

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
