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**

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