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

CLASS: MPHARM **SEMESTER: II**
BRANCH: PHARMACY **SESSION: SP/2025**

SUBJECT: MPL204T CLINICAL RESEARCH AND PHARMACOVIGILANCE

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.
5. Answer any five questions.

1a.	What is pharmacovigilance? Why drug safety monitoring is important? Define the following terms: i) Adverse Event ii) Serious Adverse Event iii) Adverse Drug Reactions (ADRs)	[7]
1b.	Outline and explain different events involved in the history and development of Pharmacovigilance.	[8]
2a.	Classify and illustrate different types of ADRs with examples. Mention the management of each type of ADRs.	[7]
2b.	Describe causality assessment.	[8]
3a.	Define medication error. What are the different types of medication error? Describe the causes and factors which contribute medication error.	[7]
3b.	Explain the various pharmacovigilance methods used in pharmacovigilance study.	[8]
4a.	What is vaccine failure? Enlist the factors which contribute vaccination failure. Describe types of vaccination failure.	[7]
4b.	Define clinical trials and elaborate on their phases.	[8]
5a.	Elaborate on the International Conference on Harmonization (ICH), and ICH-Good Clinical Practice (GCP)	[7]
5b.	Describe Rule 122 of Drugs and Cosmetics Act.	[8]
6a.	How do cohort and case-control studies contribute to drug development and identification of disease mechanisms?	[7]
6b.	Elaborate on clinical trial documentations.	[8]
7a.	Describe pharmacoeconomics and their role in health policy decision-making.	[7]
7b.	Describe the role and responsibilities of clinical trials personnel.	[8]

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