Subject Code: BP702T

PAPER ID-410865

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

BPHARM
(SEM VII) THEORY EXAMINATION 2023-24
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.	Write the benefits of technology transfer.
b.	Define NRDC.
c.	Write the responsibilities of regulatory affair department.
d.	Define six sigma concept.
e.	Define out of specifications (OOS).
f.	Write the purpose of establishing CDSCO.
g.	Write the requirement of regulatory affairs in technology transfer.
h.	Write the purpose of investigational brochure.
i.	Define QbD.
j.	Write the Functions of NABL.

SECTION B

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

a.	Discuss the pilot plant scale up considerations for solid dosage forms.
b.	Write the WHO guidelines for technology transfer.
c.	Describe the regulatory requirements and approval procedures for New Drugs.

SECTION C

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

a.	Discuss SUPAC guidelines.
b.	Describe quality risk management.
c.	Describe the regulatory requirements of Non-Clinical Drug Development.
d.	Describe the general considerations of investigational new drug.
e.	Write the role of Biostatistics in Pharmaceutical Product development.
f.	Describe the ISO 9000 series of quality systems standards.
g.	Discuss the regulations for Management of Clinical Studies.