Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm - SEMESTER–VII • EXAMINATION – WINTER-2016

Subject Code: 2270010 Date: 29/11/2016

Subject Name: Pharmacovigilance

Time: 10.30 am - 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. Write in brief about the methods of Pharmacovigilance	**06**
	(b)	Write a short note on impact of ADRs on public health	**05**
	(c)	Discuss pharmacogenetic causes of ADRs	**05**
Q.2	**(a)**	Define ADRs. What are the types of ADRs	**06**
	(b)	Write a note on adverse drug reactions of liver.	**05**
	(c)	Explain ICSR. Discuss its role in Pharmacovigilance	**05**
Q.3	**(a)**	Write a note on Pharmacovigilance in clinical trials	**06**
	(b)	What are the merits and demerits of spontaneous ICSR reporting systems	**05**
	(c)	Write a brief note on SSFFC medicines	**05**
Q.4	**(a)**	Discuss the causes and prevention of medication errors.	**06**
	(b)	Explain the terms (i) Medication errors (ii) medDRA	**05**
	(c)	Discuss the format of spontaneous reporting system.	**05**
Q.5	**(a)**	Discuss sources and scope of signal detection.	**06**
	(b)	Give brief account on WHO international drug monitoring programme	**05**
	(c)	Discuss the various mechanisms of ADRs	**05**
Q. 6	**(a)**	Discuss the contents and structure of Individual Case Safety Reports (ICSRs),	**06**
	(b)	Write in short about the cutaneous adverse drug reactions	**05**
	(c)	Give explanation to Pattern and scale of counterfeiting	**05**
Q.7	**(a)**	Discuss about Pharmacovigilance system in INDIA	**06**
	(b)	Write a brief note on ADRs of various anti infective drugs	**05**
	(c)	Discuss the validity and assessment of ICSRs reports	**05**

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