Reg. No.										

MANIPAL INSTITUTE OF TECHNOLOGY

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V SEMESTER B.TECH. (BIOTECHNOLOGY)

END SEMESTER EXAMINATIONS, NOV/DEC 2016

SUBJECT: BIOPHARMACEUTICAL ENGINEERING [BIO 4010]

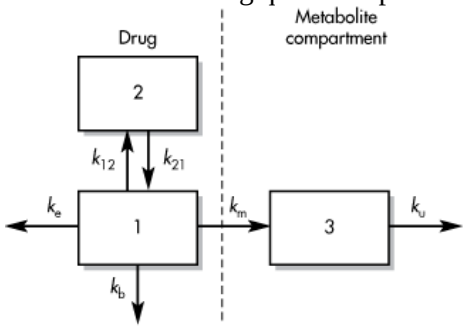
REVISED CREDIT SYSTEM

(11/11/2015)

Time: 3 Hours MAX. MARKS: 50

Instructions to Candidates:

- Answer **ALL** the questions.
- Missing data may be suitable assumed.

1A.	What are the uses of pharmacokinetic models?	**3**
1B.	List out the advantages & disadvantages of the following route of administration of drug (a) Oral (b) Intravenous	**4**
1C.	Develop the mathematical expression to calculate K from urinary excretion data using sigma minus method. Assume drug follows one compartment model and drug is administrated through IV injection?	**3**
2A.	The pharmacokinetic model presented in represents a drug that is eliminated by renal excretion, biliary excretion, and drug metabolism. The metabolite distribution is described by a one-compartment open model. The following questions pertain to.  (a) How many parameters are needed to describe the model if the drug is injected intravenously (ie, the rate of drug absorption may be neglected)? (b) Which compartment(s) can be sampled? (c) What would be the overall elimination rate constant for elimination of drug from compartment 1? (d) Write an expression describing the rate of change of drug concentration in compartment 1 (dC_1/dt).	**4**
2B.	A rather intoxicated young man (75 kg, age 21) was admitted to a rehabilitation center. His blood alcohol content was found to be 210 mg/L. Assuming the average elimination rate of alcohol is 10 mL of ethanol per hour, how long would it take for his blood alcohol concentration to decline to less than the legal blood alcohol concentration of 100 mg/L (*Hint:* Alcohol is eliminated by zero-order kinetics.) The specific gravity of alcohol is 0.8. The apparent volume of distribution for alcohol is 60% of body weight.	**4**

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2C.	If the half-life for decomposition of a drug is 10 hours, how long will it take for 125 mg of the drug to decompose by 30%? Assume first-order kinetics and constant temperature.	**2**
3A.	An antibiotic is to be given to an adult male patient (58 years old, 75 kg) by IV infusion. The elimination half-life is 8 hours and the apparent volume of distribution is 1.5 L/kg. The drug is supplied in 60-mL ampules at a drug concentration of 15 mg/ml. The desired steady-state drug concentration is 20 µg/ml. (a) What infusion rate, in milliliters per hour, would you recommend for this patient? (b) What loading dose would you recommend for this patient? By what route of administration would you give the loading dose? When? (c) Why should a loading dose be recommended? (d) According to the manufacturer, the recommended starting infusion rate is 15 ml/hr. Do you agree with this recommended infusion rate for your patient? Give a reason for your answer. (e) If you were to monitor the patient's serum drug concentration, when would you request a blood sample? Give a reason for your answer. (f) The observed serum drug concentration is higher than anticipated. Give two possible reasons based on sound pharmacokinetic principles that would account for this observation.	**6**
3B.	A patient was infused for 6 hours with a drug (k = 0.01 hr^{-1}; V_D = 10 L) at a rate of 2.5 mg/hr. What is the concentration of the drug in the body 3 hours after cessation of the infusion?	**2**
3C.	What is flip-flop phenomenon and when it is observed?	**2**
4A.	Explain briefly transcellular and paracellular transport of molecules in the body	**3**
4B.	Two drugs, A and B, have the following pharmacokinetic parameters after a single oral dose of 500 mg: Drug | k_a (hr^{-1}) | k (hr^{-1}) | V_D (mL) A | 1 | 0.2 | 10,000 B | 0.2 | 1 | 20,000 Both drugs follow a one-compartment pharmacokinetic model and are 100% bioavailable. Calculate the t_{max} and C_{max} for each drug and comment on the results.	**4**
4C.	Write the step by step procedure to calculate absorption rate constant using Wagner Nelson method.	**3**
5A.	Gentamicin has an average elimination half-life of approximately 2 hours and an apparent volume of distribution of 20% of body weight. It is necessary to give gentamicin, 1 mg/kg every 8 hours by multiple IV injections, to a 50-kg woman with normal renal function. Calculate (a) C_{max},(steady state) (b) C_{min},(steady state) and (c) C^{∞}_{av}.	**3**
5B.	A cephalosporin (k = 0.2 hr^{-1}, V_D = 10 L) was administered by IV multiple dosing; 100 mg was injected every 6 hours for 6 doses. What was the plasma drug concentration 4 hours after the 6th dose, if (a) the 6th dose was omitted, (b) the 5th dose were given an hour late (c) the steady-state plasma drug concentration C^{∞}_{p} at 3 hours after the last dose	**3**
5C.	What are the main reasons for drug recall from the market	**2**
5D.	Explain the role of lubricants in manufacturing of tablets and capsules.	**2**