



B.E/B.TECH DEGREE EXAMINATIONS: APRIL /MAY 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)

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| 1. Recall the Importance of pharmacopoeia. | CO1 [K ₁] |
| 2. Cite the role of FDA and WHO in pharmaceutical industry. | CO1 [K ₂] |
| 3. Distinguish pharmacokinetics from pharmacodynamics. | CO2 [K ₂] |
| 4. How do radioactivity elements help in the Production of therapeutical? | CO2 [K ₂] |
| 5. Name some biopharmaceutical products produced by animal cells. | CO4 [K ₁] |
| 6. Define Biogenerics. | CO3 [K ₁] |
| 7. Write down the purpose of Schedule M and Y. | CO3 [K ₂] |
| 8. What is the need for a dosage form of a drug? | CO5 [K ₂] |
| 9. Differentiate ointments from creams. | CO5 [K ₄] |
| 10. Write the function of erythropoietin in humans. | CO6 [K ₂] |

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

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|-----|--|----|-----|-------------------|
| 11. | Examine the detailed functions of CDSCO. With suitable examples. | 16 | CO1 | [K ₃] |
| 12. | How do drugs cross the cell membrane in the human body? Summarise the detailed mechanism. | 16 | CO2 | [K ₂] |
| 13. | “Introducing a novel medicine to the market is a time-consuming and costly process”. Justify and brief the detailed process of the same. | 16 | CO3 | [K ₃] |
| 14. | Describe in detail the production process and application of Cytokine with suitable diagram. | 16 | CO6 | [K ₃] |
| 15. | a) Illustrate any one process of compressed tablet manufacturing. | 06 | CO5 | [K ₂] |
| | b) Identify the basic component of a transdermal drug delivery system. | 10 | CO5 | [K ₃] |
| 16. | a) With neat diagram explain the steps involved in the production of human insulin by rDNA technology. | 12 | CO4 | [K ₃] |
| | b) Classify validation processes | 04 | CO4 | [K ₂] |
