Register Number:……..

KUMARAGURU
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B.E/B.TECH DEGREE EXAMINATIONS: NOV/ DEC 2024

(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.	List any two important roles of the Drugs Controller General of India (DCGI)	CO1	[K_2]
2.	What is the difference between enteral and parenteral routes of drug administration?	CO2	[K_4]
3.	Name the five basic principles of drug action.	CO2	[K_1]
4.	Identify the sources of biopharmaceuticals for drug development process.	CO3	[K_2]
5.	Outline the significance of patenting a process (or) product.	CO3	[K_2]
6.	Write the importance of GMPs in pharmaceutical sector. How they help in ensuring the product quality and safety?	CO4	[K_3]
7.	Name the key provisions of The Drugs & Cosmetics Act, 1940, in regulating the manufacture, distribution, and sale of drugs and cosmetics in India.	CO4	[K_2]
8.	What is the reason for capsule preparation in solid dosage form?	CO5	[K_1]
9.	Define transdermal drug delivery system and provide an example.	CO5	[K_2]
10.	What are the therapeutic uses of haemopoietic growth factors?	CO6	[K_2]

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

11.		Compare the functions of Food and Drug Administration (FDA) and Medicines and Healthcare products Regulatory Agency (MHRA). Discuss the significance of their guidelines in ensuring global drug safety and efficacy.	16	CO1	[K_4]
12.	a)	Give a brief account on drug absorption and distribution.	08	CO2	[K_2]
	b)	Describe the mechanism of drug action mediated through receptors, with suitable examples.	08	CO2	[K_2]
13.	a)	Write a short note on the manufacturing process of biopharmaceuticals, highlighting the challenges and required facilities.	08	CO3	[K_3]
	b)	Discuss the importance of final product analysis in ensuring drug quality.	08	CO3	[K_2]
14.		Explain the principles of Good Clinical Practices (GCP) and their importance in ensuring the integrity of clinical research. Also, discuss the regulatory framework overseeing clinical trials in India.	16	CO4	[K_2]
15.	a)	Elaborate the role of excipients in tablet formulation, including binders, fillers, disintegrants, lubricants, and glidants, and discuss their functions in tablet manufacturing.	08	CO5	[K_2]
	b)	Compare and contrast the traditional methods with modern technologies of manufacture of vaccines (Hint: Live attenuated, Inactivated subunit and mRNA vaccines.	08	CO5	[K_2]
16.		Differentiate the production and clinical uses of hormones insulin and glucagon. Explain their mechanisms of action and how they are used in managing diabetes.	16	CO6	[K_3]

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