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

CLASS: M.PHARM **SEMESTER: II**
BRANCH: PHARMACY **SESSION: SP/23**

SUBJECT: MPL204T CLINICAL RESEARCH & 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. Enumerate different partners in Pharmacovigilance. How National centres & Health professionals act as important partners. [7]

1b. How Erice declaration of 1997 provides a framework in drug safety issues. [8]

2a. Depending on risks involved, IEC review falls under how many categories. [7]

2b. Give objectives of ICH-GCP guidelines. Define ADR, GCP & Informed consent as per GCP. [8]

3a. Discuss compensation for participants& selection of special groups as research participants. [7]

3b. What general principles to be followed with regards to research using human beings. [8]

4a. How education & training are important approach for pharmacovigilance in clinical practice [7]

4b. Define observational study. Illustrate Prospective &Retrospective cohort Study with suitable examples. [8]

5a. Explain case control and cross sectional study with suitable examples. [7]

5b. Describe types of Randomized and Non Randomized clinical trial design in different clinical Studies. [8]

6a. Illustrate types of clinical trials and types of blind study design in clinical trial. [7]

6b. Explain types of clinical trial documentation and write detail description about clinical trial protocol documents with respect to Investigator brochure's and during the clinical conduct of the trial. [8]

7 Write notes on a) IND b) NDA c) IRB d) FDA e) ICH f) GLP & GCP (6x2.5) [15]

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