

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – WINTER -2024

Subject Code:BP706TT

Date: 30-11-2024

Subject Name: Quality Assurance

Time:10.30 AM TO 01.30 PM

Total Marks: 80

Instructions:

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

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|-------------|-----|--------------------------------------------------------------------------------------------------------------|----|
| Q.1 | (a) | What are QA and QC? What are the responsibilities of QA and QC departments in Pharmaceutical plant? | 06 |
| | (b) | What are the requirements for sterile area manufacturing plant? How should be it maintained? | 05 |
| | (c) | Short Note: Quality control tests for rubber closures and containers. | 05 |
| Q.2 | (a) | What is Quality Audit? Which documents are required for it? | 06 |
| | (b) | What is Qualification? Explain Various types of Qualification. | 05 |
| | (c) | What is TQM? Discuss the elements of TQM. | 05 |
| Q.3 | (a) | Write a note on principle and procedure for NABL accreditation. | 06 |
| | (b) | Discuss about design, construction and plant layout for Pharmaceutical manufacturing plant according to GMP. | 05 |
| | (c) | What is the protocol for conduct of Nonclinical laboratory study? Discuss in brief. | 05 |
| Q.4 | (a) | What is Validation? Give importance and scope of Validation. | 06 |
| | (b) | Write a note on: Master Formula Record. | 05 |
| | (c) | Write a note on: Good Warehousing Practice. | 05 |
| Q.5 | (a) | What are Q-series guidelines? Discuss in brief about ICH stability testing guidelines. | 06 |
| | (b) | What is QbD? Discuss the elements of QbD program. | 05 |
| | (c) | What should be the criteria for equipment selection? What is equipment purchase specification? | 05 |
| Q. 6 | (a) | Which records and reports required to be maintained in laboratory according to GLP? Discuss about it. | 06 |
| | (b) | What is SOP? Explain with one example. | 05 |
| | (c) | Explain in brief about Calibration. How to calibrate pH meter? | 05 |
| Q.7 | (a) | What are ISO 9000 and ISO 14000? Discuss its steps for registration. | 06 |
| | (b) | What is complaint? Explain its types and procedure for handling of complaints. | 05 |
| | (c) | Explain Qualification of UV-visible spectrophotometer. | 05 |
