Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 8 EXAMINATION – SUMMER-2024

Subject Code: BP804TT **Date: 13/05/2024**

Subject Name: Pharmaceutical Regulatory science

Time: 10.30 a.m. to 1.30 p.m. **Total Marks: 80**

Instructions:

1. **Attempt any five questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1	**(a)**	Discuss in detail about various phases of drug development.	**06**
	(b)	Discuss briefly about Innovators and Sponsors.	**05**
	(c)	Explain in detail the sources of new drug.	**05**
Q.2	**(a)**	Differentiate INDA and ANDA. Describe various type of INDA.	**06**
	(b)	Explain classification of drugs in NDA. Prepare a NDA chart showing NDA review process.	**05**
	(c)	Explain the concept of paragraph I to IV and generic exclusivity.	**05**
Q.3	**(a)**	Write a note on clinical studies as per CDSCO.	**06**
	(b)	Explain in detail CTD Vs eCTD. Describe various CTD modules.	**05**
	(c)	What is MHRA? Discuss in brief about approval of new drug by MHRA.	**05**
Q.4	**(a)**	Discuss the pharmacovigilance safety monitoring in clinical trials.	**06**
	(b)	What is Post Marketing Surveillance (PMS)? Give it's important in clinical trials.	**05**
	(c)	What is the importance of investigator's brochure? Give a brief outline of clinical research protocols.	**05**
Q.5	**(a)**	Discuss about 21 CFR Part 211 for packaging and labelling requirements of Pharmaceuticals in USA.	**06**
	(b)	What is mean by bioequivalence and explain drug product assessment related to BE.	**05**
	(c)	Discuss the importance of documentation in Pharmaceutical industry.	**05**
Q. 6	**(a)**	Write a note on Hutch Waxman Act and Amendments for generic drugs.	**06**
	(b)	What is DMF? Write a note on Type of DMF.	**05**
	(c)	Write note on Orange book.	**05**
Q.7	**(a)**	Describe Informed Consent process and procedures for clinical trial study.	**06**
	(b)	Discuss special emphasis on approval under 505 (b) (2).	**05**
	(c)	Describe HIPAA-new requirement to clinical study process.	**05**

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