

**Roll No.**

**Total No. of Pages : 02**

**Total No. of Questions : 13**

**B.Pharm (Sem.-6)**

**Subject Code : BP-606T**

**M.Code : 77991**

**Date of Examination : 03-01-23**

**Time : 3 Hrs.**

**Max. Marks : 75**

**INSTRUCTIONS TO CANDIDATES :**

1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains THREE questions carrying TEN marks each and students have to attempt any TWO questions.**
3. **SECTION-C contains NINE questions carrying FIVE marks each and students have to attempt any SEVEN questions.**

## SECTION-A

- 1. Define briefly :**
- a) TQM
  - b) Quality by Design.
  - c) Quality Audit.
  - d) Accreditation
  - e) Installation Qualification (IQ).
  - f) Batch Formula Record.
  - g) Performance Qualification (PQ).
  - h) NABL.
  - i) ISO 14000
  - j) Contamination control in Sterile Area.

## SECTION-B

2. What is ICH? What is the purpose of ICH guidelines? Explain briefly the various categories of ICH guidelines. Enlist various ICH Quality guidelines. Discuss the ICH stability testing guidelines.
3. Define Good Laboratory Practices (GLP). What are the objectives of GLP? Discuss the GLP provisions regarding the Organization and Personnel, Facilities, Equipment and testing facilities.
4. Discuss the role of quality assurance department in equipment selection, framing purchase specifications, maintenance of stores and raw materials.

## SECTION-C

5. Differentiate between quality control and quality assurance.
6. Write an account on TQM.
7. What is GMP and cGMP? Discuss the benefits of GMP in pharmaceuticals.
8. Define calibration. Discuss the characteristics of calibration.
9. What is Master Formula Record? Give its contents.
10. What is product recall? Explain procedure of product recall.
11. Write an account on general principles of analytical method validation.
12. Discuss good warehousing practices.
13. Enlist various quality control tests on containers. Explain hydrolytic resistance test on glass.

**NOTE : Disclosure of identity by writing mobile number or making passing request on any page of Answer sheet will lead to UMC against the Student.**