

DEPARTMENT OF PHARMACEUTICAL SCIENCES & TECHNOLOGY

BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(Internal Assessment I)

CLASS: BPHARM
BRANCH: PHARMACY

SEMESTER: VIII
SESSION: SP 2025

SUBJECT: BP805ET PHARMACOVIGILANCE

TIME: 2.00 Hour

FULL MARK: 30

PART I

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

1. What is ICH? What are the main goals of ICH guidelines.
2. What is DDD and its application by WHO
3. What is ICD and its application by WHO
4. Define Pharmacovigilance
5. Classify AEFI.

PART II

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

1. Classify Adverse Drug Reactions .How to detect ADR & how do we manage it
2. Classify Vaccine & Vaccine Reactions with example. What is vaccine failure.

PART III

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

1. Summarize the main components of Individual Case Safety Report (ICSR).
2. What are periodic safety reports? Why are periodic safety reports required? Outline the main components of PSUR.
3. Explain five different levels & structure of ATC code classification by WHO with suitable examples

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