PAPER ID-310135

Subject Code: BP702T

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

B PHARM
(SEM VII) THEORY EXAMINATION 2020-21
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.	Enlist the GMP consideration required for pilot plant studies.
b.	What is the purpose conduction of pilot-plant scale up studies?
c.	Define technology transfer. Enlist the names of Indian agencies which are involved in technology transfer process.
d.	What is process validation?
e.	What is meant by regulatory affairs? Why regulatory affairs are essential for pharmaceutical industry?
f.	Expand the terms: INDA, NDA, ANDA, IB.
g.	Write the names of the laboratories which are governed by CDSCO.
h.	What is COPP? Why is it required?
i.	Explain the terms: TQM and QbD. Write the benefits of QbD.
j.	What is the role of six-sigma in pharmaceuticals.

SECTION B

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

a.	Who is the Drug Controller General of India? Describe the organization and functions of CDSCO. Write the functions of the laboratories governed by CDSCO.
b.	Explain in detail about NDA. How ANDA is different from NDA?
c.	What is the importance of technology transfer in pharmaceutical industry? Write a note on NRDC.

SECTION C

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

a.	Explain in detail about SUPAC guidelines.
b.	What is QRM? What are the principles involved in QRM? Explain the process of QRM.
c.	What are the functions of different TOT related documents in industrial pharmacy?
d.	Explain in detail about INDA.
e.	What is the methodology involved in six-sigma process? Explain the different levels.
f.	What is ISO 9000? How does ISO 9000 series of quality systems standards differ from ISO 14000?
g.	Write a brief note on NABL and OOS.