Printed Pages: 01 **Sub Code: BP702T**

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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) What is CTD?

(b) Mention the major regulatory bodies in the world?

(c) what is the drug master file (DMF)?

(d) What do you mean by SU &RU?

(e) Define Confidentiality Agreement.

(f) What is the difference between pilot scale and scale-up?

(g) Define ISO 14000.

(h) what are BE & BA studies? why they are required?

(i) Write a note on non-clinical drug development process.

(j) Define platform technology?

SECTION B

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

(a) Explain in detail various factors affecting design of a pharmaceutical Pilot plant facility.

(b) Describe documentation required for changes in batch size as per SUPAC guidelines.

(c) Discuss the procedure for new drug approval from CDSCO in India.

SECTION C

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

(a) Explain the investigator's brochure for IND.

(b) Summarize Six sigma concept as a tool for quality management.

(c) Write in brief note on NABL certification.

(d) Write a note on Total Quality Management.

(e) Describe a detailed note on clinical research protocol.

(f) Write a note on various agencies involved in technology transfer in India.

(g) Write a note on Certificate of Pharmaceutical Product (COPP).