INDUSTRIAL PHARMACY – II (GUESS PAPER 2025–26)

SECTION A (10 × 2 = 20)
1. Define Technology Transfer.
2. What is Pilot Plant Scale-up?
3. Define SUPAC guidelines.
4. Define Quality by Design (QbD).
5. What is Out of Specification (OOS)?
6. Define COPP.
7. What is Six Sigma concept?
8. Define CDSCO.
9. What is Investigational New Drug (IND)?
10. Define NABL.

SECTION B (Attempt any TWO – 2 × 10 = 20)
1. Discuss Pilot Plant Scale-up considerations for solid dosage forms.
2. Explain WHO guidelines for Technology Transfer.
3. Describe regulatory requirements and approval process for New Drugs.
4. Explain Bioequivalence studies and Biowaivers.

SECTION C (Attempt any FIVE – 5 × 7 = 35)
1. Explain SUPAC guidelines in detail.
2. Describe Quality Risk Management (QRM) and its tools.
3. Explain Quality by Design (QbD) and its importance.
4. Describe general considerations of Investigational New Drug (IND).
5. Explain organization structure and functions of CDSCO.
6. Explain Technology Transfer – types and steps.
7. Describe ISO 9000 series of quality system standards.

■ QUESTION FREQUENCY ANALYSIS (2019–2025)

Topic	Times Asked	Exam Weight
SUPAC Guidelines	7 / 7	■■■■■
Pilot Plant Scale-up	7 / 7	■■■■■
Technology Transfer	6 / 7	■■■■■
Quality by Design (QbD)	6 / 7	■■■■
Quality Risk Management (QRM)	6 / 7	■■■■
IND Application	5 / 7	■■■■
CDSCO & Regulatory Affairs	5 / 7	■■■■
ISO 9000 / 14000	4 / 7	■■■
Six Sigma / TQM	4 / 7	■■■