DEPARTMENT OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI

(Internal Assessment I)

CLASS: BPHARM **SEMESTER: VII**

BRANCH: PHARMACY **SESSION: MO 2024**

SUBJECT: BP702T Industrial Pharmacy -II

TIME: 2.00 Hour **FULL MARK: 30**

PART I

A. Objective type questions (Answer all questions) (5 x 02=10 marks)

1. Define technology transfer.
2. Which of the following component(s) is **NOT** governed by GLP?
   A. Test and control articles
   B. Raw material selection
   C. Approval of manufacturing process
   D. Environmental controls
3. Define NABL. Outline its objectives.
4. When does a pharmaceutical company need to file an IND?
5. Mention the importance of the investigator's brochure.

PART II

B. Long Answers (Answer any one out of two) (01x10=10 marks)

1. Describe the document required in the technology transfer and technology item checklist.
2. A. Define Accreditation. Enlist the benefits of NABL.

   B. Define generic drugs. Explain Hatch Waxman's act in light of generic drugs.

PART III

C. Short Answers (Answer any two out of three) (02x05=10 marks)

1. Discuss technology transfer and the path of commercialization.

2. Write a short note on GLP.

3. Schematically present the flow of activities from submission of an NDA application to its approval by the US FDA.

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