

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm. - SEMESTER-VIII • EXAMINATION – SUMMER -2022

Subject Code: BP805TT**Date: 04/06/2022****Subject Name: PHARMACOVIGILANCE****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) Write a note on active surveillance in pharmacovigilance.	06
	(b) Write about pharmacovigilance program in India.	05
	(c) Write about International classification of diseases.	05
Q.2	(a) Write about history and development of pharmacovigilance.	06
	(b) Discuss on differences in Indian and global pharmacovigilance requirements.	05
	(c) Write on basic drug information resources in pharmacovigilance.	05
Q.3	(a) Define and classify ADRs in details.	06
	(b) Write about CROs in pharmacovigilance.	05
	(c) Explain about eudravigilance medicinal product dictionary.	05
Q.4	(a) Discuss in details about case control and cohort study.	06
	(b) Write about effective communication in pharmacovigilance.	05
	(c) Explain about genetic related ADR.	05
Q.5	(a) Write about D&C act and schedule Y in pharmacovigilance.	06
	(b) Explain about good clinical practice in pharmacovigilance study.	05
	(c) Discuss basic terminologies used in pharmacovigilance.	05
Q.6	(a) Discuss drug safety evaluation in pregnancy and lactation.	06
	(b) Write about periodic safety update reports.	05
	(c) Write a note on vaccination failure.	05
Q.7	(a) Write down organization and objectives of ICH.	06
	(b) Discuss on pharmacovigilance of vaccine.	05
	(c) Write about post approval phase.	05
