

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 I

Course: M.Sc. Bioanalytical Sciences

**(Choice Based Credit, Grading and Semester System with effect
from the academic year 2021-2022)**

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/ Coordinator 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 the 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:

The 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 subcontinent 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 the 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 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 be addressed very diligently and the proposed programme is a step in this direction. Bioanalytical evaluations are interdisciplinary programmes and require highly skilled personnel with a 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:

The 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. Students will have a firm foundation in the fundamentals and application of current advanced analytical techniques and its scientific theory.
- Students from Bioanalytical Sciences background will exhibit professional ethics, attitudes and behaviors which they will learn during 8-12 weeks internship with an industry. Students 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 systems, regulatory bodies in pharmacy, pharmacognosy, clinical trials, pharmacokinetics, pharmacodynamics, applied molecular biology and microbiology.

Personal Skills

- **Problem-solving and decision-making:** Students 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 as 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 I Semester – I**

Paper	Code	Lectures	Credits	Code	Practical	Credits
Extraction techniques and different medicine systems-I	Core-I PGBAS101	60	4	PGBASP101	60	2
Drug and Cosmetics Act,1940 and Quality Management	Core-II PGBAS102	60	4	PGBASP102	60	2
Chromatography and Spectroscopy-I	Core-III PGBAS103	60	4	PGBASP103	60	2
Molecular Biology and OMICS & Environmental Issues	DEC-I PGBASA-104	60	4	PGBASPA-104	60	2
Cosmeceuticals-I	DEC-II PGBASB-104	60	4	PGBASPB-104	60	2
Bioinformatics and its applications	SEC PGBAS105	60	4	-	-	-
TOTAL		300	20		240	8
TOTAL CREDITS			28			

M.Sc. part I Semester – II

Paper	Code	Lectures	Credits	Code	Practical	Credits
Extraction techniques and different medicine systems- II	Core-I PGBAS201	60	4	PGBASP201	60	2
Research methodology	Core-II PGBAS202	60	4	PGBASP202	60	2
Chromatography and Spectroscopy-II	Core-III PGBAS203	60	4	PGBASP203	60	2
Immunoassays and clinical pharmacology	DEC-I PGBASA-204	60	4	PGBASPA204	60	2
Cosmeceuticals-II	DEC-II PGBASB-204	60	4	PGBASPB-204	60	2
General Statistics and Biostatistics	SEC PGBAS205	60	4			
TOTAL		300	20		240	8
TOTAL CREDITS			28			

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES PART-I

SEMESTER I

Core I (6 credits) (4 credits for theory +2 credits for practical)

Paper code :PGBAS101

Name of the paper: Different Medicine System Of India And Drug Extraction Techniques

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Choose an extraction technique for the analysis.
2. Describe the principles and practices of ASU.
3. Identify the disease(s) and then compare and decide its management with respect to ASU and Modern drugs.
4. Summarize the concept of Pharmacognosy.
5. Assess the Herbal raw material and its evaluation.

Module No.	Topics
101.1	<p><u>Title:</u> Principle of extraction and Isolation of analytes (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none">1. Physico-chemical properties of drugs and solvents2. Concept of partition & Partition Coefficient3. Selection of solvent4. Extraction efficiency5. Introduction to classical methods of extraction6. Introduction to modern methods of extraction- advantages & disadvantages7. Ionization and its effect on the extraction of drugs8. Matrix components & isolation, purification and quantification of analytes.
101.2	<p><u>Title:</u> Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani</p> <p>(15) <u>Subtopics:</u></p> <ol style="list-style-type: none">1. Introduction of AYUSH2. Principles and practice of ASU3. Types of Drug Formulation4. Methods of Manufacture – Raw Material To Finish Product5. Types of Drug6. Excipients in various dosage form

<p>101.3</p>	<p><u>Title: Modern Medicine (15)</u></p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Principles and practice 2. API and concept of its formulation into a dosage form 3. Different types of Drug Formulations 4. Excipients in various dosage forms 5. Disease Management (Comparison of ASU and Modern Drugs) <ol style="list-style-type: none"> a. Diabetes b. Obesity c. Hypertension d. Hepatitis e. Malaria f. Dengue g. Influenza
<p>101.4</p>	<p><u>Title: Pharmacognosy (15)</u></p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Introduction, Plants and their medicinal uses 2. Concepts of ethnobotany, ethno medicines, and pharmacology 3. Phytogeographical regions to be explained for endemism and hot spots (explain only concepts) 4. Herbaria evaluation includes 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)
<p>Core I (6 credits) (4 credits for theory +2 credits for practical) Paper code :PGBAS101 practical Name of the paper: Different Medicine System Of India And Drug Extraction Techniques Total no of lectures : 4 lectures equivalent to 1 practical</p>	

- Liquid-liquid extraction of a modern drug from plasma and formulations (e.g. Diclofenac sodium, Glimepiride, Aceclofenac, Metformin, etc.)
- Microscopic evaluation of sections and powders with adulteration and formulation comparison of the following medicinal plants;
 1. *Emblica officinalis* – (Amla - dried fruit)
 2. *Vitex negundo* - 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 students 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

SEMESTER I

Core II (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS102

Name of the paper: Drug Act and Quality Management

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Formulate the documentation required for laboratory work and also prepare SOPs for analytical laboratories.
2. Associate WHO guidelines with pharmacopeial standards.
3. Explain and compare the different pharmacopeias.
4. Summarize the personnel requirements in QA and QC.
5. Understand the guidelines on stability evaluation and estimate the product's stability.

102.1

Title: Good Laboratory Practice (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

<p>102.2</p>	<p><u>Title:</u> Drug Act and Pharmacopeial standards (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Indian Drugs and Cosmetics Act w.r.t Schedule Y, M, H. Include Schedule A,S (introduction) 2. Introduction to CFR 21 part 11 3. Introduction to WHO guidelines 4. Introduction to foreign guidelines w.r.t US, EU, Australia & Japan 5. Introduction to Pharmacopoeias IP, BP, USP 6. Specified test in Monographs w.r.t liquid formulation (injectible) and solid dosage form (USP, EP, BP, IP) 7. Include AP, Indian HP and AFI (wherever applicable)
<p>102.3</p>	<p><u>Title:</u> Stability Studies (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 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
<p>102.4</p>	<p><u>Title:</u> Quality Control (QC) and Quality Assurance (QA) (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. <u>Introduction</u> 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 <ol style="list-style-type: none"> a. Preliminary requirements of a discriminatory quantitation b. Detection of the analytes of interest c. Separation of analytes form the matrix components d. Sample preparation for quantitation e. Support work & documentation f. Validation g. Audit requirements ,audits and audit reports h. Personnel Responsibility in QA
<p>Core II (6 credits) (4 credits for theory +2 credits for practical) paper code :PGBAS102 Practical Name of the paper: Drug Act And Quality Management Total no of lectures : 4 lectures equivalent one practical</p>	

- Carry out dissolution and disintegration,
- hardness and friability on any one tablet preparation
- Accelerated stability studies of various formulations or drugs with respect to (a) Temperature (b) Effect of buffers / pH dependent
- 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 25oC, 60% RH and 40oC, 75% RH and at different Pressure

SEMESTER I

Core III (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS103

Name of the paper: Chromatography and spectroscopy I

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Explain the different chromatographic and spectroscopic techniques.
2. Illustrate the different analytical instruments.
3. Compare the different chromatographic techniques and choose the appropriate chromatographic separation technique.
4. Measure the quantity of analyte(s) in sample using chromatographic and spectroscopic techniques.
5. Select the appropriate spectroscopy techniques for sample analysis.

103.1 Title: Theory of Chromatographic separation, TLC &its

1

application(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

<p>103.2</p>	<p><u>Title:</u> HPLC – 1 (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Introduction and principle 2. Instrumentation <ol style="list-style-type: none"> a. Reservoir b. Pump c. Injection system d. Column and column chemistry e. detectors 3. Gradient and Isocratic system 4. Normal and Reverse phase HPLC 5. The chromatogram
<p>103.3</p>	<p><u>Title:</u> GC – I (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Introduction and Principle 2. Instrumentation <ol style="list-style-type: none"> a. Gases used in GC b. Injection system c. Types of columns and its application d. Oven (column –oven temperature programming) e. Detectors in GC 3. Introduction to flow and pressure controllers 4. GC sample injection techniques 5. Recent advanced in GC
<p>103.4</p>	<p><u>Title:</u> Spectroscopy – I (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Introduction to atomic and molecular Spectroscopy 2. UV ,Visible and fluorescence Principles & Instrumentation, Applications 3. Nephelometry -Principles & Instrumentation ,Applications 4. Turbidimetry- Principles & Instrumentation , Applications 5. IR -Principles & Instrumentation , Applications 6. Basic concepts of NMR spectroscopy

Core III (6 credits) (4 credits for theory and 2 credits for practical)

paper code :PGBAS103 Practical

Name of the paper: Chromatography and Spectroscopy I

Total no of lectures : 4 lectures equivalent to 1 practical

- Gas Chromatographic separation of solvent mixtures (e.g., Menthol & Ethanol, Toluene & Methanol etc.)
- HPLC separation of herbal raw phytoconstituent of a raw material from its formulation (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Phyllanthus amarus* from LIV 52, *Tribulus terrestris* from Gokshuradi guggulu etc.)
- HPLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimepiride, Aceclofenac, Metformin etc.)
- HPLC separation of modern drugs from their combination formulation (e.g., Diclofenac Sodium & Paracetamol, Metformin Glimepiride etc.)
- Determination of Caffeine from a given sample by
 - i)UV-VIS Spectrophotometer
 - ii)HPLC
- IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)

SEMESTER I

DSC (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS104 A

Name of the paper: Biomolecules and OMICS

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Describe the concept of OMICS and its various branches.
2. Calculate the molecular weight of the biomolecules by electrophoretic techniques.
3. Compare the classical and modern techniques of electrophoresis.
4. Classify different types of electrophoretic techniques.
5. Memorize the guidelines for regulation of the Pollution Control Board for laboratories.
6. Identify the different types of wastes and determine the disposal of Bioanalytical laboratory generated wastes.

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

104.2	<p><u>Title:</u> Electrophoresis (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 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 /pulse field 6. Standardization of electrophoretic technique 7. Detection techniques 8. Applications of electrophoresis
104.3	<p><u>Title:</u> Capillary Electrophoresis (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Introduction 2. Principle 3. CE hardware 4. types of CE 5. Applications
104.4	<p><u>Title:</u> Environmental Issues of Bioanalytical Laboratory Waste</p> <p>(15) <u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Management, control and Regulatory issues 2. Introduction to types and sources of Laboratory waste 3. Chemical & Biological materials: Hazards and Handling 4. Hazard Controls & Information (Workplace Hazardous Materials 5. Information System {WHMIS} as example) 6. Introduction to : Management, control and Regulatory issues

	<ol style="list-style-type: none"> 7. Chemical Storage and Segregation 8. Chemical Laboratory Emergency Response <ul style="list-style-type: none"> • Equipment Safety • Laboratory Inspections • Transportation and Receiving of Hazardous Materials 9. Regulations of the Pollution Control Board for Laboratories.
--	--

<p>DSC (6 credits) (4 credits for theory +2 credits for practical) paper code :PGBAS104 A Practical Name of the paper: Biomolecules and OMICS</p>
--

Total no of lectures : 4 lectures equivalent to 1 Practical

- Separation of human serum / plasma proteins / egg white using PAGE((Protein molecular weight determination kit may be used)
- Separation of proteins using 2D gel electrophoresis
- 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)

SEMESTER I

DSC (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS104 B

Name of the paper: Cosmetics and Cosmeceuticals

Total no of lectures: 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Discuss the basic concept of cosmetics in the Indian market.
2. Classify the different types of cosmetics.
3. Formulate the different cosmetic products.
4. Recall the basic Human anatomy relevant to cosmetic application.

104.1

Title: Introduction to cosmetics (15)

Subtopics:

1. Basic concept and background of cosmetics
2. Plant based natural cosmetics
3. classification of cosmetics product
4. Indian market and cosmetics

104.2

Title: Basic Anatomy (15)

Subtopics:

1. Anatomy of skin
2. Anatomy of hair
3. Anatomy of lips
4. Anatomy of teeth
5. Anatomy of nails

104.3	<p><u>Title</u> : Raw material used in cosmetics (15)</p> <p><u>Subtopics</u>:</p> <ol style="list-style-type: none"> 1. Moisturizers 2. Antioxidant 3. Colorant 4. Conditioners 5. Cleansers 6. Diluents 7. Perfumes
104.4	<p><u>Title</u>: Formulations in cosmetics (15)</p> <p><u>Subtopics</u>:</p> <ol style="list-style-type: none"> 1. Herbal and non herbal formulations 2. Solutions 3. lotion 4. suspension 5. ointment 6. cream and emulations
<p>DSCII (6 credits) (4 credits for theory +2 credits for practical) paper code :PGBAS104 B Name of the paper: Cosmetics and Cosmeceuticals Total no of lectures:4 lectures equivalent to 1 Practical</p>	
<ul style="list-style-type: none"> • Preparation of emulsions (shampoo) • Preparation of Lotion • Preparation of ointment/cream 	
SEMESTER I	
<p>SBC (4 credits) paper code :PGBAS105 Name of the Course: Bioinformatics Total no of lectures : 30 lectures (lecture allotment includes periods for seminar and discussion)</p>	

<p>Course specific outcomes: The learner will be able:</p> <ol style="list-style-type: none"> 1. Outline the concept of Bioinformatics. 2. Enlist the databases and search tools. 3. Summarize the applications of Bioinformatics. 4. Describe chemi-informatics.

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

SEMESTER II

Core I (6 credits) (4 credits for theory +2 Credits for practical)

paper code :PGBAS201

Name of the paper: Extraction Techniques

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Explain the principle and working of SPE and SCFE.
2. Operate the SPE instrument.
3. Distinguish between primary and secondary metabolites in plants.
4. Recognize the factors affecting the synthesis of secondary metabolites in plants.
5. Give examples of different thermal analytical techniques.

201.1

Title: Solid Phase Extraction (SPE) (15)

Subtopics:

1. Introduction
2. General properties of bonded silica sorbents
3. Sorbent/analytes 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

201.2

Title: SuperCritical Fluid Extraction & SuperCritical 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
201.3	<p><u>Title: Phytochemistry (15)</u></p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1) Natural drug substances from plants (primary and secondary metabolites) 2) Broad classification of secondary metabolites <ol style="list-style-type: none"> a. Nitrogenous b. Non nitrogenous c. Isoprenoids

	<ol style="list-style-type: none"> 3) Secondary drug metabolite production with special reference with integrated pathway. (shikimic pathways, mevalonate pathways) 4) Key Factors affecting synthesis of secondary metabolites 5) Choice of solvent for extraction of phytoconstituents
201.4	<p><u>Title: Thermal analysis (15)</u></p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Principles of Thermal Analysis 2. Instrumentation Requirements 3. Applications of Thermal Analysis 4. Thermal analysis of Bhasma preparations 5. Thermal Analysis Techniques

<u>Semester II</u>	
Core II (6 credits) (4 credits for theory +2 Credits for practical)	
paper code :PGBAS201 Practical	
Name of the paper: Extraction Techniques	
Total no of lectures : 4 lectures equivalent to 1 Practical	
<ul style="list-style-type: none"> • 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 any medicinal plants • Effect of drying on phytoconstituents. • Evaluation of geographical / Regional variation in terms of phytochemical by TLC using 	
<u>Semester II</u>	
Core II (6 credits) (4 credits for theory +2 Credits for practical)	
paper code :PGBAS202	
Name of the paper: Research Methodology	
Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)	

Course specific outcomes:

The learner will be able to:

1. Understand various study designs and hypotheses pertaining to research topics.
2. Enlist different methods of data collection.
3. Describe various methods of sampling.
4. Compare the role of different variables in research.
5. Understand steps involved in processing data.
6. Design research review article.

202.1

Title: Fundamentals of Research Methodology (15)

Subtopics:

1. Introduction to Research Methodology

- Meaning and objectives of research
- Terminology
- Features of a good research study
- Ethics in research

2. Study designs:

basic, applied, historical, exploratory, experimental, ex-post-facto, case study, diagnostic research, crossover design, case control design, cohort study design, multifactorial design

202.2

Title: Testing of Hypothesis (15)

Subtopics:

1. Meaning, significance and characteristics of hypothesis
2. Basic concepts concerning testing of hypotheses
3. Hypothesis development
4. Steps in formulation of hypothesis
5. Statistical hypothesis testing – type 1, type 2 error, levels of significance

202.3	<p><u>Title:</u> Data Collection (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Experimental data collection <ul style="list-style-type: none"> • Types of data • Methods of primary data collection (observation, experimentation, questionnaire, schedules, interviewing, case, pilot study) • Methods of secondary data collection (internal, external) • Selection of appropriate method for data collection 2. Sampling <ul style="list-style-type: none"> • Terminology • Need for sampling • Types of Sampling (probability sampling and non-probability sampling) 3. Variable <ul style="list-style-type: none"> • Dependent • Independent • Intervening • Moderator • Control variables • Extraneous variables
202.4	<p><u>Title:</u> Data Analysis and Reporting (15)</p> <p><u>Subtopics:</u></p>

	<ol style="list-style-type: none"> 1. Data processing and processing operations <ul style="list-style-type: none"> • Problems in processing • Elements of analysis in data processing • Software for data processing e.g. SPSS & SAS 2. Scientific writing and publishing <ul style="list-style-type: none"> • Report Writing • Writing a Research Paper • Writing a Review Article
<p>Core II (6 credits) (4 credits for theory +2 Credits for practical) paper code :PGBAS202 Practical Name of the paper: Research Methodology Total no of lectures : 4 lectures equivalent to 1 Practical</p>	
<ul style="list-style-type: none"> • Students must submit a Report of the Industrial Visits including Presentation of the industrial visit. • Research Paper Review 	

SEMESTER II

Core III (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS203

Name of the paper: Chromatography and spectroscopy II

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Operate the analytical instruments: HPLC, GC, AAS, FT-IR, UV-VIS Spectrophotometer.
2. Observe and correlate TLC and HPTLC.
3. Describe and give examples of different modes of HPLC.
4. Summarize the applications of chromatography and spectroscopy.
5. Estimate and solve the complications arising during instrumental analysis.

203.1

Title: HPTLC (15)

Subtopics:

1. Principles and Instrumentation
2. HPTLC vs TLC
3. Densitometric quantitation 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. Types of HPLC
 - a. Ion –pair HPLC

- b. Ion –Exchange HPLC
 - c. Affinity chromatography
 - d. Gel permeable Chromatography
 - e. Chiral HPLC
2. Manual and Electronic data Processing
 - a. Method preparation
 - b. Sequence preparation
 - c. Chromatogram Integration
 3. Troubleshooting in HPLC
 4. Calibration of HPLC
 5. Applications of HPLC with Example
 - a. Purity assay
 - b. Impurity Profiling
 - c. Qualitative and Quantitative analysis

203.3	<p><u>Title:</u> GC – II (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. HeadSpace in GC 2. Derivatization in GC 3. Troubleshooting in GC 4. Calibration In GC 5. Application of GC with example <ol style="list-style-type: none"> a. Assay b. Lipid profiling c. Sample involving biological matrix d. Other analysis
203.4	<p><u>Title:</u> Spectroscopy – II (15)</p> <p><u>Subtopics:</u></p> <ol style="list-style-type: none"> 1. Theory and applications of ; <ol style="list-style-type: none"> i. Circular Dichroism (CD) ii. Optical Rotatory Dispersion (ORD) 2. Emission spectroscopy 3. Principles, instrumentation and applications of <ol style="list-style-type: none"> i. Flame photometry ii. Atomic Emission Spectroscopy 4. AAS <ol style="list-style-type: none"> i. Principles & Instrumentation ii. Applications 5. ICP <ol style="list-style-type: none"> i. Principles & Instrumentation ii. Applications 6. X – ray diffraction <ol style="list-style-type: none"> i. Principles & Instrumentation ii. Applications

SEMESTER II

Core III (6 credits) (4 credits for theory +2 Credits for practical)

paper code :PGBAS203 Practical

Name of the paper: Chromatography and Spectroscopy II

Total no of lectures : 4 lectures equivalent to 1 Practical

- HPTLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimepiride, Aceclofenac, Metformin etc.)
- HPTLC fingerprinting of Herbal raw material (e.g. *Asteracantha longifolia*, *Ricinus cummunis*, *Calotropis gigantea*)
- HPTLC detection of herbal raw material from its formulations (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Vitex negundo* from PANCHGUN TAILA, *Glycyrrhiza glabra* from ANU TAILA)
- Preparation of calibration graphs for Li, Na, and K by flame Photometry using their solutions of appropriate concentrations and studying interference of
 - K in Na estimation
 - OR**
 - Na in Li estimation
 - OR**
 - Li in K estimation
- Determination of iron from a given sample / sample solution by
 - Redox titration
 - ii)Colorimetric
 - iii)Atomic Absorption Spectroscopy

SEMESTER II

DSC (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS204 A

Name of the paper: Immunoassays and Clinical Pharmacology

Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

The learner will be able to:

1. Explain the principle and applications of Immunoassays.
2. Classify the different steps involved in proteomics
3. Illustrate and describe the various stages of Drug discovery and development.
4. Discuss pre-clinical trials in NCE.
5. Interpret ISO 14001, OHSAS 18002 and Red Book data.
6. Calculate carbon credits and carbon footprint.

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	<p><u>Title:</u> Proteomics (15)</p> <p><u>Subunit</u></p> <ol style="list-style-type: none"> 1. Significance of proteome 2. Overview of proteomics 3. Methods for cell disruption/protein extraction 4. Protein purification/ Fractionation 5. Protein identification and characterization 6. Modification of proteins (in vitro/in vivo) 7. Post translational modification
204.3	<p><u>Title:</u> Clinical Pharmacology, NCE and its development into a New Drug and Enzymes (15)</p> <p>Subtopics:</p> <ol style="list-style-type: none"> 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	<p><u>Title:</u> Environmental Safety in Bioanalytical laboratory (15)</p> <p>Subtopics:</p> <ol style="list-style-type: none"> 1. Strategies to reduce environmental impact of Bioanalytical laboratory 2. Standards of Laboratory Safety (Including Biosafety Levels) 3. Overview of guidelines for laboratories handling Radioactive substances 4. Introduction to ISO 14001 and OHSAS 18001. 5. Introduction to Environment Impact Assessment & Reporting 6. Biodiversity: <ul style="list-style-type: none"> Red Data Book, Endemic and endangered Medicinal Plant Species, Conservation and sustainable use of medicinal raw materials, Introduction to Wildlife Act of India & CITES 7. Carbon footprints and Carbon credits.
<p>DSC (6 credits) (4 credits for theory +2 credits for practical) paper code: PGBAS204 A Practical Name of the paper: Immunoassays and Clinical Pharmacology Total no of lectures : (4 lectures equivalent to 1 practical)</p>	

- Detection of HCG hormone in urine sample using at home pregnancy test kit.
- The screening of Hepatitis B surface antigen using HEPALISA kit.
- Protein profiling of plant seed by SDS-PAGE
- To estimate T3 and T4 hormones in serum using RIA.
- To determine the amount of TSH in serum using IRMA.
- Environment audit report
- Problem based on calculation of carbon credit and carbon footprint

SEMESTER II

DSCII (6 credits) (4 credits for theory +2 credits for practical)

paper code :PGBAS204 B

Name of the paper: Total no of lectures : 60 lectures (lecture allotment includes periods for seminar and discussion)

Course specific outcomes:

The learner will be able to:

1. Summarize the FDA guidelines for labeling and packaging of cosmetics.
2. Test the adulterants present in cosmetic products.
3. Formulate the different cosmetic products.
4. Assess the raw materials used in cosmetic preparations.
5. Distinguish between cosmetics and Cosmeceuticals.

204.1

Title :QA and QC in Cosmetics (15)

Subtopics:

1. FDA Guideline for Cosmetics labeling & Packing
2. GMP in Cosmetics
3. Adulteration in cosmetics
4. Action taken by FDA against company for marketing adulterant product
5. Registration and licenses policy in cosmetics
6. QC test in cosmetics
7. Adverse effect of cosmetics

204.2

Title: Raw materials used in cosmetics (15)

Subtopics:

1. Raw materials used in cosmetics
2. Stabilizers
3. Emulsifiers
4. Natural ingredient
5. Diluents
6. Aesthetic materials

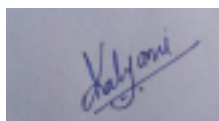
204.3

Title: Formulation in cosmetics (15)

Subtopics:

1. Gel
2. Sticks

	3. Powder 4. Tablets 5. Aerosol 6. Bar
204.4	<u>Title:</u> Cosmeceuticals (15) Subtopics: 1. Concept of Cosmeceuticals 2. Natural Cosmeceuticals 3. Products of Cosmeceuticals 4. Advantages and Disadvantages of Cosmeceuticals over cosmetics
SEMESTER II DSC (6 credits) (4 credits for theory +2 credits for practical) paper code: PGBAS204B Practical Name of the paper: Cosmetics and Cosmeceuticals Total no of lectures: 4 lectures equivalent to 1 Practical	
<ul style="list-style-type: none"> • Preparation of emulsion(shampoo) • Preparation of Lotion • Preparation of ointment/cream 	
SEMESTER II SBC (4 credits) paper code: PGBAS205 Name of the Course: General Statistics And Biostatistics Total no of lectures: 30 lectures	
Course specific outcomes: The learner will be able: <ol style="list-style-type: none"> 1. Select the appropriate statistical approach to biological samples. 2. Enlist data collection techniques. 3. Outline the design of statistical experiments. 4. Enlist the variations in biological samples and their statistical treatment. 5. Give examples of parametric and non-parametric tests. 	
<ol style="list-style-type: none"> 1. Basic concepts of sample statistics 2. Introduction to Various statistical tests - parametric and non parametric 3. Statistical approach to biological samples 4. Regression analysis with application to Std Graph 5. Use of statistical packages for data analysis (SPSS software) 	



Mrs. Kalyani Patil

Head of department