

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM – SEMESTER – 7- EXAMINATION –WINTER - 2018

Subject Code:2270010

Date: 28/11/2018

Subject Name: Pharmacovigilance

Time:10:30 AM TO 01:30 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) Define Pharmacovigilance. Discuss scope and purpose of Pharmacovigilance.	06
	(b) Write a note on ADR in public health.	05
	(c) Explain role of ICSRs in pharmacovigilance.	05
Q.2	(a) Write a note on validity and assessment of ICSRs reports.	06
	(b) Define medication error. Discuss types of medication errors.	05
	(c) Write about sources and scope of signal detection.	05
Q.3	(a) Write down characterization of pharmacovigilance in clinical trials.	06
	(b) Define SRS. Write down limitations of SRS.	05
	(c) Explain pattern and scale of counterfeiting.	05
Q.4	(a) Define ADR. Discuss various types of ADR.	06
	(b) Explain methods of pharmacovigilance.	05
	(c) Write about pharmacovigilance regulation in INDIA.	05
Q.5	(a) Explain about WHO and medDRA in briefs.	06
	(b) Write a note on SSFFC medicines.	05
	(c) Discuss the role of pharmacist to prevent medication errors.	05
Q. 6	(a) What is ICSRs? Write about types of ICSRs.	06
	(b) Write a note on adverse hepatic reactions.	05
	(c) Explain pharmacovigilance regulation in USA.	05
Q.7	(a) Discuss factors and mechanisms of ADRs.	06
	(b) Write about access and confidentiality Spontaneous ICSR Reporting Systems.	05
	(c) Write down contents and structure of ICSRs.	05
