

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM - SEMESTER-7 EXAMINATION – WINTER -2023**

**Subject Code: BP706TT****Date: 11/12/2023****Subject Name: Quality Assurance****Time: 10.30 a.m. to 1.30 p.m.****Total Marks: 80****Instructions:**

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

- Q.1** (a) Define the terms QA, QC and GMP and explain the difference between QA and QC. **06**
- (b) What is TQM? Explain the philosophies of TQM. **05**
- (c) What is the purpose of ICH guidelines? Write down the process of harmonization. **05**
- Q.2** (a) Draw plant layout of Pharmaceutical industry and discuss the design and construction requirements for pharmaceutical manufacturing unit according to GMP. **06**
- (b) Write down elements and registration process of ISO 9000. **05**
- (c) Write a note on personal responsibilities and training. **05**
- Q.3** (a) What is QbD? Explain elements of QbD in detail. **06**
- (b) Write a note on personnel hygiene and record. **05**
- (c) Explain in detail on NABL accreditation process. **05**
- Q.4** (a) Write down the quality control tests for containers. **06**
- (b) Explain in detail about utilities and maintenance of sterile areas. **05**
- (c) Write a note on purchase specification and maintenance of store for raw materials. **05**
- Q.5** (a) Define GLP. Write a note on GLP requirements for documentation in a non-clinical testing laboratory. **06**
- (b) Explain disqualification of testing facility in GLP. **05**
- (c) What are complaints? Write a note on evaluation of complaints. **05**
- Q.6** (a) What is SOP? Describe the contents of SOP. **06**
- (b) Explain in detail quality review and quality audit. **05**
- (c) Write a note on analytical method validation parameter. **05**
- Q.7** (a) Define calibration. Discuss the qualification of UV-Visible spectrophotometer. **06**
- (b) Define validation and write down different types of validation. **05**
- (c) Write a note on secondary packing material. **05**

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