

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 SSFEC 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
