Reg. No.										

MANIPAL INSTITUTE OF TECHNOLOGY

MANIPAL

(A constituent unit of MAHE, Manipal)

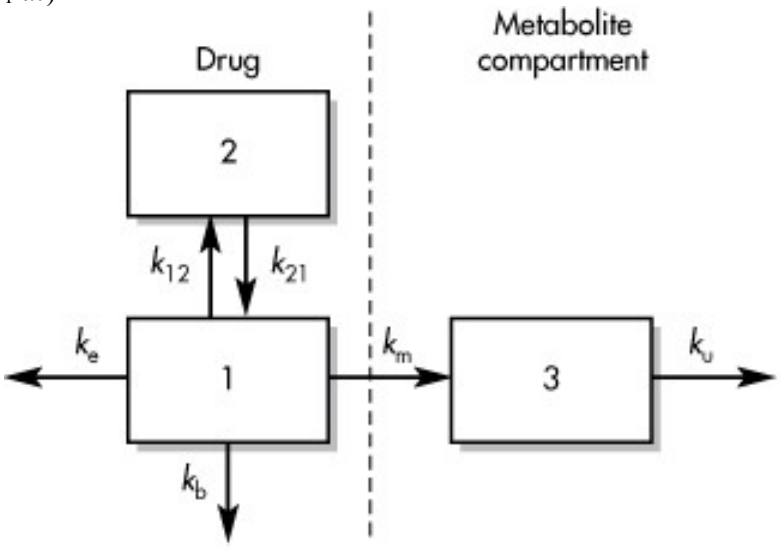
VII SEMESTER B.TECH. EXTERNAL EXAMINATIONS APRIL 2021

SUBJECT: BIOPHARMACEUTICAL ENGINEERING [BIO 4056]

Date of Exam: **24/12/2021** Time of Exam: **9.20 AM – 10.45 AM** Max. Marks: **20**

Instructions to Candidates:

- Answer ALL the questions & missing data may be suitable assumed

1A.	Why is plasma or serum drug concentration, rather than blood concentration, used to monitor drug concentration in the body?	2
1B	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. (i) How many parameters are needed to describe the model if the drug is injected intravenously (ie, the rate of drug absorption may be neglected)? (ii) Which compartment(s) can be sampled? (iii) What would be the overall elimination rate constant for elimination of drug from compartment 1? (iv) Write an expression describing the rate of change of drug concentration in compartment 1 (dC_1/dt). 	4
1C.	Urine samples were collected at various times after an i.v. bolus dose of 500 mg. The results are shown below. Calculate k, k_e from these data.	4

Time Interval(hr)	0-2	2-4	4-6	6-9	9-12	12-15
Volume of Urine Collected (ml)	120	130	125	no sample	200	190
Concentration in Urine (µg/ml)	320	210	170		45	30

<table>
<tr><td>2A.</td><td>Given the following data, collected after a 300 mg i.v. bolus dose, calculate k, Cp_0, V, $t_{1/2}$, and AUC (using the trapezoidal rule). Verify that the drug follows linear one compartment pharmacokinetics!
<table>
<tr><td>Time (hr)</td><td>1</td><td>2</td><td>6</td><td>12</td></tr>
<tr><td>Concentration (mg/L)</td><td>15.7</td><td>13.8</td><td>8.3</td><td>3.2</td></tr>
</table></td><td>4</td></tr>
<tr><td>2B.</td><td>Derive the Wagner–Nelson Method to calculate absorption rate constant when the drug is given orally (Assume drug is eliminating by first order and follows one compartment model)</td><td>4</td></tr>
<tr><td>2C.</td><td>Write a short note on process validation</td><td>2</td></tr>
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