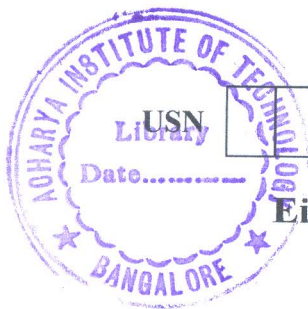


# GBCS SCHEME



17BT82

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

Time: 3 hrs.

Max. Marks: 100

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

- 1 a. Elaborate on the need of regulatory affairs in Pharmaceutical Industry. (10 Marks)  
b. Compare and contrast process validation from qualification procedures. (10 Marks)
- 2 a. With a suitable case study explain the need of SPC technique in validation. (10 Marks)  
b. Compare and contrast GMP from GLP. (10 Marks)
- 3 a. Explain how important is to validate HVAC facilities and mention its steps. (10 Marks)  
b. With suitable case study explain the steps in validating analytical instruments. (10 Marks)
- 4 a. Mention the critical parameters identified in validating the semi-solid dosage forms and explain its steps. (10 Marks)  
b. Explain the steps in validating Active Pharmaceutical Ingredient (API). (10 Marks)
- 5 a. Explain the role and responsibility of Quality Management System (QMS) in maintaining ISO standard. (10 Marks)  
b. Define ISO-14001. Explain the roles and responsibilities of environmental management system. (10 Marks)
- 6 a. Define ISO 9000. Explain the importance of ISO 9000 series in quality maintenance. (10 Marks)  
b. Mention the importance of Internal Quality Audits in maintaining the standards. (10 Marks)
- 7 Differentiate the following:  
i) Design control and data control  
ii) Quality control and quality assurance. (20 Marks)
- 8 Write short notes on the following terms:  
a. Contract Review  
b. Metrological confirmation  
c. Non-conformity  
d. Continual Improvement. (20 Marks)
- 9 a. Explain the different types of risk analysis techniques. (10 Marks)  
b. Explain the steps in computer system validation with suitable case study. (10 Marks)
- 10 a. Justify the need of Process Analytical Technology (PAT) in Biotech Industry. (10 Marks)  
b. Compare and contrast V model and Life cycle model. (10 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.