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

CLASS: M.PHARM. **SEMESTER: I**
BRANCH: PHARMACEUTICS **SESSION: MO/2024**

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. Differentiate protected health information and research health information. Mention the research areas that are covered under HIPAA. State a few identifiers of protected health information according to HIPAA. [7]

1b. Schematically present the general process to attain IEC/IRB approval to conduct a clinical trial and state the responsibilities of IRB/IEC. [8]

2a. Describe the methods used to retain documentation in the pharmaceutical industry. Explain the method of ensuring electronic records using microfilms. [7]

2b. Write short notes on the drug master file. Discuss the necessity of an authorization letter for the drug master file. Mention the components of such an authorization letter. [8]

3a. Diagrammatically present the process of bioequivalence study. Illustrate different types of bioequivalence studies performed for pharmaceutical products. [7]

3b. Write an explanatory note on the drug discovery process. [8]

4a. Briefly describe the components of the batch manufacturing record of any pharmaceutical product. [7]

4b. Compare the pharmacovigilance guidelines in Schedule Y in context to ICH guidelines. [8]

5a. Define and explain the requirements of distribution records of pharmaceutical products in industry. Briefly mention the minimum requirements of such distribution records. [7]

5b. Explain the importance of the Hatch Waxman Act. Write notes on abbreviated new drug applications and generic drugs. [8]

6a. State the contents and types of investigational new drug applications. [7]

6b. When does an IND need to submit to the regulatory agencies? Describe the circumstances when IND application would not be necessary. Briefly discuss different classification codes on NDA. [8]

7a. What is IMP dossier? Briefly discuss it. [7]

7b. Schematically present the NDA review process after applying to the US FDA. Briefly discuss different copies of NDA that need to be submitted by the drug sponsors to the FDA. [8]

::::::12/12/2024::::::M