Reg. No.										

Manipal Institute of Technology, Manipal

(A Constituent Institute of Manipal University)

VII SEMESTER B.TECH (BIOTECHNOLOGY)

END SEMESTER EXAMINATIONS, NOV/DEC 2015

SUBJECT: DRUGS & PHARMACEUTICAL BIOTECHNOLOGY [BIO 437]

REVISED CREDIT SYSTEM

Time: 3 Hours MAX. MARKS: 50

Instructions to Candidates:

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

1A.	What are the uses of pharmacokinetic models?	**3**
1B.	Why is plasma or serum drug concentration, rather than blood concentration, used to monitor drug concentration in the body?	**2**
1C.	Briefly explain the following terms: (a) Biopharmaceutics (b) Toxicokinetics (c) Clinical Toxicology	**5**
2A.	Develop the mathematical expression to calculate K from urinary excretion data using rate method and sigma minus method. Assume drug follows one compartment model and drug is administrated through IV injection?	**7**
2B.	A single IV bolus injection containing 500 mg of cefamandole nafate (Mandol, Lilly) is given to an adult female patient (63 years, 55 kg) for a septicemic infection. The apparent volume of distribution is 0.1 L/kg and the elimination half-life is 0.75 hour. Assuming the drug is eliminated by first-order kinetics and may be described by a one-compartment model, calculate the following: (a) The C_p^0 (b) The amount of drug in the body 4 hours after the dose is given (c) The time for the drug to decline to 0.5µg/mL, the minimum inhibitory concentration for streptococci	**3**
3A.	List out the advantages & disadvantages of the following route of administration of drug (a) Oral (b) Buccal & Sublingual (c) Intravenous	**6**
3B.	Explain briefly transcellular and paracellular transport of molecules in the body.	**4**

Reg. No.										

प्रज्ञानं ब्रह्म

Manipal Institute of Technology, Manipal

(A Constituent Institute of Manipal University)

INSPIRED BY LIFE

KNOWLEDGE IS POWER

MANIPAL INSTITUTE OF TECHNOLOGY

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>4A.</td><td>A 500 mg of a drug was administrated by rapid IV injection into 70 kg adult male. Blood samples were withdrawn over a 7 hours period and assayed for intact drug. The results are tabulated below.
<table>
<tr><td>Time(hr)</td><td>0</td><td>0.25</td><td>0.5</td><td>0.75</td><td>1</td><td>1.5</td><td>2</td><td>2.5</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td></tr>
<tr><td>C_P(µg.mL)</td><td>70</td><td>53.8</td><td>43.3</td><td>35</td><td>29.1</td><td>21.2</td><td>17</td><td>14.3</td><td>12.6</td><td>10.5</td><td>9</td><td>8</td><td>7</td></tr>
</table>
(a) Calculate K, K_{12} and K_{21}
(b) Volume of Central Compartment
(c) Volume of distribution at steady state
(d) Extrapolated volume of distribution
(e) Apparent volume of the tissue compartment</td><td>8</td></tr>
<tr><td>4B.</td><td>An antibiotic is to be given by IV infusion. How many milliliters per minute should a sterile drug solution containing 25 mg/mL be given to a 75-kg adult male patient to achieve an infusion rate of 1 mg/kg per hour?</td><td>2</td></tr>
<tr><td>5A.</td><td>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}.</td><td>3</td></tr>
<tr><td>5B.</td><td>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 (ie, 40 hours later) if
(a) the 6th dose was omitted,
(b) the 5th dose were given an hour late</td><td>4</td></tr>
<tr><td>5C.</td><td>Calculate the excretion rate at steady state for a drug given by IV infusion at a rate of 30 mg/hr. The C_{SS} is 20 µg/mL. If the rate of infusion were increased to 40 mg/hr, what would be the new steady-state drug concentration, C_{SS}? Would the excretion rate for the drug at the new steady state be the same? Assume first-order elimination kinetics and a one-compartment model.</td><td>3</td></tr>
<tr><td>6A.</td><td>Discuss the function of different excipients used in the formulation of tablets and capsules?</td><td>5</td></tr>
<tr><td>6B.</td><td>Develop the mathematical expressions to determine the drug concentration in plasma when the drug is given orally. Assume drug follows one compartment model and drug absorbed by zero order process and eliminated by first order process?</td><td>3</td></tr>
<tr><td>6C.</td><td>Write the different steps involved in the manufacturing of tablets using wet granulation method.</td><td>2</td></tr>
</table>