Enrollment No./Seat No.:

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm - SEMESTER - VIII EXAMINATION - WINTER 2025

Subject Code: BP804TT **Date: 19-11-2025**

Subject Name: Pharmaceutical Regulatory science

Time: 02:30 PM TO 05:30 PM **Total Marks: 80**

Instructions

1. Attempt any five questions.

2. Make suitable assumptions wherever necessary.

3. Figures to the right indicate full marks.

			Marks
Q.1	**(a)**	Explain in detail about new drug development process with the time course of each phase.	**06**
	(b)	Discuss about various stages of drug discovery.	**05**
	(c)	Discuss and differentiate innovator and generic drugs.	**05**
Q.2	**(a)**	Discuss about organization structure and overview of regulatory authority of India.	**06**
	(b)	Describe general consideration and content of NDA.	**05**
	(c)	Define IND. Discuss various types of IND.	**05**
Q.3	**(a)**	Describe how Waxman-Hatch Act has simplified and facilitated approval of generic products in US?	**06**
	(b)	Write a note on Preclinical studies.	**05**
	(c)	Discuss on TGA.	**05**
Q.4	**(a)**	What is IRB? Discuss composition and functions of IRB.	**06**
	(b)	Discuss composition and importance of Informed consent.	**05**
	(c)	Write a note on- Orange book.	**05**
Q.5	**(a)**	What is Common Technical Document? Describe various CTD modules.	**06**
	(b)	Give in details of Pharmacovigilance safety monitoring in Clinical trials.	**05**
	(c)	Write a note on Code of Federal Regulations.	**05**
Q.6	**(a)**	Define- Investigator, Sponsor and Monitor. Explain functions and responsibilities of sponsor.	**06**
	(b)	Write a note on Good Clinical Practice.	**05**
	(c)	Write a note on Purple book.	**05**
Q.7	**(a)**	What is the importance of investigator's brochure? Give a brief outline of clinical research protocols.	**06**
	(b)	What is DMF? Discuss types of DMF.	**05**
	(c)	Discuss procedure for export of pharmaceutical products.	**05**

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