PAPER ID-311037

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Subject Code: BP702T

Roll No:

BPHARM
(SEM VII) THEORY EXAMINATION 2025-26
INDUSTRIAL PHARMACY II – 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 SUPAC.
b.	Write the importance of analytical method transfer.
c.	Define "non clinical drug development".
d.	Define COPP.
e.	Write the components of ISO 14001.
f.	Define post market surveillance phase IV.
g.	Write a short note on USFDA.
h.	Write the significance of "measurement of central tendency"
i.	Define GLP.
j.	Define NRDC.

SECTION B

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

a.	Discuss the term 'Pilot Plant Scale-Up' in the context of solid dosage form manufacturing.
b.	Write the role of regulatory affairs department in a pharmaceutical industry.
c.	How ISO 9000 series ensures quality system standards?

SECTION C

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

a.	Discuss the WHO guidelines of technology transfer.
b.	What is a platform, write its types and explain platform technology.
c.	Write the specifications of premises and equipment's utilized in technology transfer protocol.
d.	Write a note on safety, efficacy and risk assessments of NDA.
e.	What do you mean by QbD; Discuss about critical quality attributes?
f.	State the primary distinction between CDSCO and the state licensing authority in drug and device regulations.
g.	Discuss the granularity of technology transfer process.