U.S.N.										

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

Autonomous Institute Affiliated to VTU

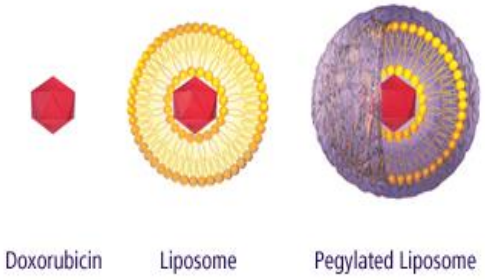
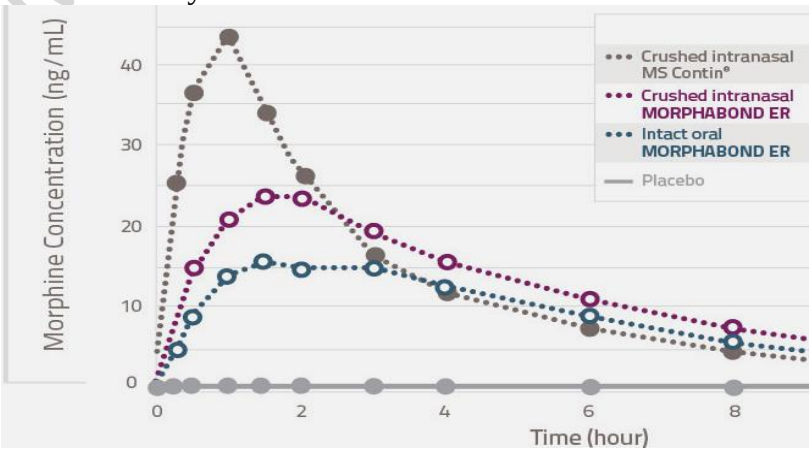
January 2024 Semester End Main Examinations

Programme: B.E. **Semester: VII**
Branch: BIOTECHNOLOGY **Duration: 3 hrs.**
Course Code: 19BT7DE5PBT **Max Marks: 100**
Course: PHARMACEUTICAL BIOTECHNOLOGY

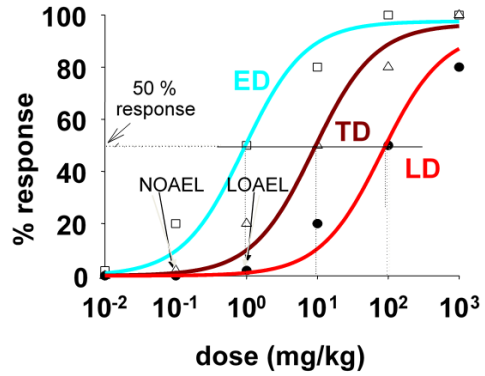
Instructions: 1. Answer any FIVE full questions, choosing one full question from each unit.
2. Missing data, if any, may be suitably assumed.

Important Note: Completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages. Revealing of identification, appeal to evaluator will be treated as malpractice.

		UNIT - I	*CO*	*PO*	Marks
1	a)	Discuss the role of FDA in drug development process.	*CO1*	*PO 06,08*	**05**
	b)	Nicotine is the primary addictive agent in tobacco. Nicotine vaccines aim to stimulate the immune system to produce nicotine -specific antibodies, which would bind with the nicotine in the bloodstream and prevent or slow the rate at which the nicotine reaches the brain. This, in turn, might reduce the urge to smoke, leading to cessation. Phase 2 trials of one such vaccine, NicVAX, were conducted by X company. All of these trials, which enrolled between 11 and 301 patients, focused on the safety and immunogenicity of NicVAX, and identifying the best dosing regimen. The phase 2b placebo-controlled trial with 301 patients also assessed efficacy of NicVAX for smoking cessation in smokers who wanted to quit. In this study, those smokers who developed the highest concentrations of anti-nicotine antibodies in response to the vaccine were significantly more likely to maintain abstinence for 8 weeks than smokers receiving placebo. Phase 3 RCTs were conducted in which about 2,000 patients were given 6 vaccinations of NicVAX or placebo. The last vaccination was at week 26, and the primary endpoint was the number of patients who remained abstinent for 16 weeks. This timeframe corresponded to the peak anti-nicotine antibody levels observed in the phase 2 trials. Despite the suggestions of efficacy in the phase 2b trial, one of phase 3 trials reported similar abstinence rates of approximately 11% in the NicVAX and placebo groups. Analyse the case study and conclude your outcomes on following: i. What is the purpose of study? ii. Whether the drug can be approved? 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?	*CO1*	*PO 06,08*	**05**

		c)	You are provided with 100 various types of alkaloids from a medicinal plant. Treatment with mixture of all these compounds showed an efficacy of only 70%. Assume that there exist standard and well-established protocol to purify individual molecules and their structure is also known. Design a drug development process which is rapid, inexpensive and significant increase in efficacy. Assume that these compounds for the treatment of a disease and with suitable target receptor.	***CO 1***	***PO 06,08***	**10**
			UNIT - II			
	2	a)	Suggest a drug delivery system which can avoid of hepatic first-pass metabolism, whose rate of absorption is comparable to IV medication with a rapid onset of pharmacological action and useful for both local & systemic drug delivery. Elaborate on their types and their mechanisms.	***CO 2***	***PO 06***	**10**
		b)	 Identify the structure. Explain its structural aspects, purpose of each of its labels. Design delivery of a lipophilic drug using these particles to specifically target to treat cancer.	***CO 2***	***PO 6***	**05**
		c)	How do you critically evaluate a manufactured tablet to meet required standards? Elaborate (any five).	***CO 2***	***PO 6***	**05**
			UNIT - III			
	3	a)	Demonstrate the pharmacokinetic model for drug elimination and formulate the rate of drug elimination.	***CO 3***	***PO 05,06***	**10**
		b)	Below are the three different formulations of morphine. Analyse the AUC of the these dosage forms. Clarify why and how they are different. If 20ng/ml is the minimum effective concentration which forms you prefer and why? Demostrate a typical AUC and the inferences you can draw from AUC . 	***CO 3***	***PO 05,06***	**10**
			OR			

	4	a)	The table:1 shows the serum concentration profiles of a certain drug in patient X. 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	***CO 3***	***PO 05,06***	**08**
		b)	Discuss the mechanism of Cytochrome P450 metabolism.	***CO3***	***PO 05,06***	**06**
		c)	Demonstrate the significance of Phase I metabolism and its types with a suitable example.	***CO3***	***PO 05,06***	**06**
			UNIT - IV			
	5	a)	A 45 year old lady contacted her social worker and expressed intent to commit suicide by ingesting prescription medicines. On arrival of emergency responders, the patient was found unconscious with an empty bottle of amitriptyline. Time of ingestion was assessed using the social worker's contact with local authorities. The patient's presentation at the emergency department (ED) illustrated tricyclic antidepressant toxidrome with a poor prognosis, based on measurable criteria and physical findings. Analyze the case and discuss the presentation features of illustrated tricyclic antidepressant poisoning and their management.	***CO3***	***PO 05,06***	**08**
		b)	Illustrate the mechanism of action of Botulinum toxin.	***CO3***	***PO 05,06***	**06**
		c)	The dose response curves of a drug is given below. (NOAEL: no observed adverse effect level LOAEL: lowest observed adverse effect level) i. Define and determine ED50, TD50 and LD50 from the given plot. ii. Define and calculate therapeutic index and highlight its significance.	***CO3***	***PO 05,06***	**06**

						
			OR			
	6	a)	A 35-year-oldman, with good health history, presented to an Emergency Department with a case report for suicidal attempt with an overdose of aspirin. He had ingested 90 tablets of regular-preparation aspirin (500 mg/tablet) around five hours before arrival. He complained of epigastric discomfort, nausea and tinnitus. He had drunk a can of beer which was around 500 ml but he denied co-ingestion of other medications. The emergency department recommended Urinary alkalinisation. Demonstrate the Bio-transformations and metabolic complications that led to toxicity and how the toxicity can be cleared?	***CO3***	***PO 05,06***	**10**
		b)	Carbon monoxide- An invisible killer! Justify	***CO3***	***PO 05,06***	**05**
		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. 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?	***CO3***	***PO 05,06***	**05**
			UNIT - V			
	7	a)	Compare and contrast the structure of the IGF-1, IGF-2 with the insulin receptors with a schematic representation	***CO5***	***PO 01,06***	**10**
		b)	Demonstrate the mechanism of action of asparginase in the treatment of patients with acute lymphoblastic leukemia.	***CO5***	***PO 01,06***	**10**

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