Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph- SEMESTER–VIII • EXAMINATION – WINTER -2022

Subject Code: BP804TT **Date: 28/12/2022**

Subject Name: Pharmaceutical Regulatory Science

Time: 02:30pm to 05:30pm **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)**	Explain generic drug product development in detail.	**06**
	(b)	Write a note on clinical studies.	**05**
	(c)	Explain in brief ANDA.	**05**
Q.2	**(a)**	Give overview of regulatory authorities of United States.	**06**
	(b)	Discuss in detail about IND.	**05**
	(c)	Briefly discuss CTD and eCTD.	**05**
Q.3	**(a)**	Discuss Procedure for export of pharmaceutical products.	**06**
	(b)	Write a note on ACTD	**05**
	(c)	Discuss in brief DMF.	**05**
Q.4	**(a)**	Discuss the procedure to develop clinical trial protocols.	**06**
	(b)	Give overview of regulatory authorities of Japan.	**05**
	(c)	Write a note on IRB.	**05**
Q.5	**(a)**	Write about Informed consent process.	**06**
	(b)	Discuss about Purple book.	**05**
	(c)	Write a note on Code of Federal Regulatory.	**05**
Q. 6	**(a)**	What is Orange book? Explain.	**06**
	(b)	Discuss about GCP obligations of Investigators, sponsors & Monitors	**05**
	(c)	Explain Pharmacovigilance.	**05**
Q.7	**(a)**	Discuss on TGA.	**06**
	(b)	Write a note on NDA.	**05**
	(c)	Explain in brief pre-clinical studies.	**05**

****