AC- 02 / 03 / 2019

Item No- 2.4

Rayat Shikshan Sanstha's
Karmaveer Bhaurao Patil College Vashi,
Navi Mumbai.
(Autonomous College)

University of Mumbai

Rayat Shikshan Sanstha's
KARMAVEER BHAURAO PATIL COLLEGE, VASHI.
NAVI MUMBAI
(AUTONOMOUS COLLEGE)

Sector-15- A, Vashi, Navi Mumbai - 400 703

Program: M.Sc. Part 1

Course: Bioanalytical Sciences M.Sc.

(Choice Based Credit, Grading and Semester System with effect from the academic year 2018-2019)

Preamble:

Introduction:

With the introduction of Autonomy in the Credit Based Semester and Grading system, the syllabus in Bioanalytical Sciences has been revised for M.Sc. Semester -I and Semester- II. This syllabus is implemented with effect from 2018-19. The revised syllabus has been approved by the concerned authorities of the Autonomous College, Committees formed by the college, BOS members and Head/ Co-ordinatior from Department of Bioanalytical Sciences.

The syllabus has been designed such that the theory goes hand in hand with the practicals thus enabling students to develop professional skill set of a research analyst. The practicals included will give hands on practice.

Each paper has been designed emphasizing the need to develop research skills and Critical thinking/reasoning in students. This will aid the students in their specific area of their interest/ specialization in particular.

This revised syllabus is aimed at equipping students with theoretical foundations and practical techniques required in R & D, quality control, regulatory function in pharmaceuticals(drug acts and regulation, GLP,GMP and GCP etc.), environmental sciences, Pharmaceutical Microbiology, Advances in Molecular Biology, and Environmental monitoring and management. Areas covered in this course of two year will boost employability of students.

Indian Pharmaceutical industry:

Indian Pharmaceutical industry has long proved its mite both at national and international arena. With the WTO regime just rising in the horizon our pharma companies are in for a great boom especially in manufacturing and marketing generics which would be out of patent regime during 2005 to 2007. The market for these molecules is expected to be around 100 billion dollars. Even if our companies make a share of 01 % percent, substantial revenue is in the offering. Coupled with this they can strive to have few new molecules up their scheme.

Ayurveda, Siddha and Unani (ASU) Medicines - Our rich heritage:

The Indian sub-continent houses one of the world's richest flora & fauna and has one of the world's oldest medicinal systems - Ayurveda. Ayurveda (Ayur - life; Veda - knowledge) is an encyclopedia of the Indian medicinal system, which has a history of over 3000 years. It reflects the law of nature, inherent to life of all living beings. Along with Ayurveda other systems of

medicine like the folk medicines, Unani and Siddha are also being practiced in the subcontinent. Ayurveda, Unani and Siddha (ASU) medicines are quite popular among the Indians, and have been followed for over several hundred years.

Department of Indian Systems of Medicine and Homeopathy, Government of India recognizes Ayurveda, Siddha and Unani as standard systems of medicine. Having given the recognition and since these medicines are gaining the trust of people the world over, the Government is trying to implement regulatory guidelines to ensure consistent quality of efficacy & quality. Therefore, standardization of herbal medicines is the need of the hour. This will help not only lead to better acceptance of medicines of Indian systems by the people but will also help to bring these systems on par with the modern medicines where modern scientific principles and techniques are employed to ensure quality and efficacy of the drug formulations.

Inadequacy of Trained personnel:

Major hurdle faced by the R&D centers at various Pharma laboratories is the lack of adequately trained and GLP oriented personnel. This forms a major setback when the application of sophisticated technology especially in the bio analytical field is concerned. The lacunae become more evident when dealing with newer dosage forms and peptide based drugs.

Indian ASU formulations are already in great demand. There is, however, a dire need for standardization techniques based on modern instrumental procedures and principles. A major hurdle in achieving this is the lack of adequate expertise among the manufacturers of ASU drugs. The same inadequacy is seen even among the national laboratories and other Testing and research centers.

This lacunae needs to address very diligently and the proposed programme is a step in this direction. Bioanalytical evaluations are interdisciplinary programmes and require highly skilled personnel with strong background of Bio-analytical techniques. There is no programme available today for such a training to generate such expertise in analysts. Though industry uses sophisticated instruments in QC and drug development, there is a dire need of technical personnel with an overall expertise in various bioanalytical techniques including biological techniques to be able to take up R&D in newer formulations and standardization of ASU formulations to come up with meaningful evaluations.

Programme Objective:

Master of Science programme is designed to increase student's academic knowledge, critical thinking ability, and problem solving skills, and research competence that will prepare them for future roles as capable administrators, practitioners, educators, and researchers.

Programme Specific Outcome:

Professional Skills

- Students in the field of Bioanalytical Sciences will turn out to be experts in bio analytical techniques which are most prominently used in current industry trends. Student will have a firm foundation in the fundamentals and application of current advanced analytical techniques and its scientific theory.
- Student from Bioanalytical Sciences background will exhibit professional ethics, attitudes and behaviors which they will learn during 8-12 weeks internship with an industry. Student will show leadership qualities by initiating and advocating change to develop new opportunities in response to problems they identify.

Knowledge

- They will have a broad perception of knowledge that includes traditional as well as modern medicine system, regulatory body in pharmacy, pharmacognocy, clinical trial, pharmacokinetics, pharmacodynamics, applied molecular biology and microbiology.

Personal Skills

- **Problem-solving and decision-making**: Student will demonstrate use of observational, analytical and critical thinking skills to develop, implement and evaluate solutions that solve real-world problems.
- **Communication presentation exercises and industrial training:** Students will be trained to listen, speak and write in a manner that facilitates positive interaction with equals and senior faculties.
- **Teamwork**: Students will demonstrate appropriate and effective team behaviours in achieving shared goals in a variety of situations such AYUSH Project and projects related to Industrial visits, botanical garden visits etc.

Scheme of examination for Each Semester:

Internal Examination: 40 Marks
External Examination: 60 Marks will be as follows:

I.	**Theory:**		
	Each theory paper shall be of two and half hour duration.		
	All questions are compulsory and will have internal options.		
	Q – I	From Unit – I (having internal options.) 15 M	
	Q – II	From Unit – II (having internal options.)15 M	
	Q – III	From Unit – III (having internal options.)15 M	
	Q – IV	Questions from all the THREE Units with equal weightage of marks allotted to each Unit. 15 M	
II.	**Practical**	The External examination per practical course will be conducted as per the following scheme.	
Sr. No.	**Particulars of External Practical Examination**		**Marks**
1	Laboratory Work		40
2	Journal		05
3	Viva		05
	TOTAL		**50**

M.Sc. Bioanalytical Sciences: SYLLABUS IN BRIEF

M.Sc. part 1 Semester – I and II

Paper	**Code**	**Lectures**	**Credits**	**Code**	**Practical**	**Credits**
Basic Chemistry, Extraction Techniques, Different Medicinal Systems & Pharmacognosy	PGBAS101	60	4	PGBASP101	60	2
GLP, Drug Act and Quality Management	PGBAS102	60	4	PGBASP102	60	2
Chromatography and Spectroscopy-I	PGBAS103	60	4	PGBASP103	60	2
Molecular Biology, Biomolecules, Omics, Proteomics, Bioinformatics & Environmental Issues	PGBAS104	60	4	PGBASP104	60	2
TOTAL		**240**	**16**		**240**	**8**
TOTAL CREDITS			**24**			

Paper	**Code**	**Lectures**	**Credits**	**Code**	**Practical**	**Credits**
Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques	PGBAS201	60	4	PGBASP101	60	2
IPR and Patenting, Stability Studies, Basic Microbiology and Medical Pharamcology and Packaging	PGBAS202	60	4	PGBASP102	60	2
Chromatography and Spectroscopy-I	PGBAS203	60	4	PGBASP103	60	2
Basic Microbiology, Immunoassays, Pharmacology, New Drug Development & Laboratory Safety Measures	PGBAS204	60	4	PGBASP104	60	2
TOTAL		**240**	**16**		**240**	**8**
TOTAL CREDITS			**24**			

M.Sc. Semester –III

Paper	Code	Lectures	Credits	Code	Practical	Credits
Regulatory Microbiology, Genomics, Toxicology, Neutaceuticals	PGBAS301	60	4	PGBAS301	60	2
MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-I	PGBAS302	60	4	PGBAS302	60	2
Standardization of ASU drugs, Statistics & GMP-I	PGBAS303	60	4	PGBAS303	60	2
BA/ BE Studies, GCP and Method Validation-I	PGBAS304	60	4	PGBAS304	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			**24**			

M. Sc. Semester- IV

Paper	Code	Lectures	Credits	Code	Practical	Credits
Bioassays, PCR, Automation, Capillary Electrophoresis	PGBAS401	60	4	PGBAS401	60	2
MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-II	PGBAS402	60	4	PGBAS402	60	2
Regulatory aspects of ASU, Nanotechnology, Drug Delivery systems,EDM, Regulatory issues	PGBAS403	60	4	PGBAS403	60	2
TDM, Pharmacovigilance, CDM,BA/BE, Environmental Safety	PGBAS404	60	4	PGBAS404	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			**24**			

M. Sc. Semester I

PGBAS101-Basic chemistry, Extraction Techniques, Different Medicinal Systems, Pharmacognosy

Course Objective:

1. **Basic principles of chemistry & Principle of extraction and Isolation of analytes:** The learner will learn about basic principles in chemistry, different methods of extraction of analyte, physico-chemical property of drugs and solvents. This topic also includes the first law of drug metabolism.
2. **Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani:** The main objective of this particular topic is to introduce student to various traditional Indian medicine system with the help of appropriate examples.
3. **Modern Medicine**: The topic, modern medicine will aid in students knowledge regarding the modern medicine which includes principle and practice of modern medicine along with detailed knowledge of API, excipients and various dosage forms.
4. **Pharmacognosy**: The Pharmacognosy subjects main goal is to introduce students with various plant systems and their medicinal uses. This topic also includes introduction to topics such as Herbaria, Ethanobotany etc.

Course Outcome: student will be to understand about different medicinal systems of India as well as its standardization and regulation in India and different extraction techniques and basic principles of chemistry.

101.1	Basic principles of chemistry & Principle of extraction and Isolation of analytes	(15)
101.2	Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani	(15)
101.3	Modern Medicine	(15)
101.4	Pharmacognosy	(15)

PGBAS102- GLP, Drug Act and Quality Management

Course Objective:

1. **GLP:** In this topic students will learn about various guidelines to be followed for good laboratory practices along with preparation of SOPs (Standard Operating Procedure) for operating various instruments.
2. **Pharmacopoeial standards and testing procedure:** In this particular module students will be introduced to WHO guidelines, pharmacopoeia and the specified test in monographs w.r.t. various formulations (i.e. Injectibles, solid dosage forms etc.)
3. **Drug Acts and Regulations:** This module aims at studying various Drug and cosmetic acts w.r.t Schedule Y, M, H, introduction to foreign guidelines and also introduction to CFR21 part11.
4. **Quality Control and Quality Assurance:** This topic will educate learner in understanding quality control and quality assurance with respect to standardizing an analytical method, factors for standardization and its documentation etc.

Course Outcome: student should understand and describe basic regulatory guideline with respect to food and Pharma Industry, using pharmacopoeias as reference and also will learn about QA & QC

102.1	Good Laboratory Practice (GLP)	(15)
102.2	Pharmacopeial standards and Testing Procedure	(15)

102.3	Drug Acts & Regulations	(15)
102.4	Quality Control (QC) and Quality Assurance (QA)	(15)

PGBAS103-Chromatography & Spectroscopy-I

Course Objective:

1. **Theory of Chromatographic separation and TLC:** This module will facilitate lerner in understanding of principles of chromatographic separation, various chromatographic seperatation techniques and principle, practices and application of TLC
2. **HPLC – 1:** This subject matter will focus students in understanding of detailed principle and instrumentation of HPLC along with different HPLC techniques.
3. **GC – I:** This subject matter will focus students in understanding of detailed principle and instrumentation of GC.
4. **Spectroscopy – I:** The spectroscopy module will make learner have a detailed knowledge about different spectroscopic techniques which includes, UV-VISIBLE, Nephalometry, Turbidometery, IR and NMR.

Course Outcome: student will trained in handling various analytical Instruments as well as student gain detailed knowledge in Analytical Chemistry

103.1	Theory of Chromatographic separation and TLC	(15)
103.2	HPLC – 1	(15)
103.3	GC – I	(15)
103.4	Spectroscopy – I	(15)

PGBAS104- Molecular Biology, Biomolocules, Omics, Proteomics, Bioinformatics & Environmental Issues

Course Objective:

1. Molecular Biology, Biomolecules & OMICS: in this module students will learn about basic molecular biology and introduction to OMICS which include Genomics, metabolomics, lipidomics and proteomics.
2. Electrophoresis: This module will facilitate learner in understanding of electrophoretic separation techniques, Agarose gel electrophoresis, SDS-PAGE etc. along with its standardization, detection and application.
3. Bioinformatics: This topic will introduce students to Basics of Bioinformatics alonf with its application in the field of Genomics and proteomics.
4. Environmental Issues of Bioanalytical laboratory: This basic topic will aid student in understanding of waste generated in bionalaytical lab and its appropriate disposal protocol.

Course Outcome: student will be able to recognize and get well versed with techniques related to molecular biology, softwears in bioinformatics and student will also recognize the importance of bio waste management.

104.1	Molecular Biology, Biomolecules & OMICS	(15)
104.2	Electrophoresis	(15)

104.3	Bioinformatics	(15)
104.4	Environmental Issues of Bioanalytical laboratory	(15)

Distribution of Topics

M.Sc. Semester II

PGBAS201-Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques

Course Objective:

1. **R and D in Pharma industry and recent trends in Indian Pharmaceutical industry**: in this module learner will know the recent market trends and activities w.r.t. pharmaceutical field, along with knowledge of Global R&D and Indian Pharmaceutical R&d
2. **Solid Phase Extraction (SPE**): This unit aims at understanding this unique technique of extaction along with the detailed instrumentation knowledge and application
3. **Phytochemistry:** This topic will help student understand primary and secondary metabolites extracted from plants and their synthesis.
4. **Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography):** This unit deals with knowledge of the concept, instrumentation and application etc. w.r.t. SCFE & SCFC.

Course Outcome: Student will be trained in advanced extraction techniques w.r.t. industry. Student will also comprehend recent trends in Pharmaceutical Industry in India.

201.1	R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry	(15)
201.2	Solid Phase Extraction (SPE)	(15)
201.3	Phytochemistry	(15)
201.4	Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography)	(15)

PGBAS202- IPR and Patenting, Stability Studies, Basic Microbiology, Medical pharmacology and Packaging

Course Objective:

1. **IPR and Patenting-I:** This topic will help students understand concept of IPR, types of IPR and global Harmonization which will assist students in their understanding of patenting process.
2. **Stability Studies:** This topic will include factor affecting stability of drug formulation, guidelines for stability evaluation which will aid in students detailed understanding towards conducting stability studies at industry level.
3. **Basic Microbiology and Medicinal Pharmacology:** this topic will emphasize on basic microbiology which will help learner in understanding of further applied microbiology concepts. Inclusion of medicinal Pharmacology will make students understand the various drug used for the disease related to particular body system.

4. **Packaging in pharma industry:** this topic includes the basic understanding of the one of the most important part in the pharma industry, which will assist students in understanding various packaging materials, guidelines and process of packaging.

Course Outcome: students will gain knowledge of IPR and Patenting with recent examples. Student will get a clear idea on concepts of stability studies as well as packaging in industry.

202.1	IPR and Patenting- I	(15)
202.2	Stability Studies	(15)
202.3	Basic Microbiology& Medicinal pharmacology	(15)
202.4	Packaging in Pharma industry	(15)

PGBAS203- Chromatography & Spectroscopy-II

Course Objective:

1. **HPTLC:** This module will facilitate students in understanding of the detailed understanding of principle, instrumentation and application of the instruments.
2. **HPLC-2:** This topic will aid in the understanding of HPLC instrument at an advanced level which will include chiral HPLC, maintenance of the instrument and troubleshooting.
3. **GC-II:** This topic will aid in the understanding of GC instrument at an advanced level which will include universal and specific detector in GC, derivatisation for GC, troubleshooting and its application.
4. **Spectroscopy-II:** This module will assist students in identifying the different concepts with respect to spectroscopy which will include ORD, Emission Spectroscopy, AAS, ICP and X-ray diffraction.

Course Outcome: student will be well trained in advanced chromatography techniques and Instrumentation

203.1	HPTLC	(15)
203.2	HPLC – 2	(15)
203.3	GC – II	(15)
203.4	Spectroscopy – II	(15)

PGBAS204- Basic Microbiology, Immunoassays, Pharmacology, New Drug Development & Laboratory Safety Measures

Course Objective:

1. **Immunoassay:** This topic will help in understanding of theory of Immunoassay, its requirements, practical aspects, data handling and advantages of immunoassay. This topic also includes principle and instrumentation in ELISA, its application and types of detection system.
2. **Pharmacokinetics, Pharmacodynamics and Drug Properties:** This topic includes course in the area of concepts related to pharamcodynamics and pharmacokinetics along

with routes of administration of dosage form, absorption, metabolism, ADR and SAF w.r.t. drug formulation.

3. **Clinical Pharmacology, NCE and its development into a New Drug and Enzymes:** this module includes introduction to clinical pharmacology, new chemical entity which will facilitate students understanding towards the research in the area of clinical pharmacology and development of new chemical entity.
4. **Laboratory Safety measures w.r.t handling of chemicals and biological materials**: this unit will provide detailed knowledge of lab safety parameters, general precautions, labels, signage's, MSDS, levels of safety, fire fighting and fire safety etc.

Course Outcome: student will understand and translate the basic concepts of immunoassays, new drug development. Student will gain knowledge in handling and classifying hazardous chemical waste.

204.1	Immunoassays	(15)
204.2	Pharmacokinetics, Pharmacodynamics and Drug Properties	(15)
204.3	Clinical Pharmacology, NCE and its development into a New Drug and Enzymes	(15)
204.4	Laboratory Safety measures w.r.t handling of chemicals and biological materials	(15)

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

60 Lectures / paper/semester
SEMESTER I -Theory
PGBAS101- Basic chemistry, Extraction Techniques, Different Medicinal Systems, Pharmacognosy
(Lecture allotment includes periods for Seminars and Discussions)

Module No.	**Topics**
101.1	Title: Basic principles of chemistry & Principle of extraction and Isolation of analytes (15) Subtopics: 1. Atom and its structure, types of bonds 2. Volumetric solutions: Solubility, Normality, Molarilty, Molality, Equivalent weight, Buffer solutions, dissociation and dissolution 3. Physico-chemical properties of drugs and solvents 4. Concept of partition & Partition Coefficient 5. Solvent properties 6. Selection of solvent 7. Extraction efficiency 8. Introduction to classical methods of extraction 9. Introduction to modern methods of extraction- advantages & disadvantages - Include LLE (Soxhlet) and LME 10. Applications of extraction 11. Microwave assisted extraction its advantages and disadvantages 12. Ionization and its effect on the extraction of drugs 13. Matrix components & analyte isolation 14. Concentration of extracts 15. Isolations of fractions 16. Purification of isolate
101.2	Title: Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani (15) Subtopics: 1. Introduction of AYUSH 2. Principles and practice of ASU 3. Types of Drug Formulation 4. Methods of Manufacture – Raw Material To Finished Product 4. Types of Drug 5. Excipients in various dosage form
101.3	Title: Modern Medicine (15)

	Subtopics: 1. Principles and practice 2. API and concept of its formulation into a dosage form 3. Different types Drug Formulations 4. Excipients in various dosage forms 5. Disease Management (Comparison of ASU and Modern Drugs) a. Diabetes b. Obesity c. Hypertension d. Hepatitis e. Malaria f. Dengue g. Influenza
101.4	Title: Pharmacognosy (15) Subtopics: 1. Introduction, Plants and their medicinal uses 2. Concepts of ethanobotany, ethno medicines and pharmacology 3. Phytogeographical regions to be explained with respect to endemism and hot spots (explain only concepts) 4. Herbaria evaluation to include Plant collection, Authentication, storage and drying techniques. 5. Raw material evaluation to include Microbial load, Raw material characterization, proximate evaluation, photomicrography 6. Concepts of GAP and GHP for medicinal plants(only introduction)

PGBASP 101

- Liquid – liquid extraction of a modern drug from plasma and formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)

- Microscopic evaluation of sections and powders with adulteration and formulation comparision of the following medicinal plants;

1) *Emblica officinalis – (Amla - dried fruit)*
2) Vitex nigundo - Leaves
3) Asteracantha Longifolia – Whole plant
4) Calotropis gigantea – Leaves
5) Phyllanthus amarus – Whole plant

Calculation in terms of percent occurrence of key anatomical characteristics in the powder to be recorded.

- Individual student must report findings of ANY THREE from the above list but in each institution evaluation on all the listed plants must be carried out.

• Separation of plant pigments using paper chromatography • Determination of sugars by paper chromatography.	
PGBAS102- GLP, Drug Act and Quality Management **(Lecture allotment includes periods for Seminars and Discussions)**	
102.1	Title: Good Laboratory Practice (GLP) (15) Subtopics: 1. What is GLP? 2. Practicing GLP 3. Guidelines to GLP 4. Documentation of Laboratory work 5. Preparation of SOPs 6. Calibration records 7. significance of validation in GLP 8. Transfer of methods 9. Documentation of results
102.2	Title: Pharmacopeial standards and Testing Procedure (15) Subtopics: 1. Introduction to WHO guidelines 2. Introduction to Pharmacopoeias IP, BP, USP(JP, EP, AP where ever applicable) 3. Specified test in Monographs w.r.t liquid formulation (injectible) and solid dosage form (USP, EP, BP, IP) 4. Include AP, Indian HP and AFI (wherever applicable)
102.3	Title: Drug Acts & Regulations (15) Subtopics: 1. Indian Drugs and Cosmetics Act w.r.t Schedule Y, M, H. Include Schedule A, S (introduction) 2. Introduction to foreign guidelines w.r.t US, EU, Australia & Japan 3. Introduction to CFR 21 part 11
102.4	Title: Quality Control (QC) and Quality Assurance (QA) (15) Subtopics: 1. Introduction 2. What is QC? What is QA? 3. Requirements for implementing QC & QA

	4. QC & QA concepts in ASU drugs 5. Standardizing an Analytical method a. Preliminary requirements of a discriminatory quantitation b. Detection of the analyte of interest c. Separation of analyte form the matrix components d. Sample preparation for quantitation 6. Support work & documentation 7. Validation 8. Audit requirements ,audits and audit reports 9. Personnel Responsibility in QA
PGBASP 102 • Students must submit a Field Note Book of their field excursion including Presentation of the field visit • Research Paper Review • Carry out dissolution test, disintegration, hardness and friability on any one tablet preparation	
PGBAS103-Chromatography & Spectroscopy-I **(Lecture allotment includes periods for Seminars and Discussions)**	
103.1	Title: Theory of Chromatographic separation, TLC & application of TLC(15) Subtopics: 1. Introduction of Chromatography 2. Principles of chromatographic separation 3. Introduction to chromatographic separation techniques (TLC, HPTLC,HPLC,GC) 4. Principles and Practice of TLC 5. Trouble shooting in TLC 6. Application of TLC 7. Detection of compounds on TLC plates
103.2	Title: HPLC – 1 (15) Subtopics: 1. Principles and Instrumentation 2. The chromatogram 3. Separation mode

	4. Column chemistry 5. System parameters 6. Reverse-phase HPLC 7. Introduction to various HPLC techniques; a. Ion-pair HPLC b. Ion-exchange HPLC c. Normal-phase HPLC d. Affinity Chromatography e. Gel permeation Chromatography
103.3	Title: GC – I (15) Subtopics: 1. Principles and Instrumentation 2. Factors that affect the chromatographic separation (Temperature, Type of column etc.) 3. GC techniques 4. Types of columns and their application 5. Selection of liquid stationary phases (Packed and capillary columns) 6. GC hardware a. Introduction to flow and pressure controllers b. Injection techniques- on column injection, large volume injection, split - splitless, PTV and various auto injectors- gas sampling as well as liquid sampling c. Column Oven- temperature programming, (High /cryogenic oven temperature)
103.4	Title: Spectroscopy – I (15) Subtopics: 1. Introduction to atomic and molecular Spectroscopy 2. UV ,Visible and fluorescence i. Principles & Instrumentation ii. Applications 3. Nephalometry i. Principles & Instrumentation ii. Applications 4. Turbidometry i. Principles & Instrumentation ii. Applications 5. IR i. Principles & Instrumentation ii. Applications

	6. Basic concepts of NMR spectroscopy

PGBASP 103

- Gas Chromatograhic separation of solvent mixtures (e.g. Menthol & Ethanol, Toluene & Methanol etc.)
- HPLC separation of herbal raw phytoconstituent of a rawmaterial from its formulation (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Phyllanthus amarus* from LIV 52, *Tribulus terrestris* from Ghokshuradi guggul etc.)
- HPLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
- HPLC separation of modern drugs from their combination formulation (e.g. Diclofenac Sodium &Paracetamol, Metformin &Glimiperide etc.)
- Determination of Caffeine from a given sample by
  i) UV spectrophotometry
  ii)HPLC
- IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)
- Derivatisation in GC

PGBAS104- Cell & Molecular Biology, Biomolocules, Omics, Proteomics, Bioinformatics & Environmental Issues
(Lecture allotment includes periods for Seminars and Discussions)

104.1	Title: Molecular Biology, Biomolecules & OMICS (15) Subtopics: 1. Introduction to molecular biology 2. Biomolecules 3. Nucleic Acid chemistry 4. Transcription, translation, DNA replication 5. Introduction to Omics: a. Genomics b. Metabolomics c. Lipidomics d. Proteomics 2. Significance of proteome 3. Overview of proteomics a. Methods for cell disruption/protein extraction b. Protein purification/ Fractionation

	c. Protein identification and characterization 4. Modification of proteins (invitro/invivo) a. Post translational b. Chemical
104.2	Title: Electrophoresis (15) Subtopics: 1. Basic Protein Chemistry 2. Principles of electrophoretic separation 3. Equipment and process 4. Agarose gel electrophoresis 5. PAGE – Native & SDS, 2DGE, Extensions of Electrophoresis- Immunoelectrophoresis/pulsefield 6. Standardization of electrophoretic technique 7. Detection techniques 8. Applications of electrophoresis
104.3	Title: Bioinformatics (15) Subtopics: 1. What is bioinformatics? 2. Databases and Search Tools 3. Applications of bioinformatics a. Genomics b. Proteomics c. Drug discovery (Docking software) 4. Using various libraries & tools w.r.t structure/ literature to drug development/ proteins 5. Introduction to Chemi-informatics
104.4	Title: Environmental Issues of Bioanalytical laboratory (15) Laboratory Waste: Management, control and Regulatory issues 1. Introduction to types and sources of Laboratory waste 2. Chemical & Biological materials: Hazards and Handling 3. Hazard Controls & Information (*Workplace Hazardous Materials Information System {WHMIS} as example)* 4. Introduction to : • Chemical Storage and Segregation • Chemical Laboratory Emergency Response • Equipment Safety

	• Laboratory Inspections • Transportation and Receiving of Hazardous Materials 5. Regulations of Pollution Control Board for Laboratories.

PGBASP 104

- Separation of human serum / plasma proteins / egg white using PAGE((Protein molecular weight determination kit may be used)
- Evaluate the given data of protein and nucleic acid sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis of the findings.
- Evaluate the given data of peptide sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis on the functional annotation of the peptide.
- Bioinformatics : Clustal W. omega, BLAST A, Blast O, Fasta, Alignment, Prosite, SCOP, Rasmol, CATH, Identification of Protein.
- Separation of proteins using 2D gel electrophoresis
- Protein profiling of plant seed by SDS-PAGE

SEMESTER II-theory
PGBAS201-Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques
(Lecture allotment includes periods for Seminars and Discussions)

201.1	Title: R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry (15) Subtopics: 1. Historical background with emphasis on Post 1947 period 2. Market trends and activities 3. Govt. initiatives and the public sector in Pharmaceutical Industry 4. The role of Drug Pricing policy in India and its impact on the Indian Pharmaceutical Industry 5. Role of Analytical chemist in Pharmaceutical Industry 6. Golbal Pharma R&D 7. R&D strategies in Indian Pharma 8. Bulk Drug manufacturing & its R&D 9. Varied Dosage forms and its R&D
201.2	Title: Solid Phase Extraction (SPE) (15)

	Subtopics: 1. Introduction 2. General properties of bonded silica sorbents 3. Sorbent/analyte interactions 4. Sample pretreatment of different biological matrices 5. Developing SPE methods 6. Disc cartridges 7. 96-Well Format (e.g. Porvair Microsep TM system) 8. Direct injection of plasma in cartridges 9. Other new developments in extraction techniques
201.3	Title: Phytochemistry (15) Subtopics: 1) Natural drug substances from plants (primary and secondary metabolites) 2) Broad classification of secondary metabolites a. Nitrogenous b. Non nitrogenous c. Isoprenoids 3) Secondary drug metabolite production with special reference with integrated pathway. (shikmic pathways, mevalonate pathways) 4) Key Factors affecting synthesis of secondary metabolites 5) Choice of solvent for extraction of phytoconstituents 6) Extraction Techniques of Crude plant material w.r.t a)maceration b)percolation c)steam distillation
201.4	Title: Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography) (15) Subtopics: 1. The concept of SCFE & SCFC 2. Instrumentation of SCFE & SCFC 3. Factors affecting SCFE & SCFC 4. Benefits of SCFE & SCFC 5. Application of SCFE and SCFE 6. Conclusions and future perspectives 7. Introduction of Spray Dry Extraction and its application

PGBASP 201

- SPE of a modern drug from formulation (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.)

- SPE of a modern drug from plasma (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.)

- Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans, steroids and glycosides using TLC. Compare the results using standards (if available).

- Preparation of Herbarium of following medicinal plants;
  1) Asteracantha longifolia
  2) Trigonellafoenum
  3) Clitoria ternatea
  4) Coriandrum sativum
  5) Achyranthus aspera
  6) Scopariadulcis
  7) Amaranthus spinosa
  8) Phyllanthus amarus
  9) Calotropri sgigantea
  10) Vitex nigundo

  Individual student must **submit** herbaria of ANY THREE from the above list but in each institution herbarium of all the listed plants must be prepared.

- Preparation of calibration graphs for Li, Na, and K by flame Photometry using their solutions of appropriate concentrations and studying interference of
  i) K in Na estimation
  OR
  ii) Na in Li estimation
  OR
  iii) Li in K estimation

- Determination of percentage purity of CaCO3/MgCO3 by
  i) Titrimetry
  ii) Complexometry

- Comparison of classical and modtern method of extraction of phytoconstituent of medicinal plants.
  (microwave extraction, soxhlet extraction)

- Effect of drying on phytoconstituents.

- Evaluation of geographical / Regional variation interms of phytochemical by TLC using a

suitable plant example.

PGBAS202- IPR and Patenting, Stability Studies and Packaging
(Lecture allotment includes periods for Seminars and Discussions)

202.1 Title: IPR and Patenting- I (15)

Subtopics:

1. Concept of IPR - Understanding the meaning of IPR & its significance in knowledge based economy.
2. Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, Geographical indications, Protection of New Plant Varieties, Different Plant Extract and process patent, Copyright.
3. Global Harmonization - Impact of IPR on global trade and the need for harmonization, WTO and its role in a global harmonization, TRIPS and introduction to the articles in TRIPs document as well as the flexibilities provided by TRIPS.
4. Indian Patent Act
    a. Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step, useful/capable of industrial application.
    b. Non-patentable subject matter - what is not patentable.
    c. Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance.
    d. Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, servicing of patents.
    e. Provisional Patents, Divisional Patents & Patents of Addition.
5. IPR as a strategic tool-
    a. Concepts of Piracy, reverse engineering and knowledge worker.
6. International Agreements related to IPR & patents - Paris Convention, PCT.

202.2 Title: Stability Studies (15)

Subtopics:

1. Factors that influence stability of drug formulations
2. Types of Stability chambers and their design considerations
3. Stability issues of ASU raw materials and finished products
4. Guidelines on Stability evaluations
5. Approaches to stability studies of ASU formulations

202.3 Title: Basic Microbiology & Medicinal Pharmacology(15)

Subtopics:

1. Microbes & Their environment, Significance and scope of Microbiology, Biodiversity

	and types of Microorganisms, Visualization of Microorganisms: staining and Simple and compound microscopy, Electron Microscopy 2. Growth of Microorganisms, methods to study growth of microorganisms, preservation of microorganisms, maintenance media, etc. 3. Types of Drugs & mode of action a) Drugs Acting on Autonomic Nervous System b) Autacoids and Related Drugs c) Respiratory System Drugs d) Hormones and Related Drugs e) Drugs Acting on Peripheral (Somatic) Nervous System f) Drugs Acting on Central Nervous System g) Cardiovascular Drugs h) Drugs Acting on Kidney i) Drugs Affecting Blood and Blood Formation j) Gastrointestinal Drugs k) Antimicrobial Drugs l) Chemotherapy of Neoplastic Diseases m) Miscellaneous Drugs
202.4	Title: Packaging in Pharma industry (15) Subtopics: 1. Introduction to Packaging 2. Fundamentals of Distribution 3. Packaging Forms & their Significance 4. Packaging Materials (covering basic mfg process, applications and significance) 5. Paper, Paper Board and CFB Glass,metals, Basic Polymer based materials, Polymer based composite materials 6. Ancillary Mats 7. Package Material Testing 8. Compatibility & Migration Studies 9. Accelerated Shelf Life Testing - Theory and Problems. 10. GMP 11. Packaging Validation 12. Packaging Laws and regulatory compliance
PGBASP 202 • Students must submit a Report of the Industrial Visits including Presentation of the industrial visit. • Patent Claim Drafting	

- Accelerated stability studies of various formulations or drugs with respect to Temperature (b) Effect of buffers / pH dependent (2 – 4 Expts.)
- Test for degradation of compounds using TLC for any two drugs.
- Stability testing of solution and solid dosage forms for photo degradation.(2 experiments).
- Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
- Stability studies of drugs in dosage forms at 25^{o}C, 60% RH and 40^{o}C, 75% RH and at different Pressure

SEMESTER II-theory
PGBAS203- Chromatography & Spectroscopy-II
(Lecture allotment includes periods for Seminars and Discussions)

203.1	Title: HPTLC (15) Subtopics: 1. Principles and Instrumentation 2. HPTLC vs TLC 3. Densitometry & quantitaion in HPTLC 4. Fingerprint development and quantification of marker compound for formulation using HPTLC 5. Applications of HPTLC
203.2	Title: HPLC – 2 (15) Subtopics: 1. Chiral HPLC 2. Column switching in HPLC 3. Column conditions 4. HPLC detectors d. Introduction e. Principles of detection f. Universal and Specific a. Detectors g. Detector response h. Sensitivity considerations i. Selectivity 5. Manual and Electronic data Processing 6. Recent advances (Fast LC, online extractions, add on pumps, online derivatization,

	multi dimensional LC) 7. Troubleshooting 8. Applications of HPLC
203.3	Title: GC – II (15) Subtopics: 1. Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD) 2. Derivatisation for GC 3. GC strategy for analysis involving biological matrices 4. Troubleshooting 5. Applications
203.4	Title: Spectroscopy – II (15) Subtopics: 1. Theory and applications of ; i. Circular Dichroism (CD) ii. Optical Rotary Dispersion (ORD) 2. Emission spectroscopy 3. Principles, instrumentation and applications of i. Flame photometry ii. Atomic Emission Spectroscopy 4. AAS i. Principles & Instrumentation ii. Applications 5. ICP i. Principles & Instrumentation ii. Applications 6. X – ray diffraction i. Principles & Instrumentation ii. Applications

PGBASP 203

- HPTLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
- HPTLC fingerprinting of Herbal raw material (e.g. *Asteracantha longifolia, Ricinus cummunis, Calotropisgigantia*)
- HPTLC detection of herbal raw material from its formulations (e.g. Asteracantha longifolia from LUKOL / SPEMAN, Vitexnigundo from PANCHGUN TAILA, Glycerrizhaglabra from ANU TAILA)
- Gas Chromatographic separation of solutes from their matrix (e.g. Diclofenac sodium from its formulation, Methanol from plasma etc.)
- Determination of Caffeine from a given sample by
  i) HPTLC

  ii) HPLC

  iii) UV

SEMESTER II-theory
PGBAS204- Basic Microbiology, Immunoassays, Pharmacology, New Drug Development & Laboratory Safety Measures
(Lecture allotment includes periods for Seminars and Discussions)

204.1	Title: Immunoassays (15) Subtopics: 1. Introduction, Definitions and Theory of Immunoassays 2. Requirements for immunoassay 3. Practical aspects 4. Data handling 5. Advantages of immunoassay 6. Principles and instrumentation in ELISA 7. Applications of ELISA 8. Types of Detection systems

204.2	Title: Pharmacokinetics, Pharmacodynamics and Drug Properties (15) Subtopics: 1. Basic concepts of Pharmacokinetcs & pharmacodynamics n) Different pharmacokinetic & pharmacodynamics parameters and their meanings o) Basic techniques of evaluating Pharmacokinetic & pharmacodynamics parameters p) Basic types of models in pharmacokinetics & pharmacodynamics q) General classification of Drugs and their formulations r) Drug – Route of entry, Absorption and Distribution with examples s) Concepts of Drug Metabolism & elimination with examples t) Adverse Drug reactions(ADRs) u) Serious Adverse Events(SAEs)
204.3	Title: Clinical Pharmacology, NCE and its development into a New Drug and Enzymes (15) 1. Introduction to Clinical Pharmacology and Drug Development 2. What is NCE? 3. Stages in the development of NCE 4. Preclinical studies on NCE 5. Enzyme as Therapeutics agents, as diagnostics, as catalyst in processes as drug target
204.4	Title: Laboratory Safety Measures w.r.t handling of chemicals and biological materials (15) Subtopics: 1. General Precautions, labels and signage's 2. Material handling and disposal 3. Material Safety Data Sheets(MSDS) and SOP (Standard Operating Procedure) 4. Personal safety & Clothing 5. Levels of safety 6. Fire safety and fire fighting 7. Working in Biosafety Cabinets and hoods

M. Sc. Semester III

PGBAS301 – Regulatory Microbiology, Genomics, Toxicology, Neutraceuticals

Course Objective:

1. **Regulatory microbiology and its application in pharmaceuticals and food industry :** The learner will be taught about basic concepts of microorganisms, production of antibiotics and their applications in Pharmaceutical industry.
2. **Genomics :** Concepts of DNA and RNA will be emphasized on and how their manipulations will help in producing transgenic organisms.
3. **Basic and Regulatory Toxicology :** The topic of toxicology would help gain understanding in the results of pre-clinical trials.
4. **Neutraceuticals and Functional Foods, Food as remedy in human nutrition and nutritional genomics :** The topics that would be covered in this would help in understanding the concept of neutraceuticals and its application in Clinical Dietetics. This topic would also cover the instruments used in neutaceutical evaluation.

Course Outcome: Learner will be able to assess the advance concept and procedure in the field of Microbiology, Genomics and toxicological studies. The concept of neutraceutical will be help learner to develop a clear concept about the topic.

PGBAS302 – MS applications, Metabolite studies, Thermal analysis and Tracer Techniques – I

Course Objective:

1. **MS basics:** Basic principle of Mass spectroscopy along with it's instrumentation will be covered.
2. **Hyphenation:** The objective of this unit includes hyphenation of MS with different analytical instruments like LC, GC.
3. **Thermal analysis:** The main objective to be covered in this topic is the principle and instrumentation of various analytical instruments used in thermal analysis of a sample and its application in Indian Medicinal system.
4. **Analytical Methods:** The student will learn on the theoretical criteria required to develop a method and sample preparation. They will also learn fundamentals of GC and Headspace GC.

Course Outcome: learner will be inculcated with Knowledge of spectroscopic techniques and its application in various fields.

PGBAS303 – Standardization of ASU drugs, Statistics & GMP – I

Course Objective:

1. **Standardization of ASU drugs :** Why and approach of Standardization towards Indian Medicinal systems will be taught.
2. **General Statistical Methods :** The learner will learn about various types of Biostatistical methods.

3. **Concepts of Biostatistics :** In this unit various concepts of Biostatistics like ANOVA, COV, F test, etc. are enlighten to students wherein it gets applicable in statistical analysis in many experiments at research/industrial level.
4. **Good Manufacturing Practices :** In this topic a general idea about GMP is given to students that takes place in an industry and general idea about regulatory certification is also given.

Course Outcome : All the major concepts of standardization of ASU drugs, Biostatistical analysis and GMP whose knowledge is required inorder to work in an industry/research institute is taught.

PGBAS304 – BA/BE Studies, GCP and Method Validation – I

Course Objective :

1. **Ethical issues in Clinical Trials :** Objectives in this unit helps in better understanding of Clinical Trials and Human rights participating in Clinical Trials.
2. **Good Clinical Practice (GCP) :** In this unit emphasis is basically done on understanding concepts of GCP of it's origin, need of GCP and requirements in GCP compliance. Guidelines of GCP wrt ICH and ICMR is emphasized on.
3. **Bioavailability(BA) & Bioequivalence(BE) :** In this unit introduction to BA/BE is done, it's evaluating parameter and various factors that influence BA/BE of a drug. It has it's application while formulating a generic drug.
4. **Analytical Method Validation :** The main aim of this unit is to teach students which parameters are considered while validating a method. The applicable use of reference standards and working standards is also taught.

Course Outcome : Major part of Clinical trials, ethics committee, BA/BE of a drug, subject rights is emphasized on along with the knowledge of validating a method.

M. Sc. Semester IV

PGBAS401 – Bioaasays, PCR, Automation, Capillary electrophoresis.

Course Objective:

1. **Bio assay in Pharmaceutical evaluation :** It involves general idea about bioassays and it's types wrt to invivo and invitro assay. It also teaches about animal ethics and animal rights used in invivo assays also alternative methods to invivo assays.
2. **Polymerase Chain Reaction (PCR) & DNA fingerprinting :** Concept of DNA amplification, DNA fingerprinting ,types of PCR and applications of genomic techniques is taught.
3. **Automation and analysis :** This unit helps to understand advanced automation and robotic workstations and its advantages in sample preparation and handling the samples.
4. **Capillary Electrophoresis:** Students will study CE because other important instrument like HPLC, GC, CE has excellent reproducibility, sensitivity & linearity for rapid analysis in minimal sample and solvent requirement.

Course Outcome: Student learn important techniques in the field of molecular biology which has major applications in Industry

PGBAS402 – MS Applications, Metabolites Studies and tracer techniques.

1. **MS Applications,:** Students learn MS application in various field as well as understand hyphenated techniques with MS and its applications.
2. **Tracer techniques in Bioanalytical assay:** This unit covers concept of Radioactivity and different radioactive emitters and their biological applications.

Course Outcome: Students will inculcate deep knowledge about MS and its Applications.

PGBAS403 – Regulatory aspects of ASU, Nanotechnology, Drug delivery systems EMD

1. **Regulatory aspects of ASU:** Student will learn schedule T &Y. they will also study approaches of US and EU and WHO for ASU regulations.
2. **Nanotechnology, Drug delivery systems:** student will understand the concept of nanosciences, nanomaterials and its application in biological an environmental filed. They will also be able to study drug delivery system.
3. **Electronic data management:** the aim of this unit to understand the concept electronic signature and its regulation as well as regulatory requirement of data evaluation**.**
4. **Regulatory issues:** students will study the current scenario about regulatory issues w.r.t. OTC, cosmetic and neutraceutical product.

Course Outcome : Concepts of Regulatory aspects and issues of ASU and modern medicine wrt to different guidelines will be covered along with Nanotechnology and it's applications. E-Data managing as a requirement will be covered.

PGBAS404 – TDM and Pharmocovigilance, CDM, BA&BE environmental dafety

1. **TDM and Pharmocovigilance:** Student will understand the concept of TDM, pharmacovigilance, pharmacoeconomics and its significances.
2. **Basics of Clinical Data Management**: this unit help to understand the basic concept of CDM, its significance and different clinical study phases.
3. **Bioavailability & Bioequivalence study:** student will understand the concept of BA&BE study design its data collection and reporting, assessment as well as its regulatory requirement
4. **Environmental Safety in Bioanalytical laboratory:** Student will get the overview of guidelines for laboratory handling,ISO 14001, OSHAS 18001

Course Outcome: Learner will be able to understand Pharmacovigilance and basic of clinical data management. students will get a deeper insight on how to conduct BA/BE Trials

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES SEMESTER III-theory PGBAS301- Regulatory Microbiology, Genomics, Toxicology, Neutaceuticals (**Lecture allotment includes periods for Seminars and Discussions)**	
301.1	Title: Regulatory Microbiology and its application in pharmaceuticals and food industry (15) Subtopics: 1. Asepsis, Sterilization and Disinfection, concept of Death curve of microbial population, Aseptic filling in pharmaceutical industry, Classification Clean rooms / Clean areas, QA and QC in Microbiology Laboratory 2. Important Microbes for Food & Drug Industry, Pathogenic Organisms in Food & Pharma Industry 3. Sources of contamination, Microbial Contamination in ASU preparations 4. Regulatory Microbiological testing in pharmaceuticals 5. Microbiological Assays for pharmaceutical products 6. Sources of antimicrobial agents: plants and microorganisms, therapeutic Antimicrobial Agents e.g. Erythromycin, Amphotericin B, Cephalosporins and their commercial production, Antimicrobial Drug Resistance and Drug Discovery
301.2	Title: Genomics (15) Subtopics: 1. Principles of DNA sequencing 2. DNA & RNA probes 3. Concepts of Gene manipulation (introduction only) 4. Restriction enzymes & their uses 5. Vectors & their uses 6. Producing Transgenic organisms 7. Hybridoma technology 8. cDNA production & applications 9. Gene libraries & applications
301.3	Title: Basic and Regulatory Toxicology (15) Subtopics: 1. Introduction, scope and types of toxicological studies. 2. Toxicants, their route of entry, distribution 3. Metabolism & elimination of toxicants 4. Concept of LD50, ED50 Title: Regulatory Toxicology

	5. Types of toxicity studies 6. Design considerations. 7. Evaluation of results 8. Extrapolation to man. 9. OECD Guidelines on Toxicological studies 10. Schedule Y and its interpretation.
301.4	Title: Neutraceuticals and Functional Foods, Food as remedy in human nutrition and neutritional genomics Subtopics: 1. Structure , function and property of neutraceuticals 2. Functional foods 3. Human nutrition 4. Clinical dietetics 5. Nutritional genomics 6. Instruments involved in neutraceutical evaluation
	PGBAS 301 • Plant DNA extraction and separation using agarose Gel. • DNA fingerprint (Genomic DNA isolation kit may be used) of two bacterial strains e.g. Resistant and wild strains of E. coli) • Sterility testing (Microbial load) of drug formulations (According to IP 2013) • CCl4 liver dysfunction in rats and evaluation using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out) • LD 50 evaluation using a suitable model (e.g. *Daphnia* / rice weevil) • Isolation & screening of industrially important microorganisms • Strain improvement by mutation (by UV radiation & Chemical mutagens) • Central streak with Bacillus species isolated from soil • Extraction and quantitation of Fatty substances (Oleic acid etc.) from packed food product (biscuits, nuts etc.)

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES **SEMESTER III-theory** **PGBAS302- MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques - I** **(Lecture allotment includes periods for Seminars and Discussions)**	
302.1	Title: MS basics (15) Subtopics: 1.MS 2. MS/MS, TQ/Ion Trap 3. Components: Inlets, Ion sources, Analyzers, Detectors, Vacuum System, etc Introduction
302.2	Title: Hyphenation (15) Subtopics: 1. LC/MS and LC/MS/MS 2. GC/MS and GC/MS/MS 3. Scan events in TQ and other tandem systems and hybrid systems 4. ICP/MS and its applications in pharmaceuticals and food 5. Recent advances in the field of mass spectrometry
302.3	Title: Thermal analysis (15) Subtopics: 1. Principles of Thermal Analysis 2. Instrumentation Requirements 3. Applications of Thermal Analysis 4. Thermal analysis of Bhasma preparations 5.Thermal Analysis Techniques
302.4	Title: Analytical Methods (15) Subtopics: 1. Method development and applications 2. Sample preparation

	3. Headspace GC and GC-MS

PGBAS 302

- LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.) (Demonstration and Calculation)
- GC/MS separation of plant essential oil (Demonstration)
- Mass Fingerprinting of peptides using a suitable sample.
- Preparation of Ayurvedic formulation and Standardization Research work report submission and presentation: (Project will continue till Semester IV)
  1. Any oil based preparation or ayurvedictaila preparation
  2. Any vatti(Ayurvedic) or Guliga(Siddha)
  3. Awahela (semi-solid,jiggery/sugar syrup based formulation)
  4. Any preparation from unani e.g. Saffoof, Jawarish, Majoon.

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

SEMESTER III-theory
PGBAS303- Standardization of ASU Drugs, Statistics and GMP - I
(Lecture allotment includes periods for Seminars and Discussions)

303.1	Title: Standardization of ASU drugs (15) Subtopics: 1. Need of standardization of Ayurvedic drugs 2. What does standardization involve? 3. Bioanalytical tools for standardization 4. Clinical studies in Standardization 5. Approaches to standardization; 6. Raw materials 7. In-process materials 8. Finished products 9. Developing standardized QC methods 10. Shelf life studies on finished products
303.2	Title: General Statistical Methods (15) Subtopics: 1. Basic concepts of sample statistics 2. Concept of sample size and power 3. Concept of randomisation and sampling techniques 4. Concept of significance and confidence limits 5. Introduction to Various statistical tests - parametric and non parametric

	6. Use of Statistical Packages for Data evaluation 7.Concept of random sampling and sampling techniques 8. Concept of level of significance, power of test and confidence limits 9.Concept of sample size 10.Application of normal distribution
303.3	Title: Concepts of Biostatistics (15) Subtopics: 1. Statistical approach to biological samples 2. Variations in biological samples & their statistical treatment 3. Introduction to Data collection techniques 4. Design of experiments with eg. Block designs, Latin square 5. COV and ANOVA 6. Student's t test and F test 7. Regression analysis with application to Std Graph 8. Non parametric tests with examples 9. Statistical Guidance from regulatory agencies 10. . Student's T test, chi square test, Z test and F test 11.Single sample and two sample Non parametric tests with examples 12.Use of statistical packages for data analysis (SPSS software)
303.4	Title: Good Manufacturing Practice (15) Subtopics: 1. What is GMP? 2. Requirements of GMP implementation 3. Documentation of GMP practices 4. Regulatory certification of GMP 5. GMP in production of ASU drugs 6. Harmonization of SOP of manufacture 7. Audit for GMP compliances

PGBAS 303

- The project should involve industrial training of 8 to 12 weeks period. Report making and presentation.
- Problem based on Biostatistics
- Test for herbal powder/modern drug as per Indian Pharmacopoeia (Astercantha longifolia, Phyllanthus amarus, Dicofenac sodium and paracetamol)

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES SEMESTER III-theory PGBAS304- BA/BE Studies, GCP and Method Validation - I (Lecture allotment includes periods for Seminars and Discussions)	
304.1	Title: Ethical Issues in Clinical Trials (15) Subtopics: 1. Origin of Ethical Issues 2. Dealing with Ethical issues 3. Ensuring compliance to ethical issues 4. Ethical Committees & their set up 5. Regulatory powers of ethical committees 6. Ethical issues in animal studies 7.Compliance to ethical guidelines 8.Dealing with Ethical issues (subject compensation and subject rights) 9. Compliance to current ethical guidelines
304.2	Title: Good Clinical Practice (GCP) (15) Subtopics: 1. What is GCP? 2. Origin of GCP 3. Earlier Guidelines for GCP 4. Requirements of GCP compliance 5. Guidelines for GCP with respect to ICH 6. Guidelines for GCP with respect to ICH
304.3	Title: Bioavailability (BA) & Bioequivalence (BE) studies – 1 (15) Subtopics: 1. What is BA? 2. Parameters to evaluate BA of a drug 3. Factors that influence BA of a drug 4. Evaluating BA of a drug 5. Estimating BA parameters of a drug 6. What is BE? 7. Parameters to evaluate BE of a drug 8. Factors that influence BE of a drug 9. Evaluating BE of a drug 10. Estimating BE parameters of a drug

304.4	Title: Analytical Method Validation (15) Subtopics: 1. Strategies for Method development 2. What and Why of method validation 3. Regulatory requirements of validation 4. IQ, OQ and PQ of analytical instruments 5. Use of Reference standards 6. Issues of Method transfer 7. Intra and inter lab – Validation 8. Sampling 9. Calibration of glassware and instruments, concepts of Good weighing Practice 10. Use of Reference standards and working standards 11. format of Certificate of Analysis

PGBAS 304

- Determination of iron from a given sample / sample solution by
  i) Redox titration
  ii)Colorimetry
  iii)Atomic Absorption Spectroscopy

- Study of matrix effect on IR spectra using solution IR technique and quantitate the solute from a given sample. Identify solute from a given solution using IR library and carry out quantitative assay.

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

SEMESTER IV-theory
PGBAS401- Bioassays, PCR, Automation, Capillary Electrophoresis
(Lecture allotment includes periods for Seminars and Discussions)

401.1	Title: Bio assays in Pharmaceutical evaluation (15) Subtopics: 1. General idea about bio assay systems used in pharmaceutical evaluations 2. In vitro assays and in vivo assays with examples 3. Ethical issues of using animal assay systems 4. Alternatives to animal assays – one or two examples
401.2	Title: Polymerase Chain Reaction (PCR) & DNA Fingerprinting (15) Subtopics: 1. Types of PCR & its applications 2. DNA amplification w.r.t its applications

	3. DNA fingerprinting and applications 4. Use of genomic techniques in diagnostics
401.3	Title: Automation and analysis (15) Subtopics: 1. Automation and its advantages in sample preparation 2. Automation in bioanalysis 3. Advanced automated liquid handling systems 4. Robotic Workstations 5. High throughput Screening
401.4	Title: Capillary Electrophoresis (15) Subtopics: 1. Introduction 2. How capillary electrophoresis works 3. Why capillary electrophoresis works 4. CE hardware Use in bioanalysis
	PGBAS 401 • CE separation of a modern drug from plasma and its formulation (e.g. DFS) • CE separation of peptides (e.g. erythropoietin as per E.P.) • CE separation of N. Acids (all CE experiment for demonstration) • PCR (PCR Kit may be used) for Plant DNA and RFLP (RFLP kit may be used) • DNA sequencing using sample from a suitable organism OR • Identification of Genetically Modified Organism (GMO identification kit may be used) • Blue white screening of mutated organism • Serum levels of drug attained by agar cup method • Zone of inhibition assay for antibiotics (using spiked plasma and formulation)

	• Zone of exhibition assay for Vitamin B12
DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES **SEMESTER IV-theory** **PGBAS402-MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques -II** **(Lecture allotment includes periods for Seminars and Discussions)**	
402.1	Title: Applications of Quantitative Analysis (15) 1.SM quantitation for e.g. 2. Macromolecule quantitation for e.g
402.2	Title: Applications of Qualitative Analysis (15) Subtopics: 1. Technique of generating drug metabolites 2. Metabolite Identification 3. Impurity profiling
402.3	Title: LC/MS/MS (15) Subtopics: 1. Impurity profile in drugs and drug products 2. Proteomics 3. Pesticides, pesticide residues in food
402.4	Title: Tracer techniques in Bioanalytical assays (15) Subtopics: 1. Concept of Radioactivity & Half life 2. $\propto$, β, γ emitters and their biological applications 3. Using tracers in assays 4. Detectors and counters 5. Concept of autoradiography 6. Radio labeled probes and their uses
	PGBAS 402 • The project started in third semester should be finalised which will includes

	Preparation of herbal formulations and standardization of herbal formulation. Students should involve any modern chromatographic techniques, microscopic evaluation, chemical and physical tests for QC of formulation prepared. (Report making and presentation)
DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES **SEMESTER IV-theory** **PGBAS403- Regulatory aspects of ASU, Nanotechnology, Drug Delivery systems,EDM, Regulatory issues** **(Lecture allotment includes periods for Seminars and Discussions)**	
403.1	Title: Regulatory Aspects of ASU drugs (15) Subtopics: 1. National initiatives for regulation of ASU drugs 2. Schedule T and Schedule Y of Drugs and Cosmetics Act 3. International initiatives for regulation of ASU drugs with special reference to - WHO guidelines on traditional medicine - Approaches of US and EU to ASU drug regulation 4. Provisions of Drugs and Cosmetics Act applied to ASU (e.g. Schedule T and Y)
403.2	Title: Introduction to Nanotechnology and Drug Delivery system (15) Subtopics: 1. Background of nanoscience 2. Types of nanostructure and properties of nanomaterials 3. Application of Nanomaterial: biological and environmental, membrane based application and polymer based application 4. Types of drug delivery systems 5. Dendrimers 6. Moleculary imprinted polymers(MIPs) in drug delivery 7. Liposomes: Enzyme activated, photo triggering and thermo sensitive
403.3	Title: Electronic Data Management (15) Subtopics: 1. Electronic Acquisition of data 2. Management of data in Computers 3. Electronic Data Validation and regulatory requirements 4. Electronic signatures & its regulation 5. Generating reports using computers 6. Regulatory requirements of Data evaluation

403.4	Title: Regulatory Issues (15) Subtopics: 1. OTC drugs 2. Cosmetics 3. Food supplements 4. Nutraceuticals w.r.t. FSSI regulations
	PGBAS 403 • IR patterns of an Ayurvedic Bhasma preparation (e.g. calcium containing shanka bhasma – comparison with pure $CaCO_3$ and formulations like Calcium supplement tablets) • AAS of a suitable Ayurvedic metal bhasma preparation (e.g. Tamara bhasma) / Paracetamol • Environment audit report • Problem based on calculation of carbon credit and carbon footprint
	DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES **SEMESTER IV-theory** **PGBAS404- TDM, Pharmacovigilance, CDM,ba/be, Environmental Safety** **(Lecture allotment includes periods for Seminars and Discussions)**
404.1	Title: Therapeutic drug monitoring and Pharmacovigilance (15) Subtopics: 1. Purpose of therapeutic Drug Monitoring 2. Bioanalytical techniques in TDM 3. Analytical and practical issues of TDM 4. Pharmacoeconomics of TDM 5. Significance and need for Pharmacovigilance 6. Indian scenario and the role of regulatory in Pharmacovigilance 7. Pharmacovigilance and safe use of medicines (with case studies)
404.2	Title: Basics of Clinical Data Management (15) Subtopics: 1) What is CDM? 2) Need and significance of CDM

	3) Different terminologies in CDM 4) Clinical study phases and CDM 5) Important documents in CDM 6) Other Aspects of Data Management
404.3	Title: Bioavailability (BA) & Bioequivalence (BE) studies – 2 (15) Subtopics: 1. Design of a BA study 2. Conduct of a BA study 3. Data collection and evaluation 4. Reporting a BA study 5. Regulatory requirements of BA 6. Design of a BE study 7. Conduct of a BE study 8. Regulatory requirements of BA and BE 9. Data record and evaluation 10. Estimating Pharmacokinetic parameters 11. Assessment of Bioequivalence 12. Regulatory requirements and their compliance in pharmacokinetics
404.4	Title: Environmental Safety in Bioanalytical laboratory (15) Subtopics: • Strategies to reduce environmental impact of Bioanalytical laboratory • Standards of Laboratory Safety (Including Biosafety Levels) • Overview of guidelines for laboratories handing Radioactive substances • Introduction to ISO 14001 and OSHAS 18001. • Introduction to Environment Impact Assessment & Reporting • Biodiversity: Red Data Book, Endemic and endangered Medicinal Plant Species, Conservation and sustainable use of medicinal raw materials, Introduction to Wildlife Act of India & CITES • Carbon footprints and Carbon credits.
	PGBAS 404 • BA & BE of a modern drug (Demonstration – witnessing an actual trial) • Calculation of AUC and bioequivalence from the given data (2 expts.) • Total viable count of herbal formulations/raw material

- Screening of pathogens from herbal formulation/raw material (*E.coli*, *S. aureus*, *Candida albicans*)

LIST OF REFERENCE BOOKS

1. Douglas A.Skoog ,Principles of Instrumental Analysis,Saunders College Publihsing
2. Allen J.Bard,Electroanalytical Chemistry,A series of Advances Volume –5,Marcel Dekker, Inc; New York
3. Allen J.Bard ,Electroanalytical Chemistry,A series of Advances Volume – 12,Marcel Dekker, Inc; New York
4. Allen J.Bard, Electroanalytical Chemistry, A series of Advances Volume – 13, Marcel Dekker, Inc; New York
5. I.P.Alimarin,V.I.Fadeeva ,E.N.Dorokhora,Lecture Experiments in Analytical Chemsitry, Mir Publishers, Moscow
6. William David Cooper,Albert D.Helfrick ,Electronic Instrumentation and Measurement Technique ,Prentice Hall of India Pvt.Ltd
7. Hobart H.Williard, Lynne Merritt, John Dean, FrankSettle, Instrumental Methods of Analysis 6th Ed.,CBS Publishers and Distributors
8. Dale G.Deutsch, Analytical Aspects of Drug Testing, John Wiley and Sons
9. Rober D.Brown ,Introduction to Instrumental Analysis ,Mcgraw-Hill International Ed.
10. C.M.Earnest ,Thermal Analysis of Clays Minerals and Coal, Perkin Elmer
11. Randoll C.Baset ,Advances in Analytical Toxicology Vol 2 ,Year Book Medical Publishers
12. Garry D.Christian , Analytical Chemistry 5th ed ,John Wiley and Sons Inc
13. Karel Eckschlager ,Klans Danzer,Information Theory in Analytical Chemistry ,John Wiley and Sons
14. Alice J.Cunningham ,Introduction to Bioanalytical Sensors ,John Wiley and Sons
15. Peter Roper, Shaura ,Burke, Richard Lawn,Vicki Barwick andRon Walker,Applications of Reference Materials in Analytical Chemistry
16. Royal Society of Chemistry
17. Chung Chow Chan ,Y.C.Lee, Analytical Method Validation and Instrumental Performance Verification, Wiley Interscience
18. G.Schwedt ,Chromatographic Methods in Inorganic Analysis,Dr.Alfred Huthg Verlag
19. Tatsuya Sekine, Yuko ,Hasegawa, Dr.V.Mshinde ,Solvent Extraction Chemistry Fundamentals and Applications ,Marcel Dekker Inc
20. Robert White, Chromatography / Fourier Transform Infrared Spectroscopy and its Applications ,Marcel Dekker Inc
21. Roy M.Harrison ,Spyridon Rapsomanikis ,Environmental Analysis Using Chromatography Interfaced with Atomic Spectroscopy ,Ellis Horwood Ltd
22. Dr.P.D.Sethi ,Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography ,CBS Publishers and Distributors
23. D.Cagniant ,Complexation Chromatography ,Marcel Dekker Inc
24. B.Ravindranath ,Principles and Practice of Chromatography , Ellis Horwood Ltd
25. G.Subramanian ,Preparative and Process Scale Liquid Chromatography ,Ellis Horwood

26. Jack Cazes ,Chromatographic Analysis of Pharmaceuticals ,Marcel Dekker Inc
27. Heman J.cortes ,Multidimensional Chromatography Techniques and Applications ,Marcel Dkker Inc
28. Norberto A.Guzman ,Capillary Electrophoresis Technology ,Marcel Dekker Inc
29. K.Robards ,Principles and Practice of Modern Chromatographic Methods ,Academic Press
30. Walter D.Conway ,Countercurrewnt Chromatography ,VCH
31. Alian P.Foucault ,Centrifugal Partition Chromatography ,Marcel Dekker Inc
32. Yoichiro Ito ,Welter D. Conway ,High Speed Countercurrent Chromatography ,John Wiley and Sons
33. Dr.P.D.Sethi ,HPTLC High Performance Thin Layer Chromatography
34. Raymond P.W.Scott ,Chromatographic Detectors Design Function Function and Operation ,Marcel Dekker Inc
35. Larry T.Taylor ,Supercritical Fluid Extraction ,John Wiley and Sons
36. John A.Adam ,Chromatographic Analysis of Pharmaceuticals 2nd ed ,Marcel Dekker Inc
37. W.M.A.Niessen ,Liquid Chromatography Mass Spectrometry 2nd ed ,Marcel Dekker Inc
38. P.D.Sethi ,Dilip Charegaokar ,Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography, CBS Publishers and Distributors
39. Dale R Baker ,Capillary Electrophoresis ,John Wiley and Sons
40. H.E.Schwartz, R.H.Palmieri ,Introduction to Capillary Electrophoresis of Proteins and Peptides ,Beckman
41. Kelvin Altria and Manus Rogan ,Introduction of Quantitative Applications of C.E in Pharmaceutical Analysis ,Beckman
42. Margaret D.Le Compte, Wendy L.Millroy ,Judith Preissle ,The Handbook of Qualitative Research in Eductaion ,Academic Press
43. Bohdan O.Szuprouiez ,Multimedia Networking, McGraw - Hill
44. Margaret D.Le Compte ,Wendy L.Millroy,Judith Preissle ,The Handbook of Qualitative Research in Eductaion ,Academic Press
45. Richard Friary,Jobs in the Drug Industry ,Academic Press
46. Jonathan Anderson ,Millicent Poole ,Assignment and Thesis Writing ,John Wiley and Sons
47. WHO ,Specification for the Identity and Purity of some enzymes and certain other substances ,W.H.O
48. S.F.Bloomfield , R.Baird, R.E.Leak, R.Leech ,Microbial Quality Assurance in Pharmaceuticals,Cosmetics and Toiletries ,Ellis Horwood
49. William Hewitt ,Stephen Vincent ,Theory and Application of Microbiology Assay,Academic Press
50. Michael Pelczar ,E.C.G Chan, Noel R.Krieg ,Microbiology ,McGraw Hill
51. Randall C.Baselt ,Biological Monitoring Methods for Industrial Chemicals Biomedical
52. Ronald M.Atlas ,Lawrence C.Parks ,Handbook of Microbiological Media ,CRC Press
53. Lily Y.Young,Microbial Transformation and Degradation of Toxic ,Dermot Diamond ,John Wiley & Sons

54. Simon Benita ,Microencapsulation Methods and Industrial Applications ,Marcel Dekker
55. R.K.Dart ,Microbiology for the Analytical Chemist ,The Royal Soc
56. John E.Ladbury ,Babur Chowdhry ,Biocalorimetry Applications of Calorimetry in the Biological Sciences, John WileyAnd Sons
57. Dermot Diamond ,Principles of Chemical and Biological Sensors ,John Wiley &Sons
58. Aspi F.Golwalla ,Sharukh A.Golwalla ,ABC of Medicine ,A.F.Golwalla
59. Richard A.Guarino ,New Drug Approval Process ,Marcel Dekker
60. M.D.B.Stephens ,Detection of New Adverse Drug Reactions, Macmillan Publisher
61. Lisbeth Illum ,Stanley S.Davis ,Polymers in Controlled Drug Delivery,Wright IOP
62. John E.Conte ,Steven L.Barriere ,Manual of Antibiotics and Infectious Disease 6th ed ,Lea & Febiger
63. Ivan H.Stockley ,Drug Interactions -A Source Book of Adverse Interactionstheir Mechanisms Clinical Importance & Management, Blackwell ScientificPublications
64. John B. Taylor ,Peter D. Kennewell ,Modern Medicinal Chemistry, Ellis Horwood
65. Jens T. Carstensen ,Drug Stability Principles & Practices 2nd e.d.,Marcel Dekker
66. Gene S.Gilbert ,Drug Safety Assessment in Clinical Trials ,Marcel Dekker
67. F.D.King ,Medicinal Chemistry Principles and Practice,The Royal Soc.Of Chem
68. Alex Gringauz ,Introduction to Medicinal Chemistry ,Wiley VCH
69. Camille George Wermuth ,The Practice of Medicinal Chemistry 2nd ed.,Academic Press
70. James W.Robinson ,Practical Handbook of Spectroscopy,Crc Press
71. R.W.Hannah ,J.S.Swinehart ,Experiments in Techniques of Infrared Spectroscopy ,Perkin Elmer
72. Patrick Hendra ,Catherine Jones ,Gavin Warnes ,Fourier Transform Raman Spectroscopy Instrumentationand Chemical Applications, Ellis Horwood
73. G.L.Moore ,Introduction to Inductively Coupled Plasma Atomic Emission Spectrometry,Elsevier
74. Gordon M.Barrow ,Introduction to Molecular Spectroscopy ,McGraw Hill
75. Stephen G.Schulman ,Molecular Luminescence Spectroscopy Methods andApplications Part I ,John Wiley and Sons
76. George G.Guilbault ,Practical Fluorescence ,Marcel Dekker
77. B.J.Clark, T.Frost ,M.A.Russell ,UV Spectroscopy Techniques Instrumentation Data Handling.Chapman and Hall
78. W.O.George, H.A.Willis ,Computer Methods in UV Visible and IR Spectroscopy ,Royal Society of Chemistry
79. Richard D Beaty ,Concepts, Instrumentation and Techniques in AtomicAbsorption Spectrophotometry.,Pekin-Elmer
80. A-Knowles , C.Burgess ,Practical Absorption Spectrometry,Chapman & Hall
81. Takekiyo Matsoo ,Richard M.Capridi ,Michael L.Gross ,Yousuke Seyama ,Biological Mass Spectrometry Present and Future ,John Wiley and Sons

82. Barbara Stuart ,Modern Infrared Spectroscopy - ACOL ,John Wiley and Sons
83. George Turrell ,Jacques Corset ,Raman Microscopy Developments and Applications ,Academic Press
84. Irving Sunshine ,Handbook of Spectrophotometric Data of Drugs ,CRC Press
85. Codric M.Smith, Alan M.Reynard ,Textbook of Pharmacology ,W.B.Saunders Comp.
86. Umesh V.Banakar ,Pharmaceutical Dissolution Testing ,Marcel Dekker
87. Howard C.Ansel ,Introduction to Pharmaceutical Dosage Forms 4th ed., Lea & Febiger
88. H.J.Roth, A.Kleemann ,Pharmaceutical Chemistry Vol 1 ,Ellis Horwood
89. P.Johnson ,J.G.Lloyd-Jones ,Drug Delivery Systems Fundamentals and Techniques ,Ellis Horwood
90. M.H.Rubinstein ,Pharmaceutical Technology Controlled Drug Release Vol 1 ,Ellis Horwood
91. Michael G.Palfregman ,Peter McCann ,Walter Lovenberg ,Joseph G.Temple ,Albert Sjoerdsrna Enzymes as Targets for Drug Design, Academic Press
92. Milo Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics 4th ed., Lea and Febiger
93. David B.Jack, Handbook of Clinical Pharmacokinetic Data, Macmillan Publisher
94. Betram G.Katzung, Basic and Clinical Pharamcology 4th ed., Prentice-Hall
95. Kenneth A.Connors, Gordon L.Amidon, Valentino J.Stella, Chemical Stability of Pharmaceuticals, John Wiley & Sons
96. Hamed M.Abdon, Dissolution Bioavailbaility and Bioequivalence, MACK Publishers
97. Varro E.Tyler, Lynn R.Brody, James E.Robbers, Pharmacognosy 9th ed., Lea and Febiger
98. James I.Wells, Pharmaceutical Preformulation the Physicochemical Properties of Drug Substances, Ellis Horwood
99. B.Widdop, Therapeutic Drug Monitoring, Churchill & Livingstone
100. Peter G.Welling, Pharmacokinetics, Marcel Dekker
101. D.R.Karsa, R.A.Stephenson, Excipients & Delivery Systems for Pharmaceutical Formulations, The Royal Society of Chemistry
102. R.S.Iyer, Schedule M and Beyond Good Manufacturing Practices, Indian Drug Manufacturers Association
103. Takeru Higuchi, Einar Brochmann, Hanffen Hanssen, Pharmaceutical Analysis, CBS Publishers & Distributors
104. H.Jackson Knight, Patent Strategy for Researchers and Research Managers 2nd ed, John Wiley and Sons
105. David Lee, Pharmaceutical analysis, CRC Press
106. A.F.Rudole Hoernle, Vaidya Bhagwan Dash, Studies in the Medicine of Ancient India, Concept Publisher Co.
107. J.F.Royle, Antiquity of Hindoo Medicine, Wm.H.Allen and Co
108. Prof.(Mrs) Asima Chatterjee, Dr.Satyesh Chandra Prakash, The Treatise on Indian Medicinal Plants Vol 1, Publications & Information Direct
109. Richard P.Steiner, Folk Medicine - The Art and the Science, American Chemical soc

110. Roberto Chiej, The Macdeonald Encyclopedia of Medicinal Plants, Macdonald and co
111. P.A.G.M.De Smet, K.Keller, R.Hansel, Chandler, Adverse Effects of Herbal Drugs-1, Springer Verlag
112. W.Tang, G.Eisenbrand, Chinese Drugs of Plant Origin, Springer Verlag
113. Alan Harvey, Drugs From Naturall Products Pharmaceuticals and Agrochemicals, Ellis Horwood
114. Dr.R.O.B.Wijesekera, The Medicinal Plant Industry
115. V.V.Sivarajan, Indira Balachandran, Ayurvedic Drugs and Their Plant Sources, Oxford and IBH
116. Dr.V.B.Athavale, Bala-Veda Pediatrics and Ayurveda
117. Dr.V.B.Athavale, Bastivijnyana Urology in Ayurveda,
118. L.D.Kapoor, Handbook of Ayurvedic Medicinal Plants, CRP Press
119. Chandra Chakraberty, An Interpretation of Ancient Hindu Medicine, Neeraj Publishing House
120. S.K.Ramcachandra Rao, Encyclopedia of Indian Medicine Vol 1, Popular Prakashan
121. H.Wagner, S.Bladt , Zgainski, Plant Drug Analysis A Thin Layer Chromatography Atlas, Springer Veriag
122. Govind Kelkar, Directory of Herbal Health Care Products, Chemexcil
123. S.T.Han, Research Guidelines For Evaluating the Safety Andefficacy of Herbal Medicines, World Health Org.
124. Govt. Of India Ministry of Health & Family Welfare National Formlary of Unani Medicine - Part I 1ed., J.M. Jaina and Bros
125. Govt.Of India Ministry of Health & Family Welfare The Ayurvedic Formulary of India Part I 1 ed., J.M.Jaina and Bros
126. Govt. Of India Ministry of Health & Family Welfare The Ayurvedic Pharmacopoeia of India Part I Vol I, J.M.Jain and Bros
127. Prof.Dr.F.C.Czygan, D.Frohne, C.Hohxel, A.Nagell, H.J., Pfainder, G.Willuhn , W.Buff, Herbal Drugs and Phytopharmaceuticals, CRC Press
128. A.Vinaya Kumar, Principles of Ayurvedic Therapeutics, Sri Satguru Publisher
129. Dr.C.R.Karnick, Pharmacopoeial Standards of Herbal Plants Vol I, Sri Satguru Publisher
130. Dr.C.R.Karnick, Pharmacopoeial Standards Of Herbal Plants Vol II, Sri Satguru Publisher
131. Dr.V.Rajpal, Standardization of Botanicals Vol I, Eastern Publishers
132. Regional Research Lab & IDMA, Indian Herbal Pharmacoepoeia Vol II, Regional Research Lab
133. World Trade Centre, Export Potential of Herbal and Ayurvedic Drugs, Quest Publications
134. P.C. Sharma, M.B. Yelne, T.J. Dennis, Database on Medicinal Plants use in Ayurveda Vol. 1 - Vol. 5, Central Council for, Research in Ayurved and Siddha
135. Edward Johnson, Robert Stevenson, Basic Liquid Chromatography, Varian Associate
136. W.M.A.Niessen, J.Van der Greef, Liquid Chromatography Mass Spectrometry, Marcel Dekker

137. Thomas M. Vickrey, Liquid Chromatography Detectors,
138. L.R.Snyder, J.J.Kirkland, Introduction to Modern Liquid Chromatography 2nd ed., John Wiley & Sons
139. W.R.Day, An Introduction to Liquid Chromatography (L.C), Water Associates
140. Willaim V.Willis, Laboratory Experiments in Liquid Chromatography, CRC Press
141. A.Zlatkis, R.E.Kaiser, HPTLC High Performance Thin Layer Chromatography, Elsevier Scientific
142. Nelu Grinberg, Modern Thin-Layer Chromatography, Marcel Dekker
143. W.Bertsch, S.S.Hama, R.E.Kaiser, A.Zlatkis, Instrumentelle HPTLC, Dr.Alfred Huthig
144. A.M.Krstulovic, Chiral Separations by HPLC,
145. Lioyd R.Snyder, Joseph L.Glajch, Joseph J.Krikland, Practical HPLC Method Development
146. Ante M.Krstulovic, Reversed-Phase High Performance Liquid Chromatography - Theory Practice and Biomedical Applications, John Wiley & Sons
147. William S.Hancock, High Performance Liquid Chromatography in Biotechnology, Joh Wiley and Sons
148. Dennis J. Runser, Maintaining and Troubleshooting HPLC Systems, John Wiley and Sons
149. I.N.Papadoyannis, HPLC in Clinical Chemistry, Marcel Dekker Inc
150. Roger M.Smith, Gas and Liquid Chromatography in Analytical Chemistry, John Wiley and Sons
151. J.B.Pattison, A Programmed Introduction to Gas Liquid Chromatography, Heyden & Sons
152. D.J.David, Gas Chromatographic Detectors, John Wiley & Sons
153. H.M.McNair, Basic Gas Chromatography,
154. John W.Dolan, Lloyd R.Snyder, Troubleshooting LC Systems, Human Press
155. Fulton G.Kitson, Barbara S.Larsen, Gas Chromatography and Mass Spectrometry A Practical Guide, Academic Press
156. George Lunn, HPLC Methods for Pharmaceutical Analysis Vol 2 (A-D), John Wiley and Sons
157. George Lunn, HPLC Methods for Pharmaceutical Analysis Vol 3 (E-O), John Wiley & Sons
158. George Lunn, HPLC Methods for Pharmaceutical Analysis Vol 4 (P-Z)
159. Eric Reid, Ian D.Wilson, Analysis for Drugs and Metabolites, Royal Society of Chemistry
160. Malcolm R.Smyth, Chemical Analysis in Complex Matrices, Ellis Horwood Ltd
161. J.P.Hart, Electroanalysis of Biologically Important Compounds, Ellis Horwood
162. Quanyun A.Xu, Lawrence A.Trissel, Stability - Indicating HPLC Methods for Drug Analysis, Pharmaceutical Press
163. A.Fajgelj, A.Ambrus, Principles and Practices of Method Validation, Royal Society of Chemistry
164. ED Metcalfe, Atomic Absorption and Emission Spectroscopy, John Wiley & Sons
165. Rey Davis, Martin Frearson, Mass Spectrometry, John Wiley & Sons
166. Brian W. Woodget, Derek Cooper, Samples and Standards, John Wiley & Sons
167. Richard Anderson, Sample Pretreatment and Separation, John Wiley & Sons

168. James W.Dodd, Kenneth H.Tonge, Thermal Methods, John Wiley & Sons
169. James F.Lawrence, Trace Analysis Vol 1, Academic Press
170. Ronald C.Denney, Ray Sinclair, Visible and Ultraviolet Spectroscopy, John Wiley & Sons
171. Clive Whiston, X-ray Methods, John Wiley & Sons
172. David Hawcroft, Diagnostic Enymology, John Wiley & Sons
173. Judith W.Zyskind, Sanford Bernstein, Recombinant DNA Laboratory Manual, Academic Press, INC
174. Mark D.Adams, Automated DNA Sequencing and Analysis, Academic Press, INC
175. A.T.Rhys Williams, luoroimmunoassay, Perkin-Elmer
176. Edouard Kurstak, Enyme Immunodiagnosis, Academic Press Inc
177. David T.Plummer, An Introduction to Practical Biochemistry 2nd ed., Tata McGraw-Hill
178. H.Robert Horton, Laurence Moran, Raymond S.Ochs, J.David Rawn, K.Gray Scrimgeour, Principles of Biochemistry, Neil Patterson
179. Martin Vanderlaan, Larry H.Stanker, Bruce Watkins, Dean, Roberts, Immunoassays for Trace Chemical Analysis, American Chemical Society
180. Rodney E.Longman, The Immune System, Academic Press Inc
181. Quentin Myrvik, Russell S.Welser, Fundamentals of Immunology 2nd ed, Lea & Febiger
182. Julia M.Polak, Susan Van Noorden, Immunocy to Chemistry 2nd ed, Wright Bristol
183. Terry M.Phillips, Analytical Techniques in Immunochemistry, Marcel Dekker Inc
184. Radiommunoassay Ria in Theory and Practice, Pakard
185. S.Lam, G.Malikin, Analytical Applications of Immobilized Enzyme Reactors, Blackie Academic and Professional
186. Richard F.Venn, Principles and Practice of Bioanalysis, CBS Publishers
187. Bruce H.Mahan, College Chemistry, Addison Wesley P.Co
188. Voltrath Hopp, Ingo Hennig, Handbook of Applied Chemistry, McGraw-Hill Book Co.
189. V.Semishin, Laboratory Exercises in General Chemistry, Peace Publishers
190. K.M.Gokhale, R.G.Limaye, D.A.Bhagwat, Y.R.Wani, A Textbook of Industrial Chemistry, Pragati Agencies
191. K.D. Tripathi. Essentials of Medical Pharmacology 7th Edition, Jaypee Brothers Medical Publishers (P) Ltd., New Delhi India.
192. Gabor L. Hornyak, H.F. Tibbals, Joydeep Dutta, John J. Moore, Introduction to Nanosciences & Nanotechnology,Published December 22, 2008
193. Herausgeber: **Bhushan**, Bharat (Ed.). Springer Handbook of Nanotechnology
194. **Heldman**, Dennis R. Food Science Text Series
195. Shubhangini A joshi, Nutrition and dietetics
196. Susanne Prokscha, Practical Guide to Clinical Data Management, Third Edition
197. Mark. Elsley, A Guide to GCP for Clinical Data Management