PAPER ID-410550

Subject Code: BP606T

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

BPHARM

(SEM VI) THEORY EXAMINATION 2023-24

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.	What is the purpose of warehousing?
b.	Why formulations in pharmaceutical industry are prepared batch wise?
c.	Mention benefits of getting ISO Certification.
d.	What do you understand by calibration curve? Why do we need it?
e.	Mention the names of QC Tests of Glass.
f.	What is Total quality management (TQM)?
g.	Write Steps involved in complaint handling.
h.	Mention regulatory body of Australia.
i.	Quality by design (QbD) is an initiative of?
j.	Define retrospective validation.

SECTION B

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

a.	What do you understand by the term "Validation"? Explain its types and purpose of validation.
b.	Discuss in detail about quality control test for containers.
c.	Discuss in detail about good warehousing practice

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.	What is the purpose of ISO? Write in brief about ISO 9000 and ISO 14000
c.	Discuss about Qualification of UV-Visible spectrophotometer
d.	Write in detail about Batch Formula Record (BFR).
e.	Discuss in detail about complaints and evaluation of complaints.
f.	Write about personal responsibilities associated with Quality control (QC) department. Also discuss about control of contamination in pharmaceutical industry.
g.	Discuss quality by design in detail.