is given ora $a_{11}$ for a first order and follows one compartment model)	$\begin{tabular}{ c c c c c c c c c c c c c c c c c c c$	