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

CLASS: M. PHARM. **SEMESTER: I**
BRANCH: PHARMACEUTICS **SESSION: MO2022**

SUBJECT: MPH104T REGULATORY AFFAIRS

TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:

1. **Answer any five out of the seven questions**
2. **The missing data, if any, may be assumed suitably**
3. **Before attempting the question paper, be sure that you have got the correct question paper.**
4. **Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.**

1a.	Discuss documentation process in the pharma industry.	[7]
1b.	Write notes on bioequivalence studies with pharmacokinetic endpoints.	[8]
2a.	Schematically present the NDA review process.	[7]
2b.	What is IMP dossier? Briefly discuss it.	[8]
3a.	Write a note on drug master file.	[7]
3b.	Discuss the role of in silico assays in the new drug development process.	[8]
4a.	Explain the responsibilities and functional modalities of an institutional review board.	[7]
4b.	Briefly explain the drug discovery process.	[8]
5a.	Describe the categories and types of IND.	[7]
5b.	Compare the pharmacovigilance guidelines followed in India in context to the FDA guidelines.	[8]
6a.	Define medical devices and explain various regulations binding them?	[7]
6b.	Define QTPP and CQA and explain with reference to a solid dosage form?	[8]
7a.	Write in details the components of CTD?	[7]
7b.	Enlist various quality guidelines and explain Q6 with an example?	[8]

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