BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: B. PHARM **SEMESTER: VII/ADD**
BRANCH: PHARMACY **SESSION: MO 2025**

SUBJECT: BP702T INDUSTRIAL PHARMACY-II

TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:

1. **The missing data, if any, may be assumed suitably.**
2. **Before attempting the question paper, be sure that you have got the correct question paper.**
3. **Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.**
4. **This question paper consists of (03) three parts. Read the part wise instructions before attempting the questions.**

PART-I
Objective type questions (Instruction: Answer all questions)

Q1. (10 x 2 = 20 Marks)

A. State the objectives of documentation in pharmaceutical industry.

B. Differentiate between generic and brand drugs.

C. Explain the accelerated approval process of new drugs.

D. Define distribution record and state its purpose in pharmaceutical industry.

E. List any four countries with their respective pharmaceutical regulatory agencies.

F. Define technology transfer in the pharmaceutical industry.

G. What are the two main advantages of fluidized bed drying compared to conventional oven drying in scale-up process?

H. Describe the purpose of a gap analysis in technology transfer.

I. Define total quality management. Enlist its benefits in an organization.

J. Explain NABL. Outline its objectives.

PART-II
Short Answers
(Instruction: Answer seven out of nine questions)

(7 x 5 = 35 Marks)

Q2. Explain the process and significance of quality risk management.
Q3. Discuss the key challenges and potential solutions involved in scaling up the production of semi-solid dosage forms, with a focus on mixing efficiency, temperature control, and homogenization processes.
Q4. Describe the WHO guidelines for technology transfer and explain the general principles for successful transfer.
Q5. Define good laboratory practice. Discuss its purpose and areas of application.
Q6. Discuss the process of NABL accreditation.
Q7. Describe any four agencies in India that facilitate the transfer of technology from laboratory to industrial scale.
Q8. Write notes on the Drug Controller General of India.
Q9. Schematically present the review process of a new drug application for obtaining marketing approval from the US FDA.
Q10. Briefly discuss the ICH's common technical document for filing the abbreviated new drug application in the US FDA.

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PART-III
Long Answers
(Instruction: Answer two out of three questions)

(2 x 10 = 20 marks)

Q11. Discuss the major considerations in blending and granulation parameters in tablet manufacturing scale-up.

Q12. A. Explain the management responsibilities based on Quality Management System (QMS). [5]
B. Categorise different types of investigational new drug applications with proper illustrations. [5]

Q13. Describe the responsibilities of personnels working in the regulatory affairs department of a pharmaceutical industry.

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