

Reg. No.

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

B.E. / B.TECH. DEGREE EXAMINATIONS, MAY 2023

Sixth Semester

BT18002 – BIOPHARMACEUTICAL TECHNOLOGY*(Biotechnology)***(Regulation 2018)****TIME: 3 HOURS****MAX. MARKS: 100**

COURSE OUTCOMES	STATEMENT	RBT LEVEL
CO 1	Recognize the legal steps involved in progressing a new drug to market and to grab the current regulatory acts and safety norms of the modern pharmaceutical industries.	2
CO 2	Illustrate the mechanism of drug action and pharmacokinetics of a given drug.	2
CO 3	Identify the requirements to set up a biopharmaceutical industry and the applications of unit operations in biopharmaceutical industry.	2
CO 4	Evaluate different pharmaceutical parameters for the current and future biotechnology related products on the market.	3
CO 5	Investigate the novel pharmaceutical products, current medicines and their applications in therapeutic and diagnostic fields.	3

PART- A (10 x 2 = 20 Marks)

(Answer all Questions)

	CO	RBT LEVEL
1. Define pharmacoeconomics.	1	1
2. List out the functions of pharmaceutical industries and its governance.	1	1
3. Define Therapeutic index.	2	2
4. What is meant by first pass effect?	2	2
5. Comment on current scenario of an Indian pharmaceutical industry meant for bulk drug manufacture.	3	2
6. What is meant by API? Give few examples.	3	2
7. Sort-out the mechanical properties of the plastic packaging materials.	4	1
8. List the analytical methods and tests for various drugs and pharmaceuticals.	4	1
9. What are the various ways by which vitamin deficiency can occur?	5	1
10. Give the meaning of the followings: vasectomy & Expectorant.	5	2

PART- B (5 x 14 = 70 Marks)

	Marks	CO	RBT LEVEL
11. (a) Elaborately discuss the importance of drug discovery, drug design and various phases involved in the clinical development of investigational drugs as dosage form.	(14)	1	3

(OR)

- | | | | | |
|---------|--|------|---|---|
| (b) | (i) What are the main implications of patent law in pharmaceutical industry? | (7) | 1 | 3 |
| | (ii) What are the important good manufacturing practices to be followed in a pharmaceutical manufacturing unit? | (7) | 1 | 3 |
| 12. (a) | Biological activity of a drug does not simply depend on its chemical structure but also on its physicochemical properties. Illustrate the above statement with suitable examples. | (14) | 2 | 4 |
| (OR) | | | | |
| (b) | Explain the various factors which influence the distribution and metabolism of drugs in the body. | (14) | 2 | 4 |
| 13. (a) | Discuss in detail about the important chemical conversion processes used in pharmaceutical industries. | (14) | 3 | 3 |
| (OR) | | | | |
| (b) | Outline the chemical factors that need to be considered when scaling up a research scale synthesis to pilot plant scale and to bulk manufacture. | (14) | 3 | 3 |
| 14. (a) | Give a detailed account on manufacturing principles of tablets, with a neat illustration and its applications. | (14) | 4 | 4 |
| (OR) | | | | |
| (b) | Identify any two topical diseases where each of the four various types of ointment bases might be employed to deliver (an) active ingredient (s) and explain their formulation in detail. | (14) | 4 | 4 |
| 15. (a) | What are the targets for drug in human body? Illustrate the interaction of aspirin with the human body and tabulate the changes in the biological process with its advantages and disadvantages. | (14) | 5 | 3 |
| (OR) | | | | |
| (b) | Define and classify laxatives with examples. Write a note on the irritant and lubricant laxatives. | (14) | 5 | 3 |

PART- C (1 x 10 = 10 Marks)

(Q.No.16 is compulsory)

- | | | Marks | CO | RBT
LEVEL |
|-----|--|-------|----|--------------|
| 16. | Discuss the standardization and validation of various vaccines used against COVID-19 along with merits and demerits. | (10) | 5 | 5 |
