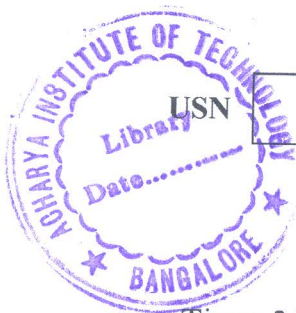


# CBCS SCHEME

15BT82



## Eighth Semester B.E. Degree Examination, July/August 2021 Regulatory Affairs in BT Industry

Time: 3 hrs.

Max. Marks: 80

**Note: Answer any FIVE full questions.**

- 1 a. Briefly explain the concept of process validation with the help of case study. (08 Marks)  
b. Explain the importance of GMP in a pharmaceutical sector. (08 Marks)
- 2 a. Compare and contrast process validation and process qualification. (08 Marks)  
b. Justify the need and use of statistical process control technique in BT industry. (08 Marks)
- 3 a. List out the steps in validating a HVAC system. (10 Marks)  
b. Explain the validation process for Non-sterile processes. (06 Marks)
- 4 a. With a case study justify need for validating the analytical instruments. (08 Marks)  
b. List out the steps to troubleshoot out of control systems. (08 Marks)
- 5 a. Give a brief description on ISO 9000 series of standards. (08 Marks)  
b. Describe the managements responsibility in maintaining quality standards. (08 Marks)
- 6 a. Define Quality Management System (QMS). Give the roles and responsibilities of QMS. (08 Marks)  
b. Describe how measurement, analysis and improvement is done to maintain the quality of products. (08 Marks)
- 7 Critically comment on:  
a. Quality Assurance.  
b. Quality Policy.  
c. Quality Improvement.  
d. Quality planning. (16 Marks)
- 8 Compare and contrast on:  
a. Conformity and Non conformity.  
b. Preventive action and Corrective action.  
c. Final inspection and Testing Inspection.  
d. Design control and Data control. (16 Marks)
- 9 a. Compare and contrast Vmodel and life cycle model to validation. (08 Marks)  
b. Justify the need for Risk Analysis Techniques through failure mode and Effect Analysis (FMEA) in BT industry. (08 Marks)
- 10 a. List out the steps in computer system validation. Justify with case study. (08 Marks)  
b. Explain the need of Process Analytical Technology (PAT) in pharmaceutical industry. (08 Marks)

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Important Note : 1. On completing your answers, compulsorily draw diagonal cross lines on the remaining blank pages.  
2. Any revealing of identification, appeal to evaluator and /or equations written eg. 42+8 = 50, will be treated as malpractice.