



PAPER ID-311319

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Subject Code: BP606TR

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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.	What is the purpose of warehousing?
b.	Why formulations in pharmaceutical industry are prepared batch wise?
c.	Differentiate between internal and external (Regulatory audit)
d.	Enlist benefits of getting ISO Certification
e.	Mention the names of quality control tests of rubber closures.
f.	What do you understand by calibration curve? Why do we need it?
g.	What is Fragmentation test?
h.	Mention about 5 waste disposable methods.
i.	Write about Standard operating procedure (SOP).
j.	Differentiate between recall and withdrawal.

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

a.	Discuss in detail about complaints and evaluation of complaints.
b.	What is the purpose of ISO? Write in brief about ISO 9000 and ISO 14000.
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.	Write in detail about Q series guidelines.
b.	Discuss in detail about good warehousing practice
c.	Write about personal responsibilities associated with Quality control (QC) department.
d.	What is the purpose of pH meter calibration? Explain the process of calibration of pH meter.
e.	Write in detail about Batch Formula Record (BFR).
f.	Discuss Protocol for Conduct of a Nonclinical Laboratory Study
g.	Discuss about the elements and tools associated with QbD