Subject Code: BP606T

PAPER ID-311179

Roll No: | | | | | | | | | | | | | |

BPHARM
(SEM VI) THEORY EXAMINATION 2024-25
QUALITY ASSURANCE– THEORY

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Differentiate QA and QC.
b.	Enlist various elements of QbD.
c.	Define cross-contamination.
d.	Give the significance of HEPA filters.
e.	Discuss the principle of hydrolytic resistance test.
f.	What do you understand by test and control articles?
g.	Describe the importance of SOP.
h.	Summarize the significance of distribution records.
i.	Enumerate different types of validation.
j.	Differentiate between Qualification and Validation.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Describe the principles and procedures for NABL accreditation.
b.	Discuss environmentalcontrol, utilities, and maintenance of sterile areas in a pharmaceutical plant.
c.	Illustrate the protocol for the conduct of a Nonclinical Laboratory Study.

SECTION C

3. Attempt any *five* parts of the following: **5 x 7 = 35**

a.	Discuss the steps for registration to get ISO9000 certification.
b.	Describe various elements of TQM.
c.	Explain the purchase specifications and maintenance of stores for raw materials.
d.	Summarize the evaluation of complaints in the pharmaceutical industry.
e.	Describe the contents of the 'Master Formula record'.
f.	Discuss the calibration of the pH meter.
g.	Write a short note on 'Good Warehousing Practices'.