CBCS SCHEME

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

18BT81

Eighth Semester B.E. Degree Examination, June/July 2024
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. How does GCP help in process validation of pharmaceutical manufacturing? Explain. **(10 Marks)**

b. Justify that concurrent validation is distinct from retrospective validation. **(10 Marks)**

OR

2 a. What is GMP? Describe how GMP requirements will help to maintain the products quality. **(10 Marks)**

b. What is ISO – 9000 series? Provide examples of how ISO 9000 affects GMP and International harmonization. **(10 Marks)**

Module-2

3 a. Make succinct notes about :
i) Limits of Detection (LOD) ii) Limits of Quantification (LOQ). **(10 Marks)**

b. Describe the procedure for HVAC system validation. **(10 Marks)**

OR

4 a. How does the SPC tool acids in the process of process validation? Explain with the case of HPLC. **(10 Marks)**

b. Explain the validation process concepts with respect to semi – solid dosage forms. **(10 Marks)**

Module-3

5 a. ISO 9000 QMS prescribes 8 Quality management principles as a guide for forming and managing the system. Briefly describe 5 of them. **(10 Marks)**

b. What do you mean by document and data control? Write a note on its implementation. **(10 Marks)**

OR

6 a. Explain the importance of maintaining ISO standards would assist with product realization. **(10 Marks)**

b. Describe the Managements role in sustaining ISO standards. **(10 Marks)**

Module-4

7 a. Is there a difference between Quality Control and Quality Assurance? If yes, what is it? **(10 Marks)**

b. Explain Quality policy and objectives related to Pharmaceutical Industry. **(10 Marks)**

OR

8 a. What are the benefits of Total Quality Management? Mention atleast 5. **(10 Marks)**

b. Put up a short note on :
i) Inspection and Testing ii) Training and Servicing. **(10 Marks)**

Module-5

9 a. Explain with an example Failure Mode Effects Analysis (FMEA). **(10 Marks)**

b. Describe the concept of Clinical Trials Quality Assurance Management System. **(10 Marks)**

OR

10 a. Discuss on the concept of model validation and verification during the life cycle manufacture process description. **(10 Marks)**

b. Give your opinion on the guidelines and procedures for manufacturing of solid dose pharmaceuticals. **(10 Marks)**

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