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B.M.S. College of Engineering, Bengaluru-560019

Autonomous Institute Affiliated to VTU

February / March 2023 Semester End Main Examinations

Programme: B.E. **Semester: VII**
Branch: Biotechnology **Duration: 3 hrs.**
Course Code: 19BT7DE5PBT **Max Marks: 100**
Course: Pharmaceutical Biotechnology **Date: 20.02.2023**

Instructions: 1. Answer any FIVE full questions, choosing one full question from each unit.
2. Missing data, if any, may be suitably assumed.

UNIT - I

1 a) Construct a flow sheet for drug development process and deliberate the steps involved in it. **08**

b) A research team has discovered few chemical entities and wanted to continue their research to find a new drug. If they want to gain the approval to conduct clinical trials on humans then recommend the key tests undertaken to screen these chemical entities. **07**

c) Discuss the different types of pharmaceuticals of animal origin. **05**

UNIT - II

2 a) A pharma company was challenged to formulate an oral administration of a compound characterized by low solubility in both water and oil, which also degraded rapidly in acid. As might be expected, bioavailability in preliminary trials was poor. Propose an appropriate drug formulation for an effective drug delivery and a significant improve in bioavailability. **05**

b) No single method of drug administration is ideal for all drugs in all circumstances. Justify **07**

c) Colon a promising site for drug delivery. Substantiate. **08**

UNIT - III

3 a) One of the athletes works with has recently been diagnosed with diabetes. The athlete will be using insulin to control his blood sugar and will be injecting the insulin subcutaneously in the thigh. He is concerned about the effects that exercise will have on the activity of the insulin and the patient's blood sugar. Based on pharmacokinetic principles, what possible effect could exercise have on the insulin? **05**

b) The table:1 shows the serum concentration profiles of a certain drug in patient X. **08**

i. Determine if the elimination process is a first order or a zero-order process. Plot the data on a semi log paper.
ii. Calculate Ke, the first order elimination rate constant.
iii. Calculate $AUC_{0\text{-tlast}}$ and $AUC_{0\text{-inf}}$ by trapezoidal rule.
iv. Calculate the concentration of the drug X in serum at time 5hr.

Table:1

Time (hr)	Conc.(ng/ml)
0	20
1	16.37
1.5	14.82
2	13.41
4	8.99
6	6.02
8	4.04
10	2.71
12	1.81

c) Demonstrate the two-compartment model for drug distribution and formulate the pharmacokinetics of drug distribution. **07**

OR

4 a) Discuss the mechanism of Cytochrome P450 metabolism. **08**

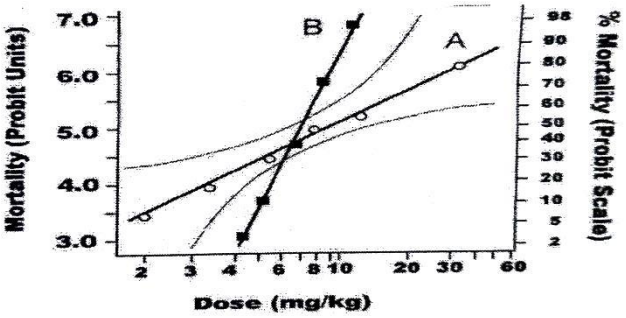
b) Consider the following data which is obtained for different formulations of a drug in volunteers of an average body weight 50 kg. Calculate the absolute bioavailability of each of the formulations and interpret your result on these formulations. **04**

Drug Product	Dose (mg/kg)	AUC (mg. hr/lt)
i.v. solution	1.2	450
oral solution	4.0	822
oral capsule	4.0	736
oral S.R. tablet	8.0	1040

c) There are different phases by which a drug is metabolized; the aim is to increase water solubility of drugs. Substantiate. **08**

UNIT-IV

5 a) The dose response curves of two drugs A and B are given below. **08**



i. Based on the slope, which of the two drug is safe and why?

ii. Define therapeutic index and highlight the difference between LC_{50} and LD_{50}.

b) What is Bio assay? Discuss the principles and types of bioassay. **07**

c) Carbon monoxide- An invisible killer! Justify. **05**

OR

6 a) Illustrate the mechanism of action of Botulinum toxin. **05**

b) Elucidate the biotransformation and clearance of acetaminophen and salicylates. **10**

c) In a post-war era when sleeplessness was prevalent, thalidomide was marketed to a world hooked on tranquilizers and sleeping pills. The demand for sedatives was even higher in some European markets, and the presumed safety of thalidomide, the only non-barbiturate sedative known at the time, gave the drug massive appeal. Sadly, tragedy followed its release, kindergartner were born with phocomelia as a side effect of the drug thalidomide, resulting in the shortening or absence of limbs. **05**

Analyse the case study and conclude your outcomes on following:

i. What is the purpose of study?
ii. Whether the drug can be approved as an alternative? Yes/No
iii. If No then what is the problem identified?
iv. Are there any divergent results? Yes/No
v. If yes then what are those results?

UNIT - V

7 a) Discuss the different domains that constitute human tPA and their biological function. **10**

b) Compare and contrast the structure of the IGF-1, IGF-2 with the insulin receptors with a schematic representation. **10**

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