PAPER ID-310286

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

BPHARM
(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.	Explain in brief about confidential agreement checklist.
b.	Enumerate the connection of regulatory affairs department with other department in company.
c.	What are the steps involving in Scale- up?
d.	Mention the various contents of technology transfer dossier.
e.	Mention the dimensions of Quality.
f.	Explain in brief about NABL and its scope.
g.	Short note on Six Sigma Concept and its levels.
h.	Enlist the reasons for occurrence of OOS (Out of specifications).
i.	Enlist the principles and key elements of TQM.
j.	Explain in brief about application of Biostatistics in pharmaceutical product development.

SECTION B

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

a.	Describe the organization and functions of Central drug regulatory Authority in India.
b.	What are Bioequivalence studies and Biowaivers? Describe in detail.
c.	Define pilot-plant and relation between pilot-plant and scale -up. Describe pilot-plant scale -up considerations for solids in detail.

SECTION C

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

a.	Explain QBD in detail. Discuss its importance in pharmaceuticals.
b.	Describe in detail about general considerations of Investigational New drug (IND) application
c.	What is quality risk management? Explain QRM process along with its tool.
d.	Explain the types and methods of technology transfer.
e.	Explain the modules of CTD in detail.
f.	Explain in detail the section that deals with changes in excipient in the drug product as per SUPAC guideline.
g.	What are the steps in obtaining ISO 9000 series certifications?