

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm. – SEMESTER – VII • EXAMINATION – SUMMER -2021

Subject Code: BP706TT**Date: 07/08/2021****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.

- Q.1** (a) Enlist analytical method validation parameters for assay of drug products. Describe LOQ and accuracy with their evaluation techniques as per ICH. **06**
- (b) Discuss validation of UV – Visible spectrophotometer. **05**
- (c) What is pharmaceutical waste? Write a note on waste disposal procedures and the records to be kept for them. **05**
- Q.2** (a) What are the tools of QbD? Discuss briefly. **06**
- (b) Differentiate: Batch Formula Record and Master Formula Record. **05**
- (c) Write in brief about handling of returned goods with suitable examples. **05**
- Q.3** (a) Describe the advantages and disadvantages of plastic containers with that of glass container. Discuss QC tests carried out on plastic containers. **06**
- (b) Write objectives of GLP? Discuss in brief the key points in GLP. **05**
- (c) What is ISO? Write benefits of ISO. Describe steps for registration in general. **05**
- Q.4** (a) What is QA? Describe concepts and differences of QA and QC in brief. **06**
- (b) Write a brief note on TQM. **05**
- (c) Why product to be recall? Write briefly about procedures to be followed for recalling a product. **05**
- Q.5** (a) Write benefits of laboratory accreditation. Explain principles of NABL accreditation? **06**
- (b) Explain the term: Storage. Discuss briefly good warehousing practices for different materials used in pharmaceutical industry. **05**
- (c) Write a note on purchase specifications for equipment. **05**
- Q.6** (a) Discuss about maintenance of sterile areas in premises. **06**
- (b) Write a note on ICH stability testing guideline. **05**
- (c) What is ICH? Give brief overview of QSEM code assigned to ICH guideline. Enlist categories in which process of harmonization implemented by ICH. **05**
- Q.7** (a) What is QbD? Discuss QTPP and CQA. **06**
- (b) Write in brief about SOP. **05**
- (c) Discuss about responsibilities and training guideline for personnel in an organisation. **05**