PAPER ID-311133

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 you require any missing data, then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define platform technology.
b.	Name the relevant documents for pilot plant scale-up considerations for solid dosage forms.
c.	Mention the role of the TT agencies in India.
d.	State the technology transfer protocol.
e.	State the role of the Regulatory Affairs department.
f.	State the general considerations of IND.
g.	Define OOS.
h.	State the QbD approach.
i.	State the responsibilities of CDSCO.
j.	Mention the regulatory requirements for new drugs.

SECTION B

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

a.	Elaborate the significance of the requirements of personnel, space and raw materials in Pilot plant scaling up.
b.	Describe the steps and protocol involved in quality risk management.
c.	Write how Biostatistics plays a major role in pharmaceutical product development.

SECTION C

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

a.	Explain the significance and applications of SUPAC guidelines.
b.	Explain the significance of the technology transfer protocol.
c.	Describe the various components of granularity of the TT process.
d.	Write down the construction and responsibilities of two major regularity authorities associated with technology transfer.
e.	Explain the important considerations of the non-clinical drug development.
f.	State and explain the specifications of ISO 9000 and ISO 14000 series of quality systems standards.
g.	Explain the roles and responsibilities of the State Licensing Authority.