PAPER ID-311145

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.	Discuss the role of QMS.
b.	Define Quality Assurance.
c.	Classify different clean room.
d.	Define GLP.
e.	Describe the benefits of SOP.
f.	Define material management.
g.	Define plant layout.
h.	Discuss GMP.
i.	Explain different types of packaging material.
j.	Discuss the importance of validation.

SECTION B

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

a.	Explain the TQM philosophies.
b.	Illustrate various key personnel and their responsibilities in pharmaceutical industry.
c.	Explain the good warehousing practices used in pharmaceutical industry.

SECTION C

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

a.	Generalize the quality control tests for primary packaging material.
b.	Explain document maintenance of batch formula record and master formula record.
c.	Explain the elements of quality by design.
d.	Illustrate environmental control in the pharmaceutical manufacturing unit.
e.	Explain about disqualification of Testing Facilities as a quality control tool.
f.	Discuss about the procedure for handling return goods.
g.	Illustrate about the general principles of Analytical method Validation.