CBCS SCHEME

USN | | | | | | | | | | |

18BT81

Eighth Semester B.E. Degree Examination, Dec.2024/Jan.2025
Regulatory Affairs in Biotech Industry

Time: 3 hrs. Max. Marks: 100

Note: ***Answer any FIVE full questions, choosing ONE full question from each module.***

Important Note : 1. On completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages.
2. Any revealing of identification, appeal to evaluator and /or equations written eg, 42+8 = 50, will be treated as malpractice.

Module-1

1 a. Write a critical note on GLP R GMD. **(10 Marks)**

b. Explain the history, importance R significance of FDA. **(10 Marks)**

OR

2 a. Write a descriptive note on Federal food R drug act ; Safe medical devices act. **(10 Marks)**

b. Explain the need and importance for regulations in Biotech industry. **(10 Marks)**

Module-2

3 a. Explain the process of validation of HVAC facilities and highlight the process of HVAC qualification. **(15 Marks)**

b. Write a short note on Non-sterile process validation in pharmaceuticals. **(05 Marks)**

OR

4 a. Highlight the importance of cleaning validation in Biotech industry. **(10 Marks)**

b. Elaborate on the importance of statistical process control for HPLC in Pharma industry. **(10 Marks)**

Module-3

5 a. Discuss ISO 9001 – 2000 in detail. **(15 Marks)**

b. Write a short note on statistical techniques. **(05 Marks)**

OR

6 a. Explain ISO – 14001 in detail. **(15 Marks)**

b. Write a short note on quality management system. **(05 Marks)**

Module-4

7 a. Explain the concept of quality and quality management with regard to regulatory affairs. **(10 Marks)**

b. Discuss the concept of Characteristics and conformity. **(10 Marks)**

OR

8	a.	Elaborate on the procedure and objectives of corrective of preventive actions.	(10 Marks)
	b.	Write a short note on Final inspection and testing.	(10 Marks)

Module-5

9	a.	Discuss the 'V' model for validation of documentation.	(10 Marks)
	b.	Write short note on validation master plans.	(10 Marks)

OR

10	a.	Explain the different types of risk analysis techniques of highlight failure mode of effective analysis techniques.	(10 Marks)
	b.	Describe solid dose manufacture principles and practices.	(10 Marks)

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