Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. – SEMESTER- VIII-EXAMINATION – SUMMER -2022

Subject Code:BP804TT **Date:06/06/2022**

Subject Name: Pharmaceutical Regulatory science

Time: 10:30am to 01:30pm **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)**	Define new drug according to FDA. Explain in detail the new drug development process with the time course for each phase.	**06**
	(b)	Explain the approval process of new drug under 505 (b) (2).	**05**
	(c)	Discuss about various Stages of drug discovery.	**05**
Q.2	**(a)**	Write a note on Preclinical studies as per CDSCO.	**06**
	(b)	Discuss about Organization structure and Overview of regulatory authorities of India.	**05**
	(c)	Describe general consideration, specific requirements and contents of an NDA.	**05**
Q.3	**(a)**	Describe the procedure for Generic drug approval from CDSCO in India.	**06**
	(b)	Explain the purpose and procedure for IND application to USFDA.	**05**
	(c)	Describe Informed Consent process and procedures for clinical trial study.	**05**
Q.4	**(a)**	What is the importance of investigator's brochure? Give a brief outline of clinical research protocols.	**06**
	(b)	What is Common Technical Document? Describe various CTD modules.	**05**
	(c)	Write a note on International Good Clinical Practices.	**05**
Q.5	**(a)**	Describe how Waxman-Hatch Act has simplified and facilitated approval of generic products in US?	**06**
	(b)	What is DMF? Write a note on Type of DMF.	**05**
	(c)	Discuss content of ASEAN Common Technical Document.	**05**
Q. 6	**(a)**	How did Bolar provision give boost to ANDA approval process in USA?	**06**
	(b)	Give the composition, functions and responsibilities of Institutional review board.	**05**
	(c)	Briefly explain about Safety monitoring of medical products.	**05**
Q.7	**(a)**	Write scope and approaches of 21 CFR part 11.	**06**
	(b)	Write note on Purple book.	**05**
	(c)	Discuss the salient features of FDA guidelines for clinical trials in India.	**05**

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