Reg. No.										

MANIPAL INSTITUTE OF TECHNOLOGY

MANIPAL

A Constituent Institution of Manipal University

VII SEMESTER B.TECH. (BIOTECHNOLOGY)

END SEMESTER EXAMINATIONS, NOV/DEC 2016

SUBJECT: DRUGS & PHARMACEUTICAL BIOTECHNOLOGY [BIO 437]

REVISED CREDIT SYSTEM
(11/11/2015)

Time: 3 Hours MAX. MARKS: 50

Instructions to Candidates:

- Answer **ANY FIVE FULL** questions.
- Missing data may be suitable assumed.

1A.	What is the significance of the plasma level–time curve? How does the curve relate to the pharmacologic activity of a drug?	**3**
1B.	A solution of a drug was freshly prepared at a concentration of 300 mg/ml. After 30 days at 25°C, the drug concentration in the solution was 75 mg/ml. (a) Assuming first-order kinetics, when will the drug decline to one-half of the original concentration? (b) Assuming zero-order kinetics, when will the drug decline to one-half of the original concentration?	**3**
1C.	List out the advantages & disadvantages of the following route of administration of drug (a) Oral (b) Subcutaneous	**4**
2A.	What are the problems in obtaining valid urinary excretion data?	**3**
2B.	A new antibiotic drug was given in a single intravenous bolus of 4 mg/kg to five healthy male adults ranging in age from 23 to 38 years (average weight 75 kg). The pharmacokinetics of the plasma drug concentration–time curve for this drug fits a one-compartment model. The equation of the curve that best fits the data is $C_p=78e^{(-0.46t)}$ Determine the following (assume units of µg/mL for C_p and h for t): (a) What is the V_D? (b) What is the plasma level of the drug after 4 hours? (c) How much drug is left in the body after 4 hours? (d) Predict what body water compartment this drug might occupy and explain why you made this prediction. (e) Assuming the drug is no longer effective when levels decline to less than 2 µg/mL, when should you administer the next dose?	**5**
2C.	If physiologic models are better than compartment models, why not just use physiologic models?	**2**
3A.	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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<tr><td>3B.</td><td>Why do we still use volumes of distribution that often are greater than the real physical volume?</td><td>3</td></tr>
<tr><td>3C.</td><td>A drug with an elimination half-life of 1 hour was given to a male patient (80 kg) by intravenous infusion at a rate of 300 mg/hr. At 7 hours after infusion, the plasma drug concentration was 11 µg/ml.
(a) What is the total body clearance for this drug?
(b) What is the apparent V_D for this drug?
(c) If the drug is not metabolized and is eliminated only by renal excretion, what is the renal clearance of this drug?</td><td>3</td></tr>
<tr><td>4A.</td><td>A patient was infused for 6 hours with a drug (k = 0.01 hr^{-1}; V_D = 10 L) at a rate of 2 mg/hr. What is the concentration of the drug in the body 2 hours after cessation of the infusion?</td><td>2</td></tr>
<tr><td>4B.</td><td>Explain the pH – partition hypothesis for the movement of drug molecules across the cell membrane.</td><td>2</td></tr>
<tr><td>4C.</td><td>Discuss briefly the mechanism of transport of particles across the cell membrane for the following processes.
(a) Facilitated Transport
(b) Ion pair formation
(c) Vesicular transport</td><td>6</td></tr>
<tr><td>5A.</td><td>Develop the mathematical expression to predict the drug concentration in plasma when the drug is given to the patient orally (Assume drug is eliminating by zero order and follows one compartment model)</td><td>5</td></tr>
<tr><td>5B.</td><td>Plasma samples from a patient were collected after an oral bolus dose of 10 mg of a new benzodiazepine solution as follows:
<table>
<tr><td>Time (hr)</td><td>0.25</td><td>0.5</td><td>0.75</td><td>1</td><td>2</td><td>4</td><td>6</td><td>10</td><td>14</td><td>20</td></tr>
<tr><td>Concentration(ng/mL)</td><td>2.85</td><td>5.43</td><td>7.75</td><td>9.84</td><td>16.20</td><td>22.15</td><td>23.01</td><td>19.09</td><td>13.9</td><td>7.97</td></tr>
</table>
From the data above:
(a) Determine the elimination constant of the drug.
(b) Determine k_a by feathering.</td><td>5</td></tr>
<tr><td>6A.</td><td>A patient receives 1000 mg every 6 hours by repetitive IV injection of an antibiotic with an elimination half-life of 3 hours. Assume the drug is distributed according to a one-compartment model and the volume of distribution is 20 L.
(a) Find the maximum and minimum amount of drug in the body at steady state.
(b) Determine the maximum and minimum plasma concentration of the drug at steady state.</td><td>2</td></tr>
<tr><td>6B.</td><td>Develop the mathematical expression to calculate drug concentration after nth dose when the drug is given by IV bolus?</td><td>5</td></tr>
<tr><td>6C.</td><td>Explain the role of following excipients in the manufacture of tablets and capsules with an example
(a) Antiadherents
(b) Coating Material
(c) Fillers</td><td>3</td></tr>
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