SAURASHTRA UNIVERSITY

RAJKOT

(ACCREDITED GRADE "A" BY NAAC)

FACULTY OF SCIENCE

Syllabus for

POST GRADUATE DIPLOMA IN SOPHISTICATED ANALYTICAL INSTRUMENTATION TECHNIQUES FOR PHARMA AND RELATED INDUSTRIES

Choice Based Credit System

With Effect From: 2010-11

Program Outcome (PO)

The following outcomes reflect the terminal skills that all PGDSAIT student should be able to demonstrate upon program completion.

PO1: Provide working knowledge of chemical instrumentation and laboratory techniques and will be able to use this knowledge to design and conduct independent work in industry.

PO2: Demonstrate mastery and application of core knowledge and skill of sophisticated instruments, regulatory affairs, ICH guidelines related to pharma industries.

PO3: Practice based learning and improvements.

Program specific outcomes (PSO)

PSO1: Understanding of various classical analytical techniques.

PSO2: Preparation of various strength solutions, reagents used in analysis by sophisticated instruments.

PSO3: Interpretation of chromatographic and spectroscopic analytical data

PSO4: Understanding ICH guideline, pharma regulate affairs and their interpretation.

Semestre-1							
Paper No.	**Title of Paper**	**No. of Hrs. Per week**	**Weightage For Internal Examination**	**Weightage For Semester end Examination**	**Total Marks**	**Duration of Semester end Exam in Hrs.**	**Course Credits**
PGDI-101	Basic Concepts Of Pharmaceutical And Chemical Analysis	4	30	70	100	2.5	4
PGDI-102	Separation Sciences And Hyphenated Techniques For Pharmaceutical And Other Analysis	4	30	70	100	2.5	4
Total		8	60	140	200	5	8

Semestre-2							
Paper No.	**Title of Paper**	**No. of Hrs. Per week**	**Weightage For Internal Examination**	**Weightage For Semester end Examination**	**Total Marks**	**Duration of Semester end Exam in Hrs.**	**Course Credits**
PGDI-201	Advanced Spectroscopic And Thermal Methods Of Analysis For Pharma And Chemical Products	4	30	70	100	2.5	4
PGDI-202	IPR, Patent, Documentation, Statutory And Regulatory Affairs	4	30	70	100	2.5	4
PGDI-203	Project Work/Dissertation	12	-	-	150	6	6
PGDI-204	VIVA-VOICE	-	-	-	50	-	2
Total		8	60	140	400	11	12

SEMESTER-I

PGDI-101

BASIC CONCEPTS OF PHARMACEUTICAL AND CHEMICAL ANALYSIS

Course outcomes (COS)

CO1: To know the fundamentals of analytical chemistry

CO2: To understand the theory and applications of basic laboratory instruments

CO3: Understanding and practices to volumetric and gravimetric analytical techniques.

- Classical methods Vs Instrumental techniques, Sampling, Analytical standards, Calibration, Standardization of instruments, Selection of methods for analysis, Selection of equipments,
- Making measurements and reporting, statistical and computational tools.
- Principles, theory and applications of Volumetric, Gravimetric, Precipitation, Redox, Complexometry, Non aqueous titrimetry.
- Principles, theory and applications of pH metry, Potentiometry including Karl-Fischer, Polarimetry, Spectrophotometery.

PGDI-102

SEPARATION SCIENCES AND HYPHENATED TECHNIQUES FOR PHARMACEUTICAL AND OTHER ANALYSIS

Course outcomes (COS)

CO1: Understanding the fundamental principles theory and applications of chromatographic techniques.

CO2: Understanding the principles, theory and applications of supplicated chromatographic techniques.

CO3: Practices of this techniques in terms of practical's and problems

- Introduction, fundamentals, Principles, theory and applications of Classical Chromatographic techniques (Paper, TLC, Column)

- Introduction, fundamentals, Principles, theory and applications of advanced chromatographic techniques. (GC-MS, LC-MS, HPTLC, IC)
- Practices

PGDI-103 PRACTICALS

Course outcomes (COs):

CO1: Understanding the theory by performing the particles.

Semester – 2

PGDI-201

ADVANCED SPECTROSCOPIC AND THERMAL METHODS OF ANALYSIS FOR PHARMA AND CHEMICAL PRODUCTS

Course outcomes (COS)

CO1: Understanding and explanation of principles, theory and applications of spectroscopic techniques.

CO2: Know the thermograpvimetric and other related instruments techniques.

- Introduction, fundamentals, Principles, theory and applications of UV-visible, FT-IR, Mass, NMR (1H and 13C) Spectroscopic technique, XRD and other important instruments.
- Introduction, fundamentals, Principles, theory and applications of DSC, DTA, TGA, Particle size analyzer and other important instruments.

PGDI-202

IPR, PATENT, DOCUMENTATION, STATUTORY AND REGULATORY AFFAIRS

Course outcomes (COS)

CO1: Learner should be able to use various parameter of pharma regulatory affairs.

CO2: Understanding ICH, SOP, GMP, GLP used in pharma and applied industries.

CO3: Case studies of related topics.

- Introduction to statutory and regulatory requirement for the industries overviews of Laws related to environmental protection and international standard certification awareness.(ISO, OHSAS, NABL)
- Regulatory requirements for Pharmaceutical products (API and Formulations) FDA, DCGI, WHO, Schedule-M, GMP, GLP, ICH Guidelines.
- Documentation in Pharmaceutical organizations, SOP's, Validations, Calibrations, Qualifications, Standardizations and preparation of various dossiers.
- Patent, IPR and related topics. IPR, Patent, Indian Patent Act , International pantentization related to generics.
- Recent updates.

PGDI-203

PROJECT WORK/DISSERTATION

Course Outcomes (COs):

- Selected analytical problem solving by Specific Sophisticated instrumental technique
- Exposure to the Scientific Database
- Statistical Analysis of the data
- Result, Data compilation and Thesis writing
- Publication

PGDI-204 VIVA-VOICE