GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm
SEMESTER: VII

Subject Name: Instrumental and Process Validation
Subject Code: 2270014

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

Sr. No.	Contents	Hours
1	**Pharmaceutical Process Validation** Introduction to pharmaceutical validation: definition, manufacturing process model, scope of validation, advantage of validation, organization for validation, validation master plan, process validation as Quality assurance tool. Types of Process validation: prospective, concurrent, retrospective and revalidation. Validation of tablet manufacturing process and manufacturing process for sterile products Equipment qualification: Design qualification, Installation qualification, Operational qualification, Performance qualification. Qualification of equipments (e.g. Dry powder mixers, and Autoclave) Cleaning validation: cleaning of equipment, cleaning of facilities.	**18**
2	Instrumentation of HPLC, HPTLC and GC, Validation of HPLC and GC instruments.	**7**
3	**HPLC Method Development** Basics of separation including Column resolution, Plate number, Plate height, Selectivity factor, Capacity factor and their optimization. Selection of detector and column Mobile phase optimization including selection of correct pH value	**10**
4	**Bio analytical HPLC method development and validation** Biological sample preparation: Protein precipitation, liquid liquid extractions, solid phase extractions and membrane separations **LC/MS** – Hints and recommendations on optimization and troubleshooting	**5**
5	**Laboratory Automation** Principle of automation, automated instruments, types of automated analytical systems, process control, flow injection analysis.	**5**

REFERENCES:

1. Pharmaceutical Process Validation, A. H. Wachter and R. A. Nash, Drugs and Pharmaceutical Sciences Series, Vol. 129, Marcel Dekker Inc., 2011, New York.
2. Validation of Aseptic Pharmaceutical Processes, F.J. Carleton and J.P. Agalloco, Marcel Dekker Inc., 1986, New York.
3. Cleaning Validation Manual: A Comprehensive Guide for the Pharmaceutical and Biotechnology Industries by S. I. Haider and E. S. Asif, CRC Press, Taylor and Francis Group, 2010, Florida.
4. Practical HPLC Method Development, Second edition, L. R. Snyder, J. J. Kirkland and J. L. Glajch, A Wiley Interscience Publication, 1997, USA.
5. HPLC Made to Measure, S. Kromidas, Wiley-VCH Verlag GmbH & Co. KGaA, 2006, Weinheim.

6. Instrumental Analysis, D. A. Skoog, F. J. Holler, S. R. Crouch, Cenage Learning India Private Limited, 2012, New Delhi.
7. Instrumental Methods of Analysis, Seventh edition, H. H. Willard, L. L. Merritt, J. A. Dean, F. A. Settle, CBS Publishers & Distributors Pvt. Ltd., 2009, New Delhi.