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

CLASS: M>PHARM **SEMESTER: II**
BRANCH: PHARMACY **SESSION: SP/22**

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.

Note: Answer any Five Questions out of Seven

1a. Give Structure of Institutional ethics committee.How many types of approval can be given by it [7]
1b. What is Informed Consent & in which cases it can be waived off.. [8]

2a. Elaborate different phases of Clinical Trials [7]
2b. Discuss the information listed in informed consent form.. [8]

3a. Why there is a trend of appointing Contract Research Organisations these days. [7]
3b. How to ensure success with CRO/ Give Roles & Responsibilities of sponsor & CRO. [8]

4a. Explain definition and different areas of Pharmacovigilance . Describe detail about product quality and Medication errors areas of Pharmacovigilance [7]
4b Write detail about stakeholders involved in pharmacovigilance and also give notes on Pharmacovigilance programme in India and Indian Pharmacopoeia Commission [8]

5a. Explain types of Clinical study design? Describe Randomized controlled Trial & Non Randomized controlled Trial. [7]
5b. Write notes on the following observational study [8]
a) Cohort b) Case Control C) Cross sectional study

6a. Write notes on Essential documents of clinical trial- Investigator's brochure. [7]

6b. Write notes on Clinical study Protocol & Clinical study Reports [8]

7a. Explain detail about Definition, types and detection of ADRS [7]
7b. Explain detail about ADRs reporting methods and describe Severity and Seriousness assessment of ADRSs with suitable examples. [8]

:::::02/05/2022:::::