

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm
SEMESTER: VII

Subject Name: Pharmacovigilance

Subject Code: 2270010

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

No	Course Content	Hrs
1	Pharmacovigilance- Introduction, Scope, Definition, Purpose, Methods, History	03
2	Fundamental Clinical Aspects of ADRs- Definition, Types, Factors, Mechanisms, Seriousness and Severity, causality assessment, Markers, Management Pharmacogenetic causes, ADR in Public Health	11
3	Important ADRs and 'Risk Driving' ADRs of Important Medicines Serious and important ADRs in various organ class, ADR of various anti infective drugs	04
4	Individual Case Safety Reports (ICSRs)- Definition, Types, Contents, Structure, Validity and assessment of ICSR reports, Role ICSRs in Pharmacovigilance	06
5	Pharmacovigilance in Clinical Trials- Characterization, Pre and post authorisation studies, observational studies	03
6	Counterfeiting, Quality Defects and Medication Errors- Definition of substandard/spurious/falsely labelled/falsified/counterfeit (SSFFC) medicines, Pattern and scale of counterfeiting, Medication error-Definition, types, detections	07
7	Spontaneous ICSR Reporting Systems (SRS) Definition, Potential and limitations of SRS, Forms and formats of ICSR transmission as per various regulatory bodies, descriptive statistics, access and confidentiality	06
8	Signal Detection and Management Definition, Sources, Validation, Assessment, Scope	02
9	Industry and Regulatory Authorities, Mandatory Procedures from Legislation Pharmacovigilance system and SOPs, Benefit risk assessment, crisis management plan, WHO international drug monitoring programme, medDRA, Pharmacovigilance regulation in INDIA, USA, EUROPE, CANADA	03

References Books:

1. Talbot J, Aronson JK (eds.) Stephen's detection and evaluation of adverse drug Reactions
2. Andrews E, Moore N (eds.) Mann's Pharmacovigilance
3. Van Boxtel CJ, Santoso B, Edwards IR (eds.) Drug benefits and risks
4. Rawlins MD Therapeutics, evidence and decision-making

5. Aronson JK (ed.) Meyler's side effects of drugs
6. Sweetman SC (ed.) Martindale - the complete drug reference
7. World Health Organization WHO model formulary
8. S. K. Gupta Text book of Pharmacovigilance