PAPER ID-420492

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

BPHARMA
(SEM VI) THEORY EXAMINATION 2021-22
QUALITY ASSURANCE– THEORY

Time: 3 Hours ***Total 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 Calibration.
b.	Compare the qualification and validation of instruments.
c.	What is the definition of Quality by design (QbD).
d.	Define the Quality Control.
e.	Outline the role of quality documentation in pharmaceutical industries.
f.	Define the applications of Q-series guidelines in quality control and assurance.
g.	List the requirements for good laboratory practices.
h.	Summarize the role of environmental control for quality control.
i.	Define Batch formula record.
j.	Define the term GMP.

SECTION B

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

a.	Write the principles and procedures of NABL Accreditation.
b.	Write a note on Total Quality management.
c.	Discuss the types of validation processes with their importance and the scope.

SECTION C

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

a.	Explain the ISO 9000 guidelines.
b.	Discuss the procedure for maintenance of sterile areas and control of contamination in pharmaceutical industries.
c.	Write a note on Master formula record and SOP.
d.	Define complaints. Discuss the procedure for evaluation of complaints.
e.	Discuss the General Provisions of Good Laboratory Practices.
f.	Construct a short note on good warehousing practices.
g.	Outline the concept of total quality management with its elements and philosophies.

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