Paper Id 250787

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.	Define the term SOP.
b.	Differentiate between primary and secondary packaging materials.
c.	Write the significance of calibration.
d.	Write any three parameters each for GMP and TQM.
e.	Discuss importance of calibration curve.
f.	Define Batch Formula Record.
g.	Name the requirements for Good Laboratory Practices.
h.	What refer to the subpart K in GLP?
i.	Write about quality documentation.
j.	What do you mean by Quality by design (QbD)

SECTION B

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

a.	Describe the design, plant layout, maintenance and sanitation of premises.
b.	Give a detail account on stability testing of dosage form as per ICH guidelines.
c.	What do you understand by the term "Validation"? Explain its types and purpose of validation.

SECTION C

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

a.	Discuss Protocol for Conduct of a Nonclinical Laboratory Study.
b.	Discuss in detail about complaints and evaluation of complaints.
c.	Explain the principles and procedures involved in NABL accreditation.
d.	Explain about recalling and waste disposal.
e.	Discuss calibration of UV-Visible spectrophotometer.
f.	Write in detail about Quality Review and Quality documentation.
g.	What is the purpose of ISO? Write in brief about ISO 9000 and ISO 14000.