**B. Pharm 6th Semester Examination**

**Subject- Quality Assurance (BP606T)**

**Full Marks- 75 Time – 3 hours**

**Answer all the questions.**

**1. Define (10x2=20)**

(a) ISO 14000

(b) GLP

(c) ICH Guidelines

(d) Validation

(e) SOP

(f) Quality Audit

(g) Distribution Records

(h) Quality by Design

(i) NABL Accreditation

(j) Calibration

**2. Answer any two of the following. (2x10=20)**

(a) Define Validation along with general principles of Analytical Method Validation.

(b) Discuss about -Provisions related to GLP.

(c) Discuss about Principles and procedures of NABL accreditation.

**3. Answer any seven of the following. (7x5=35)**

(a) Quality control test for packaging materials

(b) BFR and MFR

(c) Types of Validation

(d) Elements of TQM

(e) Brief overview on QSEM

(f) Elements of ISO 9000

(g) Premises for GMP designing

(h) Q.C test for rubber closures

(i) Concepts of Quality Assurance