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B PHARM
(SEM VII) THEORY EXAMINATION 2022-23
INDUSTRIAL PHARMACY II

Time: 3 Hours

Total Marks: 75.

Note: Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief.

10 x 2 = 20

- (a) Define Pilot Plant.
- (b) Describe Platform Technology.
- (c) Define Confidentiality Agreement.
- (d) Discuss the practical aspects of Commercialization.
- (e) Explain Drug metabolism and Toxicology.
- (f) Quote the responsibilities of Regulatory affairs professionals.
- (g) Define ISO 14000.
- (h) Write a short note on GLP.
- (i) Define CDSCO.
- (j) Define Certificate of Pharmaceutical Product (COPP).

SECTION B

2. Attempt *any two* parts of the following:

2 x 10 = 20

- (a) What are SUPAC Guidelines. Explain the SUPAC guidelines for immediate release dosage forms.
- (b) Outline Quality Risk Management. Discuss the various risk management tools and methodologies.
- (c) Explain :
 - (i) Total Quality Management
 - (ii) Out of Specification
 - (iii) Change Control
 - (iv) ISO 9000 series

SECTION C

3. Attempt *any five* parts of the following:

5 x 7 = 35

- (a) Describe the pilot plant scale up considerations for solid dosage forms.
- (b) Discuss the significance of space requirements and raw materials in pilot plant set up.
- (c) Explain various Technology Transfer agencies in India.
- (d) Outline Validation and Qualification. Write a short note on Analytical Method Transfer.
- (e) Summarize Investigational Brochure. What do you understand by IND.
- (f) Describe Six Sigma Concepts.
- (g) Explain the organization structure and responsibilities of CDSCO.