Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code:BP804TT Date: 28-11-2024

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.**

Q.1	**(a)**	How to Discover New Drug and development? Explain Stages of drug discovery.	**06**
	(b)	Explain Regulatory Concepts of Purple book.	**05**
	(c)	Write a note Investigator's Brochure (IB)?	**05**
Q.2	**(a)**	Explain Approval processes and timelines involved in Investigational New Drug (IND).	**06**
	(b)	Explain review process for New Drug Application (NDA).	**05**
	(c)	Write a note on ANDA.	**05**
Q.3	**(a)**	Write a note on Quality by Design (QbD).	**06**
	(b)	Explain Regulatory requirements of EU.	**05**
	(c)	Write a note on MHRA.	**05**
Q.4	**(a)**	Define CTD & e CTD. Explain modules of CTD.	**06**
	(b)	What is DMF? Write a short note on Type of DMF.	**05**
	(c)	How to develop Generic drug product? Explain in brief.	**05**
Q.5	**(a)**	Explain Procedure for export of pharmaceutical products.	**06**
	(b)	Explain ASEAN Common Technical Document (ACTD) research.	**05**
	(c)	Explain pre-clinical studies & non- clinical activities for New drug discovery.	**05**
Q. 6	**(a)**	How to Developing clinical trial protocols? Explain in brief.	**06**
	(b)	Explain Pharmacovigilance & safety monitoring in clinical trial.	**05**
	(c)	Explain the scope of TGA regulations.	**05**
Q.7	**(a)**	Explain CFR 21(code of federal regulation).	**06**
	(b)	Define 'Orange Book', 'Green Book' and 'Blue Book'. Explain statistical criteria for Bio-equivalence in context to orange book.	**05**
	(c)	Write a note on ANDA. Explain the concept of PARA I to IV filling.	**05**

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