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

CLASS: M. PHARM. **SEMESTER : II**
BRANCH: PHARMACY **SESSION : SP/19**

SUBJECT: MPL204T CLINICAL RESEARCH AND PHARMACOVIGILANCE

TIME: 3:00 Hours **FULL MARKS: 75**

INSTRUCTIONS:
1. The question paper contains 7 questions each of 15 marks and total 105 marks.
2. Candidates may attempt any 5 questions maximum of 75 marks.
3. The missing data, if any, may be assumed suitably.
***4*. Before attempting the question paper, be sure that you have got the correct question paper.**
5. Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.

Q.1(a)	Explain Phase-III and Phase-II Clinical trial.	[7]
Q.1(b)	Describe in detail about Cohort study design with suitable examples.	[8]
Q.2(a)	Explain different areas of Pharmacovigilance.	[7]
Q.2(b)	Write a brief explanatory notes on Case control study design.	[8]
Q.3(a)	What is IND, NDA, CPSCEA and ICH?	[7]
Q.3(b)	What is Pharmacovigilance and why is it Important?	[8]
Q.4(a)	Design informed consent form for antimalarial drug falciplus.	[7]
Q.4(b)	Explain the methods of sampling and randomization.	[8]
Q.5(a)	Explain the terms blinding, escape treatment, Investigator, comparator product.	[7]
Q.5(b)	List the components of investigator's brochure.	[8]
Q.6	Design a protocol for clinical trial on anti-diabetic drug Diacon.	[15]
Q.7(a)	Explain the process of determination of causality in pharmacovigilance.	[7]
Q.7(b)	Discuss reporting methods used for active and passive surveillance to determine ADRs.	[8]

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