Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Winter Examination-2022

Subject Name: Quality Assurance - Theory

Subject Code: BP606T **Branch: B.Pharm**

Semester: 6 **Date: 26/09/2022** **Time: 11:00 To 02:00** **Marks: 75**

Instructions:

(1) Use of Programmable calculator & any other electronic instrument is prohibited.
(2) Instructions written on main answer book are strictly to be obeyed.
(3) Draw neat diagrams and figures (if necessary) at right places.
(4) Assume suitable data if needed.

Q-1 **Attempt the following questions:** **(20)**

a) Write about the scope of validation.
b) Define calibration and state its importance pharmaceutical industry.
c) What is the significance of NABL accreditation?
d) What is Q-series ICH guidelines?
e) Define Product recall, Quality by design.
f) Briefly explain the Calibration of pH meter
g) Enumerate Elements of ISO14000.
h) What is GLP?
i) Define distribution records and Quality assurance.
j) State the importance of ISO 9000.

Q-2 **Attempt any two of following** **(20)**

A	Explain Master Formula Record in detail. Briefly Describe Qualification of UV-Visible spectrophotometer.	**10**
B	Write about general provisions, personnel, facilities required as per Good Laboratory Practices.	**10**
C	Write a short note on SOP. Write note on Protocol for Conduct of a nonclinical laboratory study.	**10**

Q-3 **Attempt any Seven of following** **(35)**

A	Briefly discuss Total Quality Management.	5
B	Discuss maintenance of stores for raw material.	5
C	Explain various factors affecting plant layout.	5
D	Briefly discuss for Personnel responsibilities and training.	5
E	Write about Batch Formula Record.	5
F	Discuss complaints and evaluation of complaints in detail..	5
G	Briefly explain Quality control test for containers.	5
H	Discuss in brief about Quality by design (QbD).	5
I	Write a note on validation master plan.	5