Register Number:……..

KUMARAGURU
college of technology
character is life

B.TECH DEGREE EXAMINATIONS: APRIL / MAY 2023

(Regulation 2018)

Sixth Semester

BIOTECHNOLOGY

U18BTT6001**:** Biopharmaceutical Technology

COURSE OUTCOMES

CO1: Outline National, International drug Standards, Control and pharmacopoeia commission
CO2: Describe the principles of drug action and mechanism of action
CO3: Discuss and obtain knowledge on the drug development, manufacture process and Regulatory practices
CO4: Understand the importance of biopharmaceutical final products production using upstream downstream process and ensure the quality of the product analysis
CO5: Explain the principles and materials involved during the drug manufacture in pharmaceutical industries
CO6: Discuss the clinical uses of biopharmaceutical therapeutics

Time: Three Hours **Maximum Marks: 100**

Answer all the Questions:-
PART A (10 x 2 = 20 Marks)
(Answer not more than 40 words)

1.	NDA- Expand and infer its function.	CO1	[K_2]
2.	Differentiate between enteral and parenteral routes of drug administration.	CO2	[K_2]
3.	Interpret the advantage of radiopharmaceuticals over external radiotherapy in cancer treatment.	CO2	[K_2]
4.	Analyze how protein based contaminants are eliminated during downstream processing of biopharmaceutical product stream.	CO4	[K_4]
5.	Is cloning of humans patentable? Justify it.	CO3	[K_4]
6.	How does prospective validation differ from retrospective validation?	CO4	[K_1]
7.	Apart from providing the mechanism for the safe and convenient delivery, give suitable reasons for accurate drug dosage forms.	CO5	[K_4]
8.	Prioritize the benefits of using rectal suppositories.	CO5	[K_2]
9.	List any two Colony-stimulating factors approved for medical use or in clinical trials.	CO6	[K_1]
10.	State the therapeutic applications of EPO.	CO6	[K_2]

Answer any FIVE Questions:-
PART B (5 x 16 = 80 Marks)
(Answer not more than 400 words)

11.		Categorize and brief the role of various national agencies that protect and safeguard the public health by assuring the safety, efficacy and quality of drugs.	16	CO1	[K_2]
12.	a)	With an example elucidate how ADME process helps the drug developers to distinguish a 'good' drug candidate.	12	CO2	[K_4]
	b)	Comment on the mechanism of tachyphylaxis.	4	CO2	[K_2]
13.	a)	Portray a suitable layout design of the special manufacturing facilities to produce quality pharmaceutical products.	12	CO3	[K_6]
	b)	Identify the major sources of biopharmaceuticals and add a note on it.	4	CO3	[K_2]
14.	a)	Compare and contrast the role of GMP, GCP and GLP type of audits in bringing pharmaceutical product to the market.	12	CO4	[K_2]
	b)	Quote the major objectives of The Drugs and Cosmetics Act, 1940.	4	CO4	[K_1]
15.	a)	Classify the different solid drug dosage forms and explain in detail.	12	CO5	[K_2]
	b)	Comment on the types and functions of elixirs.	4	CO5	[K_2]
16.	a)	Exemplify the role of cytokines as biopharmaceuticals with suitable examples.	12	CO6	[K_3]
	b)	Summarise the biological significance of IGF in fetal development.	4	CO6	[K_2]

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