

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm. - SEMESTER-VII • EXAMINATION – SUMMER 2017

Subject Code: 2270010

Date: 10/05/2017

Subject Name: Pharmacovigilance

Time: 02:30 PM to 05:30 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) Describe pattern and scale of counterfeiting.	06
	(b) Describe structure, validity and assessment of ICSRs in pharmacovigilance.	05
	(c) Write a note on pharmacovigilance in clinical trial	05
Q.2	(a) Write a note on WHO international drug monitoring programme.	06
	(b) Write a note on pharmacovigilance regulation in india.	05
	(c) Write a note on Dermatological ADRs.	05
Q.3	(a) Write role of ICSRs in pharmacovigilance	06
	(b) What are medication errors? Give types of medication errors with examples.	05
	(c) Write methods of detection of medication errors.	05
Q.4	(a) Explain the term: Substandard, Spurious, Falsely labelled, Falsified medicine	06
	(b) Describe pharmacogenetic causes of ADRs.	05
	(c) Discuss hepatic adverse reactions.	05
Q.5	(a) Explain spontaneous reporting of ADRs with suitable examples.	06
	(b) Define SRS. Discuss potential and limitation of SRS.	05
	(c) Discuss forms and formats of SRS.	05
Q. 6	(a) Compare and contrast between WHO and Naranjo scale of causality assessment of ADRs.	06
	(b) Define signal. Discuss source and scope of signal detection	05
	(c) Write mechanism of ADRs with examples.	05
Q.7	(a) Define ADRs. Explain the types of ADRs with suitable examples.	06
	(b) Explain current methods of pharmacovigilance.	05
	(c) Write role of pharmacist in the management of adverse drug reactions.	05
