SEMESTER EXAMINATION-2021
CLASS – B.PHARM VII SEM.
SUBJECT. INDUSTRIAL PHARMACY
PAPER CODE: BP702T

Time: 3 hour **Max. Marks: 75**
Min. Pass: 50%

Note: Question Paper is divided into two sections: **A and B.** Attempt both the sections as per given instructions.

SECTION-A (SHORT ANSWER TYPE QUESTIONS)

Instructions: Answer any five questions in about 150 words each. Each question carries six marks. (5 X 7 = 35 Marks)

Question-1: Write down about the need of raw materials in pilot plant scaling up.
Question-2: Discuss the factors affecting scaling up production of capsule dosage form.
Question-3: Write down SUPAC guidelines for sustained release dosage forms.
Question-4: Discuss different components of technology transfer protocol.
Question-5: Describe the significance of process, packaging and cleaning in technology transfer from R&D to production.
Question-6: Write down the responsibilities of regulatory affairs professionals.
Question-7: Write a note on management of clinical studies.
Question-8: Write a note on certificate of pharmaceutical product.
Question-9: Discuss six sigma concept in quality management system.
Question-10: Describe different series of ISO 9000 with their significance.

SECTION-B (LONG ANSWER TYPE QUESTIONS)

Instructions: Answer any FOUR questions in detail. Each question carries 10 marks. (4 X 10 = 40 Marks)

Question-11: Discuss the role of NRDC, TIFAC, BCIL in technology transfer.
Question-12: Discuss the role and responsibilities of drug regulatory department in pharmaceutical industries.
Question-13: Write down the procedure for filing Investigational new drug application and new drug application for approval from CDSCO.
Question-14: Write short notes on (Any two)-
(i) Confidentiality agreement
(ii) Bioequivalence studies
(iii) MoUs and legal issues
(iv) Role of biostatistics in drug development
Question-15: Write down applications of total quality management in drug development.

Question-16: Discuss the role and responsibilities of central standard control organization as drug licensing authority.

Question-17: Define the role of good laboratory practices in total quality management system.

Question-18: Discuss different components of ISO 14000 with their implications.

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