



**INSTITUTE OF PHARMACY**  
**GITAM (Deemed to be University)**

**B. PHARMACY 6<sup>th</sup> SEMESTER – II MID SEMESTER EXAMINATION (Section A & B)**

**BP 606T: PHARMACEUTICAL QUALITY ASSURANCE**

**Time: 1 hr 10 Min.**

**Date of Examination: 06.03.2020**

**Max Marks: 30**

**I. Multiple Choice Questions: Write the answer inside the box provided**

**4 × 1 = 04**

1. Which of the following is ICH stability guideline? [      ]  
 (a) Q1 (c) S1  
 (b) E1 (d) M1
2. The following deals with the ISO quality certification. [      ]  
 (a) ISO 18000 (c) ISO 9000  
 (b) ISO 14000 (d) ISO 2000
3. The documented evidence based on analysis of historical information is known as ----- [      ]  
 (a) Prospective validation (c) Retrospective validation  
 (b) Concurrent validation (d) Revalidation
4. Which of the following properties should be considered while selecting glass for packaging in pharma? [      ]  
 (a) Delamination (c) Leaching of alkali  
 (b) Photodegradation (d) All

**II. Objective Type Questions**

**3 × 2 = 06**

5. Define quality audit.
6. Define calibration.
7. What is NABL? Write its objective.

**III. Answer any ONE question: Each question carries 10 marks**

**1 × 10 = 10**

8. Define validation. Discuss the importance, scope and types of validation.
9. Explain the elements and benefits of QbD programme.

**IV. Answer any TWO questions: Each question carries 5 marks**

**2 × 5 = 10**

10. Write a note on batch formula record.
11. Discuss in detail the quality control tests for glass containers.
12. Describe the ICH harmonization process.



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