Enrollment No: _____ Exam Seat No:_____

C.U.SHAH UNIVERSITY

Summer Examination-2022

Subject Name: Quality Assurance - Theory

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

Semester: 6 **Date: 09/05/2022** **Time: 02:30 To 05:30** **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) What is GMP?
b) Define quality audit and quality review.
c) Define validation and state its importance pharmaceutical industry.
d) Enumerate benefits of ISO 9000.
e) Write about the scope of validation.
f) Outline the general principles of calibration.
g) Enlist four names of ICH guidelines.
h) Enumerate elements of ISO 14000.
i) Define qualification and quality assurance.
j) What is total quality management?

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

A	Write a note on validation master plan. Briefly explain quality control test for containers.	**10**
B	Discuss in brief about quality by design (QbD). Explain various factors affecting plant layout.	**10**
C	Discuss complaints and evaluation of complaints in detail. Describe maintenance of sterile areas.	**10**

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

A	Briefly discuss principles and procedures of NABL accreditation.	5
B	Discuss purchase specifications & maintenance of stores for raw material.	5
C	Write a short note on sop.	5
D	Briefly discuss for personnel selection and hygiene.	5
E	Write about handling of return good and recalling.	5
F	Write about general provisions, personnel, facilities required as per good laboratory practices.	5
G	Write note on protocol for conduct of a nonclinical laboratory study.	5
H	Briefly describe qualification of UV-visible spectrophotometer.	5
I	Explain master formula record in detail.	5