CBCS SCHEME

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

15BT82

Eighth Semester B.E. Degree Examination, June/July 2019
Regulatory Affairs in BT Industry

Time: 3 hrs. Max. Marks: 80

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? **(08 Marks)**
b. Differentiate Process Validation with Process Qualification. **(08 Marks)**

OR

2 a. Differentiate GMP with GLP. **(04 Marks)**
b. How does SPC tool helps in Process validation? **(08 Marks)**
c. Differentiate Concurrent Validation from Retrospective Validation. **(04 Marks)**

Module-2

3 a. Explain the steps in validation of HVAC system. **(08 Marks)**
b. Explain how to carry on validation of API. **(08 Marks)**

OR

4 Write short notes on :
a. Limits of detection (LOD).
b. Limits of Quantification (LOQ).
c. Minimum Detectable Amount (MDA).
d. Specificity and Accuracy. **(16 Marks)**

Module-3

5 a. Give the ISO series of standard with their scope and definitions. **(08 Marks)**
b. Explain the responsibility of Management in maintaining ISO standards. **(08 Marks)**

OR

6 a. Define ISO – 14001. Explain the role and responsibilities of Environmental Management Systems. **(08 Marks)**
b. How does product realization helps in maintaining ISO standards? **(08 Marks)**

Module-4

7 Explain the following terms :
a. Quality Policy.
b. Quality Objectives.
c. Quality Planning.
d. Quality Improvement. **(16 Marks)**

OR

8 Write short notes on :
a. Contract Review and Audit.
b. Identification and Traceability.
c. Inspection and Testing.
d. Training and Servicing. **(16 Marks)**

Module-5

9 a. Explain the different Risk Analysis techniques in Quality Management. **(08 Marks)**
b. Explain the V model and Life cycle model approach to validation. **(08 Marks)**

OR

10 a. Discuss how does Risk management will help in Pharmaceutical Industry. **(08 Marks)**
b. Explain the concept of Pharmaceutical Engineering. **(08 Marks)**

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