CBCS SCHEME

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

18BT81

Eighth Semester B.E. Degree Examination, July/August 2022
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. Explain in detail about FDA operations and Industry Compliance Regulations. **(10 Marks)**

b. Write a short note on the following :

i) Good Manufacturing Practice **(05 Marks)**

ii) Good Laboratory practice. **(05 Marks)**

OR

2 a. Describe the process of validation. **(10 Marks)**

b. Explain the following :

i) IQ, OQ and PQ **(05 Marks)**

ii) ISO 9000. **(05 Marks)**

Module-2

3 a. Explain in detail about validation of water and thermal systems. **(10 Marks)**

b. Explain the following :

i) Validation of Aseptic APIs **(05 Marks)**

ii) Validation of Non-sterile processes. **(05 Marks)**

OR

4 a. Write in detail about FDA and ICH Guidelines. **(10 Marks)**

b. i) What is limit of detection in FDA? Explain. **(05 Marks)**

ii) State the process control for HPLC. **(05 Marks)**

Module-3

5 a. Write note on :

i) Management Responsibility in ISO **(05 Marks)**

ii) Document and Data control **(05 Marks)**

b. State

i) Quality Audits **(05 Marks)**

ii) Statistical Techniques **(05 Marks)**

OR

6 a. Mention the importance of i) Quality Management System. **(05 Marks)**

ii) Documents Requirements. **(05 Marks)**

b. Write note on :

i) Environmental Management Systems **(05 Marks)**

ii) ISO 14001 **(05 Marks)**

Module-4

7 a. State

i) Customer Satisfaction **(05 Marks)**

ii) Quality Management System. **(05 Marks)**

b. Explain the following :

i) Quality policy (05 Marks)

ii) Quality control. (05 Marks)

OR

8 a. Explain in detail about quality characteristics and preventive action. (10 Marks)

b. Explain the following :

i) Corrective action (05 Marks)

ii) Final Inspection and Testing. (05 Marks)

Module-5

9 a. Write notes on

i) The "V" model and Life cycle model (05 Marks)

ii) Risk analysis Techniques. (05 Marks)

b. Explain :

i) FMEA (05 Marks)

ii) Risk Management in the Pharmaceutical Industry. (05 Marks)

OR

10 a. Explain in detail about Solid Dose Manufacture principles and practices. (10 Marks)

b. Write a short notes on :

i) Liquid and Cream Manufacture principles (05 Marks)

ii) Quality and continuous improvement in Biotech Industry. (05 Marks)

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