GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VIII

Subject Name: Bioavailability and Therapeatic Drug Monitoring
Subject Code: 2280008

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	Relative and absolute bioavailability, bioequivalence, first pass clearance, Objectives of BA studies	**2**
2	Rate and extent of absorption, Factors affecting bioavailability(physicochemical and formulation related)	**2**
3	Methods and parameters of assessing bioavailability, Determination of AUC, Pharmacodynamic and pharmacokinetic models, Invitro dissolution and Bioavailability, Theories of dissolution, Invivo - invitro correlation studies, Techniques for enhancing Bioavailability	**6**
4	Study designs and analysis of BA-BE studies (protocol preparation of BA-BE studies as per CDSCO , Schedule Y guidelines, GCP guidelines)	**4**
5	TDM- introduction and definition, Recommendations and uses of TDM, Target drug ranges for TDM	**2**
6	Collection and storage of samples of body fluids, Sample preparation (Extraction, de-proteinization), Problems of interference of biological matrix	**4**
7	Criteria for selection of method for TDM : Physicochemical parameters of drug and sample related parameters	**3**
8	Techniques used in TDM: **Physical methods** HPLC, HPTLC, GC: Sensitivity and selectivity of detection with respect to applications for TDM and related pharmacoeconomics. **Immunoassays** RIA, ELISA, FPIA, EMITH, NIIA: Sensitivity and selectivity of detection with respect to applications for TDM and related pharmacoeconomics	**9**
9	TDM of specific drugs- digoxin, gentamicin, lidocaine, lithium, theophylline, phenytoin, phenobarbitone, carbamazepine, valproic acid, addictive drugs, immunosuppressants Study of clinical pharmacokinetics, general guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reactions and drug interactions, techniques used for estimation, importance, interpretation of results of above mentioned drugs	**12**

10	Role of clinical pharmacist in TDM	**1**

Reference Books:

1. Michael Makoid, Philip Vuchetich, Umesh Banakar. Basic Pharmacokinetics. First edition. Pkinbook.
2. L. Shargel, and A. Yu, Applied Biopharmaceutics and Pharmacokinetics, Appleton and Large, Norwalk, CT, 1993.
3. Shargel Leon and Alan Mutnick. Comprehensive Pharmacy Review. Wolters Kluwer/Lippincott Williams and Wilkins, 2007.
4. Atkinsons Arthur. Principles of Clinical Pharmacology. 3rd edition. Academic Press. 2012.
5. Parthsarathi G, Karin Nyfort-Hansen, Milap Nahata. A textbook of Clinical Pharmacy practice. 2nd edition. University Press.
6. Bauer L A. Applied Clinical Pharmacokinetics. Mc Graw Hill Professional.
7. Wagner J.G. Pharmacokinetics for the Pharmaceutical Scientist, Technomic Publications. 1993.
8. M. Gibaldi and D. Perrier, Pharmacokinetics, J. Swarbrick, ed., Marcel Dekker, NY
9. M. Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics, 3rd edition. Lea & Febiger, Philadelphia.
10. P.G.Welling, F.L.S. Tse and S.V. Dighe (eds*) Pharmaceutical Bioequivalence*, Marcel Dekker Inc. New York, USA 1991.
11. Mike Hallworth, Nigel Kapps.Therapeutic Drug Monitoring and clinical biochemistry. ACB Venture. 1993.
12. Daniel Robinson, William J. Taylor. Simkin Handbook of Therapeutic Monitoring. 2nd edition. Harvey Whitney Books. 1993.
13. Evans WE, Schentag JJ and Jusko WJ. Applied pharmacokinetics, principles of therapeutic drug monitoring. 3rd edition. Applied therapeutics Inc.
14. B.Widdop. Therapeutic drug monitoring. Churchill Livingstone. 1985.
15. Irving Sunshine. Recent developments in TDM and clinical toxicology. Marcel Dekker. 1992.
16. Leonardo D. Azevedo Calderon. Chromatography- The most versatile method of chemical analysis. CC BY 3.0 license. © The Author(s)
17. Ganesh R. Naik. Applied biological Engineering . Principles and practice. InTech. 2012.
18. Michael Hallworth. Ian Watson. TDM Clinical guide. Abbott.