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

CLASS: M. PHARMACY **SEMESTER: I**
BRANCH: PHARMACEUTICS **SESSION: MO2025**

SUBJECT: MPH104T REGULATORY AFFAIRS

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. Discuss the Orange Book briefly, including its content and format. Briefly describe different sections of the Orange Book. [7]

1b. Briefly discuss different classification codes of NDA. Differentiate between different types of copies of NDA submission. [8]

2a. Briefly discuss about investigational medical product (IMP). How can this IMP dossier be used in the IND application process? [7]

2b. How does FDA ensure generic medicines work the same as brand medicines? Discuss the key criteria required for FDA approval in the case of generic medicine. [8]

3a. Discuss briefly the Code of Federal Regulations, including its titles. Differentiate between Section 505(b)(1), Section 505(b)(2) and Section 505(j). [7]

3b. Discuss the importance of the investigator's brochure (IB) in a clinical study. Briefly explain different components of IB. Discuss the procedure for IB regulation in European countries. [8]

4a. Define documentation and state its importance in the pharmaceutical industry. How documentation could be used in maintaining distribution records. State the information to be recorded while distributing a pharmaceutical product from the manufacturing site. [7]

4b. Discuss the objective and significance of bioequivalence study. Briefly discuss the steps followed in the bioequivalence study. [8]

5a. Write notes on the FDA review process of an investigational new drug application. [7]

5b. Discuss the importance of non-clinical studies in the drug discovery process. Briefly explain different types of non-clinical studies required in the process of drug development. [8]

6a. Define Good Clinical Practice (GCP). Explain the responsibilities of the IRB/IEC as defined by the ICH-GCP guidelines. [7]

6b. Define pharmacovigilance. Describe why drug safety monitoring is important. [8]
Define the following terms:

a) Adverse event
b) Serious adverse event
c) Adverse drug reaction

7a. A) Define HIPAA and mention its objectives. [7]
B) Define a Clinical Trial Protocol. Discuss the various components included in a clinical trial protocol.

7b. What is an informed consent process? Describe the essential elements of an informed consent document. [8]
Define legally acceptable representative and discuss under which circumstances the consent process can be waived off.

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