Paper ID : 250233

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Subject Code: BP702T

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BPHARMA
(SEM VII) THEORY EXAMINATION 2024-25
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.	What is technology transfer?
b.	Mention the role of TT agencies in India.
c.	What is state process validation?
d.	State two major objectives of pilot plant Scale-up.
e.	Write full form of SUPAC and its purpose
f.	Mention key roles of the regulatory affairs department.
g.	Define quality by design(QBD)
h.	Mention the two key responsibilities of CDSCO.
i.	What is the significance of COPP?
j.	What do you understand by non clinical drug development?

SECTION B

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

a.	Describe the regulatory requirements and approval process of new drug.
b.	Write the WHO guideline for technology transfer and also discuss about TT authorities in India.
c.	Define CDSCO. Organizational Framework and Operational Scope of CDSCO.

SECTION C

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

a.	Write the pilot plant scale up techniques for the solid dosage form.
b.	Explain in detail about SUPAC Guidelines.
c.	Discuss about Quality risk management. Explain QRM process with its principal.
d.	Describe the steps involve in data presentation for FDA submission.
e.	Write a short note on regulatory requirements and approval process for new drug approval.
f.	Explain the concept and benefits of Quality by Design(QBD) in detail.
g.	Define ISO. What are ISO 9000 and ISO 14000? How does the ISO 9000 series Quality system standard differ from ISO 14000?