DEPARTMENT OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI

(Internal Assessment I)

CLASS: BPHARM		**SEMESTER:**	**VII/ADD**
BRANCH: PHARMACY		**SESSION:**	**MO/2025**
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 NABL and enlist the different accreditation services provided by NABL.	
2. State the conditions when a pharmaceutical company need not submit an IND for a new chemical.	
3. State different modules of the common technical document with a clear diagram.	
4. Differentiate bioavailability and bioequivalence.	
5. Define the term 'pilot plant'.	

PART II

B. Long Answers (Answer any one out of two)	(01x10=10 marks)
1. (a) What are the key technical aspects that must be addressed during scale-up in the pilot plant? (5)	
2. (b) Write a brief note on the investigator's brochure. (5)	
3. (a) Mention the name of the regulatory authority of India for cosmetics, pharmaceuticals, and medical devices. Discuss the function of this regulatory authority. (5)	
(b) Define Accreditation. Enlist the benefits of NABL. (5)	

PART III

C. Short Answers (Answer any two out of three)	(02x05=10 marks)
1. Discuss the process of NABL accreditation.	
2. List and explain the product-related factors to be considered during pilot plant scale-up studies for solid dosage forms.	
3. Write a brief summary explaining the Hatch-Waxman Act and its importance in bringing generic drugs.	

:::::18/09/2025 :::::M