Subject Code: BP702T

PAPER ID-410405

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

B PHARM
(SEM VII) THEORY EXAMINATION 2021-22
INDUSTRIAL PHARMACY II

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.	Mention two major applications of platform technology.
b.	Mention the basic role of SUPAC guidelines.
c.	Name at least 4 agencies responsible for successful technology transfer in India.
d.	State the role of one major TT agency of India.
e.	State to important functions of the Regulatory Affairs Department.
f.	What do you mean by 'Non-Clinical Drug Development'?
g.	What do you mean by 'Six Sigma concept,'?
h.	Mention the specifications of ISO 14000 series of quality systems standards.
i.	State the responsibilities of CDSCO.
j.	Mention the significance of COPP.

SECTION B

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

a.	State and explain the Technology transfer protocol following WHO guidelines.
b.	Describe the steps of data presentation for FDA Submissions.
c.	Give a brief idea on regulatory requirements and approval procedures for new drugs.

SECTION C

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

a.	Explain the significance of personnel requirements in pilot plant scale up.
b.	Describe the steps for technology transfer from RD to production.
c.	State and explain the legal issues during technology development and transfer.
d.	Explain the responsibilities of the regulatory affairs professionals.
e.	Define clinical research and state the clinical research protocols.
f.	Write a brief note on the concept of Quality by Design (QbD).
g.	Describe the functionalities of the Central Drug Standard Control.

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