



9.	An antidiabetic drug manufactured by a major pharmaceutical company has received FDA approval. Analyze if it is necessary to receive CDSCO approval for marketing the drug in India.	2	K2	CO5
10.	A company manufacturing insulin analogue observed batch to batch variation in the yield. Identify and analyze the events that could have contributed to batch variation.	2	K2	CO5

PART – B

(5 x 13 = 65 Marks)

Q.No.	Questions	Marks	KL	CO
11. a)	Describe the principle, methodology and application of structure- based drug design with a flow chart and an example.	13	K1	CO1
	(OR)			
b)	A research group has developed a peptide-based drug that targets a carbohydrate moiety on cancer cells and induce apoptosis. The drug has shown to be less effective upon oral administration. Explain the potential reasons underlying the low effectiveness of the drug upon oral administration. Suggest the ideal route most suited for this drug and justify your selection with reference to the nature of the drug.	13	K1	CO1
12. a)	List the objectives of Phase 1 and Phase 2 metabolism. Illustrate the reactions and the role of enzymes involved in Phase 1 and Phase 2 drug metabolism.	13	K2	CO2
	(OR)			
b)	Compare and contrast the various modes of drug delivery system with examples.	13	K2	CO2
13. a)	A pharmaceutical company wants to design a small molecule inhibitor for a structurally well-defined protein target. High throughput virtual screening has not been successful in generating potential HITS.			
	i. Briefly illustrate how the de novo based design can be adopted for the above scenario.	6	K3	CO3
	ii. Explain how AUTODOCK algorithm can be applied to validate the binding of molecules generated by de novo design.	7	K3	
	(OR)			
b)	A potential HIT molecule generated by virtual screening with high binding affinity to the target exhibited a poor binding in cell line studies.			
	i. Explain how can you simulate the better protein ligand conformations by applying software packages like GROMACS.	6	K3	CO3
	ii. Justify how MM/PBSA based calculation yield better similarities to in vitro models.	7	K3	

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|--------|--|----|----|-----|
| 14. a) | A pharmaceutical company had to perform clinical trials for a drug candidate employed in the treatment of <b>PIH (Pregnancy Induced Hypertension)</b> among Indian population. Critically analyze the guidelines, regulatory framework, mandatory disclosures and social issues regarding the conduct of this trial. | 13 | K4 | CO4 |
| (OR)   |  |    |    |     |
| b)     | Analyze the ethical challenges around the use of animals in clinical trials. Provide your inputs on how to mitigate the major challenges in animal studies with the increasing need for personalized and best performing drug candidates.  | 13 | K4 | CO4 |
| 15. a) | Critically evaluate the stages of process validation (Design, Qualification, Continued Process Verification) and their impact on drug safety.  | 13 | K4 | CO5 |
| (OR)   |  |    |    |     |
| b)     | Critically analyze the role of different regulatory bodies (Indian, U.S FDA, Australian) in maintain drug standards.   | 13 | K4 | CO5 |

**PART – C**

(1 x 15 = 15 Marks)

- | Q.No.  | Questions   | Marks | KL | CO  |
|--------|---|-------|----|-----|
| 16. a) | A pharmaceutical company wants to develop a multitargeted drug for Alzheimer's by screening of potential therapeutic molecules from <i>Ganoderma lucidium</i> extract by high throughput virtual screening. Analyze the objective and methodology of the study the company will adopt from initial structure compilation to arriving at a drug that can be taken for clinical trials. | 15    | K4 | CO5 |
| (OR)   |   |       |    |     |
| b)     | A pharmaceutical company wants to manufacture a monoclonal antibody targeting HER2 receptor for the treatment of breast cancer. Analyze the role of GMP practices (plant layout, material audit, utility qualifications and regulatory compliances) that has to be employed in this biotherapeutic manufacturing unit in compliance with the regulatory standards.                    | 15    | K4 | CO5 |