

CBCS SCHEME

15BT82

USN

| | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

Eighth Semester B.E. Degree Examination, Aug./Sept.2020 Regulatory Affairs in Biotech Industry

Time: 3 hrs.

Max. Marks: 80

- Note: i) For Regular Students: Answer any FIVE full questions irrespective of modules.
ii) For Arrear Students : Answer any FIVE full questions, choosing ONE full question from each module.*

Module-1

- 1 a. Define process validation. Explain about the stages of process validation. (08 Marks)
b. Define ISO 9000. Explain about the ISO series of standards. (08 Marks)
- 2 a. Define Process Analytical Technology [PAT]. What does FDA regulates? Explain with examples. (08 Marks)
b. What are IQ, OQ, PQ? Why are they required in the pharmaceutical Industry? (08 Marks)

Module-2

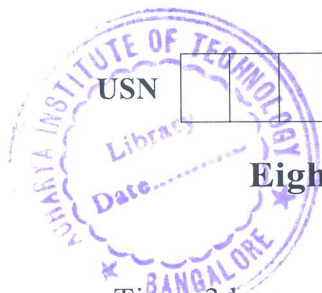
- 3 a. Define clean room. Write a note about the HVAC and cleaning validation. (07 Marks)
b. What is statistics? Discuss about the statistical process control for HPLC. (09 Marks)
- 4 a. What is active Pharmaceutical Ingredients (API's)? Explain about the Importance of API's validation. (08 Marks)
b. Define Limits of Quantification [LOQ]. Explain about the ICH guidelines with respect to the method of the evolution. (08 Marks)

Module-3

- 5 a. Define ISO-14001. Discuss about the Importance of ISO-14001 in Environmental Management System (EMS). (08 Marks)
b. Discuss about the product realization, measurement analysis and improvement. (08 Marks)
- 6 a. Explain about the preservation, delivery and control of Quality Records. (08 Marks)
b. Discuss about the document Requirements and Management's responsibility. (08 Marks)

Module-4

- 7 a. What is Quality Trilogy? Write a note about the terms relating to the Quality, Management and Quality Management Systems. (08 Marks)
b. Explain about the Quality system, contract review design control, document and data control. (08 Marks)
- 8 a. Write a note on:
i) Internal Quality Audit's, Training and Servicing
ii) Process Control, Inspection and Testing. (08 Marks)
b. Define: i) Conformity ii) Corrective Action iii) Deviation permit iv) Defect. (08 Marks)



Module-5

- 9 a. Discuss about the Failure Mode and Effects Analysis (FMEA). (07 Marks)
b. What is revalidation? Explain about the liquid and cream manufacture principles and practices? (09 Marks)
- 10 a. What is pharmaceutical engineering? Write a note on Facility, Equipment design and process design in pharmaceutical engineering. (09 Marks)
b. Explain about the quality and continuous improvement in the biotech industry. (07 Marks)
