

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Ph. – SEMESTER-VII • EXAMINATION – WINTER-2022**

**Subject Code: BP706TT****Date: 31/12/2022****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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|------------|-----|--|-----------|
| <b>Q.1</b> | (a) | Write importance and scope of validation. Discuss qualification of UV-Visible Spectrophotometer.             | <b>06</b> |
|            | (b) | Discuss validation of analytical procedures.   | <b>05</b> |
|            | (c) | What is pharmaceutical waste? Write a note on waste disposal procedures and the records to be kept for them. | <b>05</b> |
| <b>Q.2</b> | (a) | Enlist different ICH guidelines. Discuss in brief about Quality guideline.                                   | <b>06</b> |
|            | (b) | What is QA? Differences of QA and QC.  | <b>05</b> |
|            | (c) | Write a detailed note on TQM.  | <b>05</b> |
| <b>Q.3</b> | (a) | Write in brief about SOP.  | <b>06</b> |
|            | (b) | Give brief note on ISO 9000 & ISO 14000? Discuss various steps for its registration.                         | <b>05</b> |
|            | (c) | Explain importance of Quality by design. Discuss elements of QBD program.                                    | <b>05</b> |
| <b>Q.4</b> | (a) | Draw a sample plant layout for pharmaceutical industry along with space required as per schedule M.          | <b>06</b> |
|            | (b) | Write a note on Master Formula Record.   | <b>05</b> |
|            | (c) | What is a complaint? Discuss how to handle returns goods.  | <b>05</b> |
| <b>Q.5</b> | (a) | Write a brief note on GLP.   | <b>06</b> |
|            | (b) | Discuss responsibilities of personnel in Pharmaceutical organization.  | <b>05</b> |
|            | (c) | What does GMP cover? Write main principles of GMP for pharmaceutical products.                               | <b>05</b> |
| <b>Q.6</b> | (a) | Write details on DQ, IQ, OQ and PQ.  | <b>06</b> |
|            | (b) | Write the importance of training, hygiene and records of personnel in Pharmaceutical organization.           | <b>05</b> |
|            | (c) | Define calibration. Discuss principles of calibration.   | <b>05</b> |
| <b>Q.7</b> | (a) | Discuss about maintenance of sterile areas in premises.  | <b>06</b> |
|            | (b) | Discuss briefly good warehousing practices for different materials used in pharmaceutical industry.          | <b>05</b> |
|            | (c) | Explain principles of NABL accreditation?  | <b>05</b> |

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