

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm – SEMESTER VII• EXAMINATION – WINTER -2020

Subject Code: BP706TT**Date: 12/01/2021****Subject Name: Quality Assurance****Time: 10:30AM To 12:30PM****Total Marks: 54****Instructions:**

1. Attempt any THREE questions from Q-1 to Q-6.
2. Q.7 is compulsory to attempt.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks.

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|-------------|-----|--|-----------|
| Q.1 | (a) | Write is the difference between QA and QC. How QA, QC and GMP are correlated? | 06 |
| | (b) | Enlist different ICH guidelines. Discuss in brief about Quality guideline. | 05 |
| | (c) | What is QbD? Discuss different tools of QbD. | 05 |
| Q.2 | (a) | Draw a sample plant layout for pharmaceutical industry along with space required as per schedule M. | 06 |
| | (b) | Discuss maintenance of sterile area and control of contamination as a part of plant premises. | 05 |
| | (c) | Discuss various quality control tests for secondary packaging materials. | 05 |
| Q.3 | (a) | Give brief note on ISO 9000 & ISO 14000? Discuss various steps for its registration. | 06 |
| | (b) | Discuss principles of GLP. | 05 |
| | (c) | What is TQM? Explained various elements of TQM. | 05 |
| Q.4 | (a) | Give brief note on Quality control test for containers and rubber closures. | 06 |
| | (b) | What is difference between calibration, validation and qualification? Discuss any two validation parameters in detail. | 05 |
| | (c) | Discuss various characteristics to be validated for different types of analytical procedures. | 05 |
| Q.5 | (a) | What is a complaint? Discuss how to handle returns goods. | 06 |
| | (b) | Discuss BMR and its auditing with references to cGMP. | 05 |
| | (c) | Write a note on Master Formula Record. | 05 |
| Q. 6 | (a) | Define calibration. Discuss principles of calibration. | 06 |
| | (b) | Discuss general protocol for conduct of a Nonclinical laboratory study. | 05 |
| | (c) | Write brief note on SOP. | 05 |
| Q.7 | (a) | Discuss about personnel responsibility and hygiene in pharmaceutical industry. | 06 |
| | | OR | |
| | (a) | What is NABL accreditation? Discuss its importance. | 06 |
| | | OR | |
| | (a) | Write short note on Qualification of UV-Visible spectrophotometer. | 06 |
