

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

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

**Subject Code: BP706TT**  
**Subject Name: Quality Assurance**  
**Time: 10:30AM To 12:30PM**

**Date: 12/01/2021****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.

- 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**

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