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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.