

USN

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

18BT81

Eighth Semester B.E. Degree Examination, June/July 2023

Regulatory Affairs in Biotech Industry

Time: 3 hrs.

Max. Marks: 100

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

Module-1

- 1 a. Write a short notes on the following :
 - i) Good Manufacturing Practice (05 Marks)
 - ii) Good Laboratory Practice (05 Marks)
- b. Discuss about FDA operations in detail. (10 Marks)

OR

- 2 a. Explain the following :
 - i) ISO 9000 (05 Marks)
 - ii) IQ, OQ and PQ (05 Marks)
- b. Describe the process of validation. (10 Marks)

Module-2

- 3 a. Write a short note on :
 - i) Validation of Aseptic method (05 Marks)
 - ii) Validation of Non-Sterile process (05 Marks)
- b. Discuss in detail about validation of water and thermal systems. (10 Marks)

OR

- 4 a. Write in detail about FDA and ICH guidelines. (10 Marks)
- b. i) Control of HPLC (05 Marks)
- ii) LOD (05 Marks)

Module-3

- 5 a. Explain the following :
 - i) Quality Audits (05 Marks)
 - ii) Internal Quality Audits (05 Marks)
- b. Write a short note on :
 - i) Document and data control (05 Marks)
 - ii) Management responsibilities in ISO. (05 Marks)

OR

- 6 a. i) Mention the importance of Quality Management system. (05 Marks)
- ii) Documents Requirement (05 Marks)
- b. Explain the following :
 - i) ISO 14001 (05 Marks)
 - ii) Environmental Management Systems (05 Marks)

Module-4

- 7 a. Explain the following :
i) Analysis and Improvement (05 Marks)
ii) Quality Management (05 Marks)
- b. State the following :
i) Quality control (05 Marks)
ii) Quality policy (05 Marks)

OR

- 8 a. Explain the following :
i) Corrective action in Quality Management (05 Marks)
ii) Final Inspection and Testing (05 Marks)
- b. Explain in detail about quality characteristic and preventive action. (10 Marks)

Module-5

- 9 a. Write a note on :
i) Risk Analysis Techniques (05 Marks)
ii) The “V” model and life cycle model (05 Marks)
- b. Explain
i) Risk assessment and management in the pharmaceutical industry (05 Marks)
ii) FMEA (05 Marks)

OR

- 10 a. Explain the following :
i) Cream manufacture principles (05 Marks)
ii) Quality and continuous improvement in Biotech Industry. (05 Marks)
- b. Discuss in detail about Solid Dose manufacture principles and practices. (10 Marks)

* * * * *