



# Graphic Era

## HILL UNIVERSITY

Established by an Act of the State Legislature of Uttarakhand (Adhiniyam Sankhya 12 of 2011)  
University under section 2(f) of UGC Act, 1956

### Sessional I (Even) Semester Examination, March 2025

Roll no.....

Name of the Course and semester: B. Pharm VI  
Name of the Paper: Pharmaceutical Quality Assurance  
Paper Code: BP 606 T  
Time: 1.5-hour

Maximum Marks: 30

**Note:**

- (i) This question paper contains three sections.
- (ii) All the questions are compulsory.

**Section-A**

**1. Multiple Choice Questions – Attempt all questions**

**(10 X 1 = 10 Marks)**

i) In ICH, there are .....participants :

(CO1)

- a. 2
- b. 6
- c. 4
- d. 5

ii) ISO 9000 is concerned with guidelines including:

(CO1)

- a. Work management
- b. Environment management
- c. Quality management
- d. All of these

iii) Q.C. is concerned with:

(CO1)

- a. Verification of individuals
- b. Verification of sampling
- c. Verification of SOPs
- d. Verification of equipments

iv) For the first time, WHO drafted GMP guidelines in the year:

(CO1)

- a. 1969
- b. 1967
- c. 1968
- d. 1970

v) TQM is related to ..... organization service.

(CO1)

- a. Quality focused
- b. Quantity focused
- c. Management focused
- d. Customer focused

vi) Terminal processing of sterile area includes evaluation of .....contamination : (CO2)

- a. Qualitative microbial
- b. Quantitative microbial
- c. Qualitative mixed
- d. Quantitative mixed

vii) To approve or reject packaging material is duty of : (CO2)  
a. QC Head  
b. Production Head  
c. QA Head  
d. All of these

viii) Grade D area categorized under : (CO2)  
a. ISO 5  
b. ISO 7  
c. ISO6  
d. ISO 8

ix) Full form of QbD: (CO2)  
a. Quality by Design  
b. Quality by Development  
c. Quality by Draft  
d. Quality by Document

x) QMP 4 is related to: (CO2)  
a. Process approach  
b. Engagement of people  
c. Customer focus  
d. Relationship management

#### Section B

**Q. 2 Short Questions: Attempt any two questions** (2X 5 = 10 Marks)  
a. Elaborate TQM and its future scope in terms of quality assurance . (CO1)  
b. Define and classify Plant layout with examples. (CO2)  
c. In terms of team work, explain joint responsibility of key personnels. (CO2)

#### Section C

**Q. 3 Long questions: Attempt any one question** (1X10= 10 Marks)  
a. Briefly explain Quality Control Testing with reference to its parameters and steps followed. (CO1)  
b. Enlist parameters required to maintain control of contamination of sterile area. (CO2)