Resolution No. AC/I(19-20).2.RPS1

S. P. Mandali's

Ramnarain Ruia Autonomous College

(Affiliated to University of Mumbai)

RUIA COLLEGE
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Syllabus For:

Program: M.Sc. in Bioanalytical Sciences

(Post-graduate Syllabus)

Program Code: RPSBAS

(Credit Based Semester and Grading System for academic year 2019–2020)

M.SC DEGREE COURSE IN BIOANALYTICAL SCIENCES

OBJECTIVES:

- Develop trained manpower in the field of Bio-analytical Sciences with specific emphasis for exploitation of ASU system of medicine as well as its need for changing trends of modern pharmaceutical Industries
- Amalgamate traditional analytical chemical techniques with modern genomic and proteomic technologies of manufacturing and analysis
- Introduce the powerful tools of informatics in routine use at manufacturing, QC and research.
- Exposure to National & International regulatory affairs with reference to drugs

PURPOSE:

There is very a rapid change in science and technology and it is affecting all walks of life across the globe. The application of science to real world problems is becoming more complex and it is no more possible to find a simple solution to real world problems as we need to adopt what is called as a multidisciplinary approach.

In this age of plurality, application of only pure science is sine qua non! A one dimensional approach is redundant and this holds true for myriad areas of scientific endeavour. Many fields of scientific study such as Astronomy, Biotechnology, Bioinformatics, Environmental Sciences, Forensic Sciences, Nanotechnology etc are rapidly expanding in terms of the knowledge generated and as a result in these areas the one dimensional approach doesn't work.

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.

RAMNARAIN RUIA AUTONOMOUS COLLEGE, MUMBAI
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Credit Distribution

M.Sc. Semester - I						
PAPER	Code	Lectures	Credits	Code	Practical	Credits
Principles Of Bioanalysis	RPSBAS101	60	4	RPSBASP101	60	2
Spectroscopic Techniques	RPSBAS102	60	4	RPSBASP102	60	2
Introduction To Pharmacy	RPSBAS103	60	4	RPSBASP103	60	2
Applied Biology	RPSBAS104	60	4	RPSBASP104	60	2
TOTAL	**04**	**240**	**16**	**04**	**240**	**8**
TOTAL CREDITS			**24**			
Semester II						
Paper	Code	Lectures	Credits	Code	Practical	Credits
Pharmacognosy & Phytochemistry	RPSBAS201	60	4	RPSBASP201	60	2
Chromatographic Techniques	RPSBAS202	60	4	RPSBASP201	60	2
Practices In Pharmaceutical Industry	RPSBAS203	60	4	RPSBASP201	60	2
IPR, Drug Act & Regulations	RPSBAS204	60	4	RPSBASP201	60	2
Total	04	240	16	04	240	8
TOTAL CREDITS			**24**			
Semester III						
PAPER	Code	Lectures	Credits	Code	Practical	Credits
Standardization Of Ayurveda, Siddha & Unani Medicine	RPSBAS301	60	4	RPSBASP301	60	2
Bioanalytical Techniques I	RPSBAS302	60	4	RPSBASP302	60	2
Applied Microbiology & Toxicology	RPSBAS303	60	4	RPSBASP303	60	2
Biostatistics & Data Management	RPSBAS304	60	4	RPSBASP304	60	2
TOTAL	**04**	**240**	**16**	**04**	**240**	**8**
TOTAL CREDITS			**24**			
Semester –IV						
Paper	Code	Lectures	Credits	Code	Practical	Credits
Pharmaceutical Biotechnology & Pharmaceutical Manufacturing	RPSBAS401	60	4	RPSBASP401	60	2
Bioanalytical Techniques Ii	RPSBAS402	60	4	RPSBASP402	60	2
Fundamentals Of Clinical Research	RPSBAS403	60	4	RPSBASP403	60	2
Modern Analytical Techniques	RPSBAS404	60	4	RPSBASP404	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			24			

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Syllabus at a Glance

Semester I	Semester II
RPSBAS101: **Principles of Bioanalysis** 101.1: Introduction of Bioanalytical Sciences 101.2: Analysis of Biomolecules 101.3: Composition, Storage and properties of Biological Samples 101.4: Extraction Techniques for Bioanalysis	**RPSBAS201: Pharmacognosy & Phytochemistry** 201.1: Pharmacognosy 201.2: Phytochemistry 201.3: Extraction Technologies for Phytochemicals 201.4: Phytochemical Analysis
RPSBASP101: Practicals	**RPSBASP201: Practicals**
RPSBAS102: Spectroscopic Techniques 102.1: Introduction to Spectroscopy 102.2: Techniques in Atomic Spectroscopy 102.3: Techniques in Molecular Spectroscopy 102.4: Spectroscopic Techniques based on Light Scattering	**RPSBAS202: Chromatographic Techniques** 202.1: Principles of Chromatography 202.2: Planar chromatography 202.3: Gas Chromatography(GC) 202.4: High Performance Liquid Chromatography(HPLC)
RPSBASP102: Practicals	**RPSBASP202: Practicals**
RPSBAS103: Introduction to Pharmacy 103.1: Basic Pharmaceutical Chemistry 103.2: Basic Pharmacology 103.3: New Drug Development 103.4: Pharmacopoeia and its uses	**RPSBAS203: Practices in Pharmaceutical Industry** 203.1: Good Laboratory Practices (GLP) 203.2: Good Manufacturing Practices (GMP) 203.3: Quality Assurance(QA)-Quality Control(QC) in Food & Pharmaceutical Industry 203.4: Stability Studies of Pharmaceutical Products
RPSBASP103: Practicals	**RPSBASP203: Practicals**
RPSBAS104: Applied Biology 104.1: Genomics & Proteomics 104.2: Applied Enzymology 104.3: Immunoassays 104.4: Electrophoresis	**RPSBAS204: IPR, Drug Act & Regulations** 204.1: Intellectual Property Rights-I 204.2: Intellectual Property Rights-II 204:3: Drug Act & Regulations 204.4: Regulated Bioanalysis & their guidelines
RPSBASP104:Practicals	**RPSBASP204:Practicals**

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Semester III	Semester IV
RPSBAS301: Standardization of Ayurveda, Siddha & Unani Medicine 301.1: Indian Systems of Medicine 301.2: Standardization of Ayurveda, Siddha & Unani Drugs 301.3: Quality Assurance-Quality Control of Ayurveda, Siddha & Unani Drugs 301.4: Regulatory aspects of ASU Drugs	**RPSBAS401: Pharmaceutical Biotechnology & Pharmaceutical Manufacturing** 401.1: Polymerase Chain Reaction & its applications 401.2: Cell & Gene Therapy Products 401.3: Pharmaceutical Manufacturing 401.4: Biosimilars & Biopharmaceuticals
RPSBASP301: Practicals	**RPSBASP401: Practicals**
RPSBAS302: Bioanalytical Techniques I 302.1: Introduction to Mass Spectrometry 302.2: Hyphenated Techniques in Bioanalysis 302.3: LC-MS/MS & GC-MS/MS 302.4: Bioassays	**RPSBAS402: Bioanalytical Techniques II** 402.1: Qualitative Applications of Mass Spectrometry 402.2: Quantitative Applications of Mass Spectrometry 402.3: Analytical Method Development & Validation 402.4: Bioanalytical Method Development & Validation
RPSBASP302: Practicals	**RPSBASP402: Practicals**
RPSBAS303: Applied Microbiology & Toxicology 303.1: Introduction to Microbiology 303.2: Pharmaceutical Microbiology 303.3: Introduction to Toxicology 303.4: Regulatory Toxicology	**RPSBAS403: Fundamentals of Clinical Research** 403.1: Good Clinical Practices 403.2: Bioavailability-Bioequivalence Studies 403.3: Therapeutic Drug Monitoring(TDM) 403.4: Pharmacovigilance(PV)
RPSBASP303: Practicals	**RPSBASP403: Practicals**
RPSBAS304: Bioanalytical Data Handling 304.1: Bioinformatics in Disease management 304.2: Electronic Data Management 304:3: Biostatistics I 304.4: Biostatistics II	**RPSBAS404: Modern Analytical Techniques** 404.1: Thermal Analysis & X-ray Diffraction-X-ray Fluorescence 404.2: Nuclear Magnetic Resonance Spectroscopy 404.3: Tracer techniques 404.4: Chiral Chromatography & Circular Dichroism and Optical Rotary Dispersion
RPSBASP304:Practicals	**RPSBASP404:Practicals**

Learning Objectives for M.Sc. in Bioanalytical Sciences

RPSBAS101 Principles of Bioanalysis

- Considering the diverse subjects of graduation of the students, the primary objective of this course is to familiarize the students to the concepts in bioanalysis.
- To revise basic concepts of measurements such as mass, weight, molarity, density, etc.
- To make students understand biological matrices and extraction techniques.

RPSBAS201 Pharmacognosy and Phytochemistry

- To emphasize importance of plants as a source of medicine.
- To make students appreciate the abundant knowledge and rich traditions regarding medicinal plants.
- To highlight the importance of analyzing active ingredients in plants using modern methods of extraction and analysis.

RPSBAS102 Spectroscopic techniques

- To lay out fundamentals of spectroscopy with respect to electromagnetic spectrum and properties of different electromagnetic radiations.
- To imbibe the principles and instrumentation of atomic spectroscopy, molecular spectroscopy and light scattering spectroscopy.
- To inculcate analytical approach regarding correct choice of analytical method and troubleshooting.
- To train students to interpret spectral data for identification and quantification of analytes.
- To train students to confidently handle analytical instruments like UV-Visible spectrophotometer, colorimeter, turbidometer and flame photometer.
- To make students appreciate the vast scope of different spectroscopic methods with an emphasis on Bioanalysis.

RPSBAS202 Chromatographic techniques

- To lay out the fundamentals of chromatographic separation.
- To imbibe the principles and instrumentation for column chromatography (HPLC), planar chromatography (TLC, HPTLC) and gas chromatography.
- To train students to confidently handle analytical instruments like High Performance Liquid Chromatography (HPLC), Gas chromatography (GC), etc.
- To train students to interpret chromatographs or fingerprints for quantification and identification of analytes.
- To make students appreciate the vast scope of different chromatographic methods with an emphasis on Bioanalysis.

RPSBAS103 Introduction to pharmacy

- Introduction to the basic concepts of pharmaceutical chemistry with respect to therapeutic index, nomenclature of drugs, dosage forms, drug metabolism, synthesis of drugs, etc.
- To introduce the principles of Pharmacokinetics and Pharmacodynamics and highlight their importance for designing formulations and dosage.
- To make students appreciate the intricacies and complexities of drug discovery and drug development.

- To inculcate the habit of referring pharmacopoeia as a standard reference book for various analytical methods and analytical standards.

RPSBAS203 Practices in Pharmaceutical Industry

- To understand the concepts of Quality Control (QC), Quality Assurance (QA), Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP),
- To develop professional approach in students with respect to prompt and accurate documentation.
- To introduce the concept of stability and highlight the importance of stability studies for API and formulations.

RPSBAS104 Applied Biology

- To lay out fundamental concepts of genomics, proteomics, Enzymology and immunology.
- To make students understand how chemical and biological properties of various biomolecules can be exploited for their separation and analysis.
- To give practical training on analytical techniques like SDS-PAGE and immunoassays.

RPSBAS204 IPR, Drug act and Regulations

- To introduce the concepts of Intellectual Property Right (IPR) as well as Drug act and regulations.
- To highlight the importance of protection and monetization of one's intellectual property.
- To make students appreciate the importance of legal framework involved right from the discovery of new drug candidates up to the post marketing surveillance.
- To study regulatory guidelines with a special emphasis on bioanalysis.

RPSBAS301 Standardization of Ayurveda, Siddha &Unani Medicine

- To study the principles & practices involved in traditional and modern medicinal systems with detailed account of the dosage forms & formulations of each system.
- To make students compare Ayurveda, Siddha and Unani system of medicine.
- To highlight the importance of standardization of traditional medicines as per modern regulatory standards.
- With the help of small project work, give students hands-on training on preparation and analysis of herbal formulations.

RPSBAS401 Pharmaceutical Biotechnology & Pharmaceutical Manufacturing

- To make students understand the fundamental concepts of polymerase chain reaction (PCR) and cell and gene therapy products.
- To make students realize the versatility of PCR and its wide range of its applications in research and diagnostics.
- To underline the importance of cell and gene therapy as a modern and futuristic medicine.
- To train students on techniques and data interpretation of PCR and RFLP.
- To highlight the importance of good manufacturing practices in pharmaceutical industry.

RPSBAS302 Bioanalytical Techniques I

- To imbibe the theoretical principles of mass spectrometry with respect to ionization and fragmentation pattern.

- To instil analytical approach with respect to the correct choice of hyphenated technique as per the properties of analytes.
- To train students to interpret mass spectrometric data for identification and quantification of analytes.
- To introduce the concept of bioassays and underline its significance in pharmaceutical industry
- To lay out the fundamental principles of radioactivity.
- To emphasize on the applications of radioactive tracers in bioanalysis.

RPSBAS402 Bioanalytical techniques II

- To learn the Qualitative & Quantitative applications of Mass Spectrometry
- To emphasize the importance of analytical and Bioanalytical method development and validation

RPSBAS303 Applied Microbiology & Toxicology

- To introduce the basic concept of microbiology and antimicrobial agents.
- To emphasize on applications of microbiology for testing quality of pharmaceutical products.
- To introduce the theory of toxicology and introduce the concept of regulatory toxicity.
- To make students realize the utmost need to follow regulatory standards of toxicology as survival of human subjects is directly dependent on it.

RPSBAS403 Fundamentals of Clinical Research

- To learn the guidelines of Good clinical practices with respect to documentation and audit.
- To understand the fundamentals of Bioavailability & Bioequivalence (BA/BE).
- To learn the evaluation of BA/BE, design and conduct of the BA/BE studies.
- To familiarize with the concept and importance of Therapeutic Drug Monitoring (TDM) and Pharmacovigilance

RPSBAS304 Bioanalytical Data Handling

- To introduce the concepts of regulated bioanalysis and biostatistics with special emphasis on documentation, regulatory requirements and quality systems.
- To make students realize the utmost importance of data management as validity of laboratory work is assessed solely on the basis of data generated.
- To inculcate the habit of book-keeping.
- To train students analyze the biological data with the help of suitable statistical tests.

RPSBAS404 Modern Analytical Techniques

- To introduce theory and instrumentation of modern analytical techniques like thermal analysis, X-ray Diffraction (XRD), Infrared spectroscopy (IR), Nuclear Magnetic Resonance spectroscopy (NMR) and chiral chromatography.
- To give a general overview of wide range of applications of these techniques with special emphasis on bioanalysis.

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Paper Code	Semester I- Paper I	Lectures
RPSBAS101	**Principles of Bioanalysis**	**60**
	101.1: Introduction of Bioanalytical Sciences	
	1. Concepts in Bioanalysis 2. Purpose of Bioanalysis 3. Bioanalysis in Pharmaceutical industry, Hospital laboratories, Forensic toxicology laboratories, Doping control laboratories. 4. Challenges in Bioanalysis 5. Various Tools used in Bioanalysis	**15**
	101.2: Analysis of Biomolecules	
	1. Importance of accurate determination of biomolecules 2. Major methods to detect and quantify biomolecules 3. Understanding mass, weight, volume and density 4. Understanding moles and molarity 5. Understanding solubility and dilutions	**15**
	101.3: Composition, Storage and properties of Biological Samples	
	1. Introduction to Bio-matrices- Microbial, Plant & Animal 2. Collection and storage of Biological samples 3. Microbes- Bacteria, Algae, Fungi, Protozoans 4. Plants- different parts & stages of growth 5. Animals & Humans: a. Blood, or whole blood, Plasma and serum b. Urine, Feces c. Saliva d. Cerebrospinal Fluid, Synovial fluid e. Hair and Nails f. Tissue (Biopsies)	**15**
	101.4: Extraction Techniques for Bioanalysis	
	1. Physico-chemical properties of drugs and solvents 2. Concept of partition & Partition Coefficient 3. Solvent properties 4. Introduction to Liquid-liquid Extraction & Liquid-Liquid Micro-extraction, Solid Phase extraction & Solid Phase Micro-extraction Techniques 5. Ionization and its effect on the extraction of drugs 6. The 'First law of drug metabolism' 7. Matrix components & analyte isolation a. Concentration of extracts b. Isolations of fractions 8. Purification of isolate	**15**
RUSBASP101	**PRACTICALS**	

1. Preparation of analytical standard solutions
2. Extraction and Analysis of Carbohydrates, proteins and lipids from biological sample(Microbe, Plant & animal)
3. Bioanalysis of Urine, blood and serum sample
4. Liquid – liquid extraction of a modern drug from plasma and formulations
5. Solid Phase extraction of a drug from plasma

Paper Code	Semester I- Paper II	Lectures

RPSBAS102	Spectroscopic Techniques		60
	102.1:	Introduction to Spectroscopy	
		1. General properties of Electromagnetic Radiation 2. The electromagnetic spectrum 3. Components of optical instruments 4. Introduction to optical atomic spectroscopy 5. Atomic & Molecular spectroscopy	**15**
	102.2:	Techniques in Atomic Spectroscopy	
		1. Atomic Absorption Spectroscopy a. Principles & Instrumentation b. Applications 2. Atomic Emission Spectroscopy a. Principles & Instrumentation (Atomic Emission Spectrophotometer, Flame Photometer & Inductively Coupled Plasma- Mass spectrometer) b. Applications	**15**
	102.3:	Techniques in Molecular Spectroscopy	
		Principles, Instrumentation and Applications of : 1. UV ,Visible and fluorescence Spectroscopy 2. IR Spectroscopy 3. Raman Spectroscopy 4. NMR spectroscopy	**15**
	102.4:	Spectroscopic Techniques based on Light Scattering	
		Principles, Instrumentation and Applications of : 1. Nephalometry 2. Turbidimetry 3. Particle Size Analyzer 4. Refractometer	**15**
RUSBASP102	**PRACTICALS**		

1. Analysis of a modern drug by UV-Visible Spectroscopy
2. Qualitative analysis of organic solids using IR spectroscopy
3. IR analysis of modern drug (any one example.)
4. Turbidometric & Nephalometric analysis of Pharmaceutical Products
5. Flame Photometric estimation of metals with special emphasis on interference
6. Sample Preparation for AAS & analysis of pharmaceutical products/Crude drugs for their metal content using AAS

Paper Code	Semester I- Paper III	Lectures
RPSBAS103	**Introduction to Pharmacy**	**60**
	103.1: Basic Pharmaceutical Chemistry	
	1. Definition of a drug, Requirements of an ideal drug, Classification of drugs (based on therapeutic action) 2. Nomenclature of drugs: Generic name, Brand name, Systematic name 3. Definition of the following medicinal terms: Pharmacon, Pharmacophore, Prodrug, Half-life efficiency, LD50, ED50, Therapeutic Index. 4. Brief idea of the following terms: Receptors, Drug-receptor interaction, Drug Potency, Bioavailability, Drug toxicity, Drug addiction, Spurious Drugs, Misbranded Drugs, Adulterated Drugs, Pharmacopoeia. 5. Formulations, Different dosage forms (emphasis on sustained release formulations.) 6. Introduction to Drug Discovery, Design and Development: Discovery of a Lead compound: Screening, drug metabolism studies and clinical observation. 7. Drug development from Natural Sources: Anti-infective agents, Anti-cancer agents, CNS agent 8. Development of drug: The Pharmacophore identification, modification of structure or functional group. 9. Drug Metabolism :Introduction, Absorption, Distribution, Bio-transformation, Excretion 10. Different types of chemical transformation of drugs with specific examples.	**15**
	103.2: Basic Pharmacology	
	1. Scope of Pharmacology 2. Sources, Nature & Nomenclature of Drugs 3. Dosage forms & Routes of Drug Administration 4. Dose- Response Relationship 5. Factors influencing drug dosage and drug action. 6. Drug disposition & Pharmacokinetics 7. Mechanisms of Drug Action- Pharmacodynamics	**15**
	103.3: New Drug Development	
	1. Concept of New Chemical Entity(NCE) 2. Stages in the development of NCE 3. Preclinical studies on NCE 4. Enzyme as Therapeutics agents, as diagnostics, as catalyst in processes as drug target	**15**
	103.4: Pharmacopoeia and its uses	
	1. Introduction to World Health Organisation guidelines 2. Introduction to Pharmacopoeias IP, BP, USP(JP, EP, AP where ever applicable) 3. Specified test in Monographs with respect to liquid formulation (injectible) and solid dosage form (USP, EP, BP, IP) 4. AP, Indian HP and AFI (wherever applicable)	**15**
RUSBASP103	**PRACTICALS**	

1. Study of different dosage forms and classification of drugs (Assignment)
2. Use of Pharmacopoeia (Indian and US Pharmacopoeia)
3. Study of Hardness and Friability of a tablet
4. Study of Disintegration and Dissolution of a tablet as per IP/USP (uncoated)
5. Study of Disintegration and Dissolution of a tablet as per IP/USP(enteric coated)
6. Determination of percentage of $CaCO_3$/$MgCO_3$ from formulation(s) by Complexometric titration

Paper Code	Semester I - Paper IV	Lectures
RPSBAS104	**Applied Biology**	**60**
	104.1: Genomics & Proteomics	
	Genomics: Nucleic acid chemistry, Principles of DNA sequencing, DNA & RNA probes, Concepts of Gene manipulation, Restriction enzymes & their uses, Vectors & their uses, Producing Transgenic organisms, Hybridoma technology, cDNA production & applications, Gene libraries & applications **Proteomics:** Introduction to proteomics, types of proteomics Protein Extraction, separation, Purification and identification, Protein fingerprinting techniques, Endogenous peptides and concepts of post translational modifications, Chemical modification of proteins	**15**
	104.2: Applied Enzymology	
	1. General review of enzyme and properties including multi-enzyme complexes. 2. The relation of structure and kinetics mechanisms of enzymatic catalysis; studies of specific enzyme and enzyme systems, steady-state enzyme kinetics, transient kinetic methods, chemistry of enzyme catalysis. 3. Regulatory enzymes, Molecular models for allosterism. Regulation of enzyme activity. 4. Criteria for determining purity of enzymes 5. Recent advances in Enzymology.	**15**
	104.3: Immunoassays	
	1. Introduction 2. Requirements for immunoassay 3. Practical aspects 4. Advantages & Disadvantages of immunoassay 5. Principles and instrumentation in immunoassay 6. Applications of immunoassay 7. Types of Detection systems in immunoassay 8. Immunoinformatics, Immunomics & databases: IMGT, CED, IEDB, Bcipep, Syfpeithi and Applications of Immunoinformatics	**15**
	104.4: Electrophoresis	
	1. Basic Protein Chemistry 2. Principles of Electrophoretic separation 3. Equipment and process 4. Types of Electrophoresis 5. Standardization of Electrophoretic technique 6. Detection techniques 7. Applications of Electrophoresis	**15**
RUSBASP104	**PRACTICALS**	

1. Separation of proteins using SDS-PAGE(3 practicals)
2. Separation of proteins using 2D gel electrophoresis
3. Protein profiling of plant seed sample by SDS-PAGE
4. Separation of a modern drug from plasma and its formulation/ peptides by Capillary Electrophoresis
5. Immunoassay for detection of pregnancy
6. Immunoassay for detection of Hepatitis B/Dengue
7. Bioinformatics: INSDC, UniProt, GenBank, BLAST & its variants, Clustal O, Rasmol, MarvinSketch- Marvin View & Docking.
8. Immunomic databases: CED, BCIPEP, IMGT, IEDB, Epitome

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Paper Code	Semester II- Paper I		Lectures
RPSBAS201	**Pharmacognosy & Phytochemistry**		**60**
	201.1:	Pharmacognosy	**15**
		1. Introduction, Plants and their medicinal uses example of one plant to be given 2. Concepts of ethanobotany, ethno medicines and pharmacology 3. Herbaria evaluation to include Plant collection, Authentication, storage and drying techniques. 4. Evaluation of Crude drugs 5. Concepts of GAP and GHP for medicinal plants(only introduction)	
	201.2:	Phytochemistry	**15**
		1. Primary and secondary metabolites from plants 2. Classification of Plant Secondary metabolites 3. Functions of Plant Secondary Metabolites 4. Chemistry of Phenolics, Terpenoids, Alkaloids 5. Phytochemicals as Drugs 6. Key factors affecting synthesis of secondary metabolites	
	201.3:	Extraction Technologies for Phytochemicals	**15**
		1. Extraction of phytoconstituents 2. Choice of solvent for extraction 3. classical and modern methods of extraction a. Percolation & Maceration b. Soxhlet extraction c. Steam Distillation & Rotary vacuum evaporator d. Liquid- Liquid & Solid Phase Extraction e. Ultrasonication f. Microwave Assisted Extraction g. Supercritical Fluid extraction	
	201.4:	Phytochemical Analysis	**15**
		1. Classical methods of analysis (Gravimetric & Titrimetric) 2. Chromatographic & Spectroscopic analysis of phytoconstituents 3. Chromatographic fingerprints 4. Phytochemical variations in plants 5. Analysis of herbal formulations 6. Effect of drying on phytoconstituents	
RUSBASP201	**PRACTICALS**		

1. Microscopic evaluation of sections and powders with adulteration and formulation comparison of the medicinal plants (Any 5)
2. Qualitative (TLC) tests for secondary metabolites
3. Qualitative and Quantitative (gravimetric) detection of secondary metabolites
4. Herbaria preparation & Evaluation of any one annual plant available locally
5. Standardization of solvent and Phytochemical extraction by classical & modern methods
6. Proximate evaluation of crude drugs
7. Students must submit a Field Note Book of their field excursion including Presentation of the field visit

Paper Code	Semester II- Paper II	Lectures
RPSBAS202	**Chromatographic Techniques**	**60**
	202.1: Principles of Chromatography	
	1. Principles of chromatographic separation 2. Classification Of Chromatographic methods 3. Elution in Column Chromatography, The chromatogram 4. Migration rates of solutes a. Distribution constant b. Retention time c. Retention factor d. Selectivity factor 5. Band Broadening and column efficiency 6. Optimization of Column Performance	**15**
	202.2: Planar chromatography	
	1. Paper Chromatography & Thin Layer Chromatography (TLC) a. Principles and Practice b. Significance of mobile phase c. Applications d. Derivatization 2. High Performance Thin Layer Chromatography (HPTLC) a. TLC vs HPTLC b. *In Situ* Densitometric scanning c. Troubleshooting d. HPTLC Fingerprinting and other applications e. Preparative HPTLC	**15**
	202.3: Gas Chromatography(GC)	
	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) 7. Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD) 8. Derivatization for GC 9. GC strategy for analysis involving biological matrices 10. Troubleshooting 11. Applications	**15**

	202.4:	High Performance Liquid Chromatography(HPLC)	
		1. Principles and Instrumentation 2. Column chemistry, Column switching in HPLC, Column condition 3. System parameters 4. Automation in HPLC 5. Types of HPLC a. Reverse-Phase HPLC b. Gradient reverse-phase HPLC c. Ion-pair HPLC d. Ion-exchange HPLC e. Normal-phase HPLC f. Affinity Chromatography g. Gel permeation Chromatography 6. HPLC detectors 7. Data Processing: Manual and Electronic 8. Applications of HPLC 9 Recent advances (Fast LC, online extractions, add on pumps, online Derivatization, multi-dimensional LC) 10. Troubleshooting	**15**
RUSBASP202	**PRACTICALS**		

1. Standardization of mobile phase for Separation of plant pigments using paper chromatography
2. TLC analysis of Modern drugs
3. Gas Chromatographic separation of solvent mixtures or Analysis of Formulations by GC
4. HPLC separation of herbal raw material from its formulation (any one example)
5. HPTLC analysis of modern drug from plasma
6. HPTLC analysis of modern drug from formulations
7. Simultaneous Analysis of Phytoconstituents by HPTLC & GC
8. Simultaneous Analysis of Caffeine by HPTLC, HPLC & GC

Paper Code	Semester II- Paper III	Lectures
RPSBAS203	**Practices in Pharmaceutical Industry**	**60**
	203.1: Good Laboratory Practices(GLP)	**15**
	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	
	203.2: Good Manufacturing Practices(GMP)	**15**
	1. Concept of 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	
	203.3: Quality Assurance(QA)-Quality Control(QC) in Food & Pharmaceutical Industry	**15**
	1. Introduction to QC & QA 2. Requirements for implementing QC & QA 3. QC & QA concepts in ASU drugs 4. Standardizing an Analytical method 5. Factors affecting standardization 6. Support work & documentation 7. Validation 8. Audit requirements, audits and audit reports 9. Personnel Responsibility in QA	
	203.4: Stability Studies of Pharmaceutical Products	**15**
	1. Types of stability studies 2. Stability chambers 3. Regulatory requirements for stability studies (Modern and Traditional) 4.Factors affecting stability of drug products(Modern and Traditional) 5. Predicting shelf-life of a finished product 6. Stability issues of raw materials and finished products (Modern and Traditional)	
RUSBASP203	**PRACTICALS**	

1. Preparation of Standard Operating Procedure, for any one analytical Instrument
2. Study of Pharmaceutical Preparation: Chemical Assay as per IP
3. Stability studies of drugs (API & formulation Dosage form) with respect to effect of pH, Temperature, Pressure, Moisture and Light
4. Study of(on) compatibility of container(primary/secondary packaging) with the drug
5. Study of Shelf life of herbal drugs
6. HPLC separation of a modern drug from plasma
7. HPLC separation of a modern drug from formulations

Paper Code	Semester II- Paper III		Lectures
RPSBAS204	**IPR, Drug Act & Regulations**		**60**
	204.1:	Intellectual Property Rights-I	**15**
		1. Concept of IPR - Understanding 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, 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. International Agreements related to IPR & patents - Paris Convention, PCT.	
	204.2:	Intellectual Property Rights-II	**15**
		1. 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. 2. IPR as a strategic tool - a. Concepts of piracy, reverse engineering and knowledge worker. b. Benefits of creating and/or owning patents and other IPR. c. How India has leveraged the flexibilities provided by TRIPS to safeguard the industry and prevent ever-greening of patents. 3. IP clearance – Precautions before launching of product anywhere in the world - a. Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check b. Other IPR checks like trademarks, copyrights (for printed data on leaflets, packages etc.), 4. Putting IPR related disclaimers while advertising product list or selling products.	
	204.3:	Drug Act & Regulations	**15**
		1. Indian Drugs and Cosmetics Act with respect to Schedule1,2 and Schedule A,H M, S, T,X ,Y . 2. Introduction to foreign guidelines(for import of drugs) with respect to US, EU, Australia & Japan 3. Introduction to 21 CFR Part 11	

	204.4:	Regulated Bioanalysis & Guidelines	
		1. Introduction 2. The Evolution of Regulated Bioanalysis 3. Bioanalytical Method Validation 4. Pre-study Validation 5. In- study Validation 6. Documentation 7. Regulatory Requirements to Bioanalysis 8. Quality systems in Regulated Bioanalysis	**15**
RUSBASP204	**PRACTICALS**		

1. Research Paper Review
2. Abstract writing for a research paper
3. Patent Claim Drafting
4. Students must submit a comprehensive Report of the Industrial Visits including a PowerPoint Presentation on any one Visit.

RAMNARAIN RUIA AUTONOMOUS COLLEGE, MUMBAI
M.Sc. IN BIOANALYTICAL SCIENCES

Paper Code	Semester III – Paper I	Lectures
RPSBAS301	**Standardization of Ayurveda, Siddha & Unani Medicine**	**60**
	301.1: Indian Systems of Medicine	
	1. Principles and practices of ASU systems of medicine 2. Diagnosis & treatment as per Ayurveda (Special emphasis on Panchakarma) 3. Types of Drug formulations as per ASU systems 4. Dosage forms as per ASU system 4. Mode of action of drugs according to Ayurveda	**15**
	301.2: Standardization of Ayurveda, Siddha & Unani Drugs	
	1. Need of standardization of Ayurvedic, Siddha & Unani drugs 2. Approaches to standardization 3. Sources of Raw materials & Finished products as per ASU drugs 4. Methods of manufacture-raw materials to finished products 5. Bioanalytical tools for standardization 6. Clinical studies in Standardization	**15**
	301.3: Quality Assurance(QA)-Quality Control(QC) of Ayurveda, Siddha & Unani Drugs	
	1. Herbal pharmacopoeia and Ayurvedic Formulary of India 2. Shelf life studies on finished products 3. Approaches to Quality control of ASU formulations 4. Quality control of ASU drugs 5. Developing standardized QC methods 6. QC for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon, etc.)	**15**
	301.4: Regulatory aspects of ASU Drugs	
	1. Organizational setup in India for the regulation of herbal drugs, Regulatory laws in India for herbal drugs 2. Import & Manufacture of herbal drugs, Conditions for the manufacture of herbal drugs 3. Administrative agencies regarding the regulation of herbal drugs 4. Regulatory aspects of herbal drugs in India & other countries	**15**
RUSBASP301	**PRACTICALS**	

1. Simultaneous Analysis of iron from a given sample / sample solution by
   a. Redox titration b. Colorimetry c. Atomic Absorption Spectroscopy
2. Microscopic Analysis of ASU formulation
3. Study of Hepatoprotective action of a herbal drug against CCl_4 liver dysfunction in rats and using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out)
4. Analysis of Ayurvedic oil: Refractive Index, Viscosity & IR Spectroscopy

RAMNARAIN RUIA AUTONOMOUS COLLEGE, MUMBAI
M.Sc. IN BIOANALYTICAL SCIENCES

Paper Code	Semester III- Paper II	Lectures
RPSBAS302	**Bioanalytical Techniques I**	**60**
	302.1: Introduction to Mass Spectrometry(MS)	
	1. Evolution of MS 2. Importance of MS as detector 3. Interfaces used in LC-MS & GC-MS 4. Sample preparations of MS 5. Components of Mass Spectrometer: a)Inlets b) Ion sources- i) GC-MS: EI,CI ii) LC-MS: ESI,API(APCI & APPI), FI,FD,FAB,TSP, MALDI c) Analyzers- QP,TOF, Ion trap, Magnetic sector, hybrid analyzers d) Detectors e) Vacuum system & its significance f) Applications of MS g) Introduction to MS/MS (Tandem MS)	**15**
	302.2: Hyphenated Techniques in Bioanalysis	
	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. Introduction to ICP/MS and its applications in pharmaceuticals and food 5. Introduction to advances in the field of mass spectrometry E.g. Headspace GC and GC-MS TLC-MS,	**15**
	302.3: MS Applications	
	1. Impurity profile in drugs and drug products 2. Proteomics, peptide mass fingerprinting 3. Pesticides & pesticide analysis in different sample matrices e.g. food	**15**
	302.4: Bioassays	
	1. General idea about bio assay systems used in pharmaceutical evaluations 2. In vitro assays and in vivo assays 3. Ethical issues involved in animal assay systems 4. Alternatives to animal assays – one or two examples	**15**
RUSBASP302	**PRACTICALS**	
1. Mass Fingerprinting of Peptides using a suitable sample 2. LC-MS analysis of the drug from the formulations and plasma 3. Bioassay of Penicillin 4. Study of matrix effect on IR spectra of API 5. Use of IR spectroscopy as a quantitative tool		

RAMNARAIN RUIA AUTONOMOUS COLLEGE, MUMBAI
M.Sc. IN BIOANALYTICAL SCIENCES

Paper Code	Semester III- Paper III		Lectures
RPSBAS303	**Applied Microbiology & Toxicology**		**60**
	303.1:	Microbiology	**15**
		1. Introduction to Microbes & their significance 2. Visualization of Microorganisms : Staining & microscopic techniques 3. Nutritional Requirements, Different types of media 4. Methods to study growth, preservation, maintenance of microorganisms 5. Commercially important Microbes(food, Pharma) 6. Microbial contaminants in food and Pharmaceutical products)	
	303.2:	Pharmaceutical Microbiology	**15**
		1. Asepsis, Disinfection and Sterilization, Aseptic filling in pharmaceutical industry, Classification of 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	
	303.3:	Introduction to Toxicology	**15**
		1. Introduction, History, Scope and types of toxicological studies 2. Toxicants and their classification 3.Mode of action of Toxicants (Toxicokinetics and Toxicdynamics) 4. Dose Toxicity Relationship 5. Adverse drug reaction & treatment of Poisoning 6. Concept of LC 50,LD50, ED50 7. Applications of Toxicology	
	303.4:	Regulatory Toxicology	**15**
		1. Introduction to Regulatory Toxicology 2. Types of toxicity tests 3.OECD Guidelines on Toxicological studies- Design considerations, Evaluation of results, Extrapolation to man 4. Risk analysis of Food & Drug related substances 5. Environmental impact assessment	
RUSBASP303	**PRACTICALS**		

1. Gram staining of bacteria and mounting of filamentous and non-filamentous fungi
2. Study of antibiotic Producers from suitable sample
3. Sterility testing of Pharmaceutical Dosage form.
4. Total Viable count of microorganisms from herbal raw materials and formulations.
5. LC_{50} evaluation using a suitable model (e.g. Daphnia / rice weevil, *Chyronomous larvae*)

RAMNARAIN RUIA AUTONOMOUS COLLEGE, MUMBAI
M.Sc. IN BIOANALYTICAL SCIENCES

Paper Code	Semester III-Paper IV	Lectures
RPSBAS304	**Biostatistics & Data Management**	**60**
	304.1 Bioinformatics in Disease Management	
	1. Basic concepts on identification of disease genes 2. Role of bioinformatics in human disease analysis 3. OMIM database 4. Reference genome sequence & integrated genomic maps 5. Gene expression profiling	
	304.2: Electronic Data Management	
	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	
	304.3: Biostatistics I	
	1. Concepts: Population, sample, sample size, Normal distribution, level of significance, confident limits, power of test 2. Sampling Design: a. Different Types of Sampling Design: Simple Random Sampling Stratified Random Sampling, Systematic Sampling, Cluster Sampling, Area Sampling, Multistage Sampling. b. Steps in sample design 3. Data Collection a. Primary Data collection through Questionnaire & Schedules b. Collection of Secondary Data 4. Data Analysis a. Measures of central tendency (mean, median, mode) b. Measures of dispersion (range, Sample deviation, variance, CoV) c. Introduction to Parametric & Non-Parametric tests d. Introduction to correlation & regression analysis	
	304.4: Biostatistics II	
	1. Introduction to hypothesis testing & Errors in Testing 2. Z-test, t- test, Chi-Square test, F-test, ANOVA (One way and Two way). 3. Design of experiments: Block designs (CRD,RBD), Latin square design 4. Introduction to statistical packages for data analysis	
RUSBASP304	**PRACTICALS**	120 hours

1. Case studies and problems based on Biostatistics
2. Industrial training.
   Student is expected to undergo for industrial training for for 8 to 12 weeks period and submit
   a) weekly reports regarding the training will be submitted via email
   b) training notebook having chronological records of the work carried out
   c) final report on entire training
   d) PowerPoint presentation on the outcomes of the training program(to be done at the practical exam)

Paper Code	Semester IV-Paper I		Lectures
RPSBAS401	**Pharmaceutical Biotechnology & Pharmaceutical Manufacturing**		**60**
	401.1:	Polymerase Chain Reaction & its applications	**15**
		1.Introduction to Polymerase Chain Reaction 2. Types of PCR: Conventional Qualitative PCR, Hot start PCR, Colony PCR, Nested PCR, Realtime PCR, Reverse transcriptase PCR, Touchdown PCR, Mulitplex PCR, Assembly PCR, Methylation specific PCR, LAMP assay 3. PCR instrumentation: Principle of thermal cycler 4.PCR standardization 5. Primer designing: Primers for Qualitative PCR, Primers for Epitope tag, Mutagenesis primers 6. Applications of PCR: Gene expression analysis, Cloning, RFLP-PCR, AFLP, RAPD, SNP genotyping, Diagnostics, DNA sequencing.	
	401.2:	Cell & Gene Therapy Products	**15**
		1. Meaning of gene therapy, Viral & non viral methods for gene delivery 2. Gene editing techniques: RNAi, ShRNA, Crispr/Cas9 3. Stem cell therapy 4. Manufacture storage, shipping & labeling of cell & gene therapy products	
	401.3:	Pharmaceutical Manufacturing	**15**
		1. Overview of pharmaceutical manufacturing. 2.Importance of schedule M(Drugs & Cosmetics Act) in pharmaceutical manufacturing process 3.Regulatory requirements in pharmaceutical manufacturing process 4.Unit operations and advances in: Manufacturing of oral solid dosage forms, oral liquid dosage forms, sterile injectibles and topical dosage forms	
	401.4:	Biosimilars & Biopharmaceuticals	**15**
		1. Introduction to Biosimilars & Biopharmaeuticals 2. Sources of Biopharmaceuticals (*E.coli*, Animal cells, Additional systems) 3. Upstream & Downstream Processing 4. Therapeutic Hormones, Recombinant blood products & Therapeutic Enzymes 5. Biosimilars Development, Review & Approval 6. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product	
RUSBASP401	**PRACTICALS**		

1. Plant DNA and bacterial extraction and purity analysis of the same.
2. DNA fingerprinting using RFLP analysis of suitable samples
3. Analysis of Biosimilars for container compatibility/ stability
4. Detection of genetically modified organism using Polymerase chain reaction (PCR)
5. DNA sequencing using sample from a suitable organism(demo)

Paper Code	Semester IV-Paper II		Lectures
RPSBAS402	**Bioanalytical Techniques II**		**60**
	402.1:	Qualitative Applications of Mass Spectrometry	
		1. Structural elucidation by MS 2. Technique of generating drug metabolites 3. Metabolite Identification 4. Impurity profiling 5. Analysis of essential oils, pesticides 6. Peptide mapping	**15**
	402.2:	Quantitative Applications of Mass Spectrometry	
		1.Rules of fragmentation 2. Interpretation of MS spectra 3. Structural elucidation 4. Macromolecule quantitation 5. Small Molecule(SM) quantitation 6. Metabolite quantitation	**15**
	402.3:	Analytical Method Development & Validation	
		1. Strategies for Method development 2. What and Why of method validation 3. Regulatory requirements of validation 4. Intra and inter lab – Validation 5. IQ, OQ and PQ of analytical instruments(practicals for this are already done in part one as per the new syllabus) 6. Use of Reference standards 7. Issues of Method transfer 8. Sampling 9. Calibration of glassware and instruments, concepts of Good weighing Practices 10. Use of Reference standards and working standards 11. Format of Certificate of Analysis	**15**
	402.4:	Bioanalytical Method Development & Validation	
		1. Pre- study Validation. 2. Selectivity, Accuracy, Precision, Recovery, Calibration Curve, Sensitivity, Reproducibility, Stability Incurred sample re-analysis(ISR). 3. Documentation And Additional issues like Endogenous substances & Biomarkers etc. 4. In-Study Validation.	**15**
RUSBASP402	**PRACTICALS**		

1. Impurity profiling of Modern Drug using a suitable analytical technique
2. Content Uniformity analysis of drugs using a suitable analytical technique
3. Method Validation for any one analysis
4. GC-MS analysis of Essential oil
5. LC-MS-MS analysis of Metabolites of drugs
6. IR patterns of an Ayurvedic Bhasma preparation (e.g. comparison of calcium from Shankha Bhasma – with pure $CaCO_3$ and other modern Calcium supplement

Paper Code	Semester IV-Paper III	Lectures
RPSBAS403	**Fundamentals of Clinical Research**	**60**
	403.1: Good Clinical Practices and Ethics in Clinical trial	
	1. Origin of GCP & Earlier Guidelines for GCP 2. GCP guidelines of ICH 3. Ensuring GCP compliance 4. Documentation of GCP practice 5. Audit of GCP compliance 6. Ethics and ethical issues in Clinical trial	**15**
	403.2: Bioavailability(BA)-Bioequivalence(BE) Studies	
	1. Concept of BA and BE 2. Parameters to evaluate BA and BE of a drug 3. Factors that influence BA and BE of a drug 4. Evaluating BA and BE of a drug 5. Estimating BA and BE parameters of a drug 6. Design of a BA and BE study 7. Conduct of a BA and BE study 8. Data record and evaluation in BA and BE study 9. Reporting a BA study 10. Regulatory requirements of BA and BE	**15**
	403.3: Therapeutic Drug Monitoring	
	1. Purpose of therapeutic Drug Monitoring 2. Drugs suitable for therapeutic drug monitoring 3. Measuring and monitoring drug in TDM 4. Bioanalytical techniques in TDM, Analytical and practical issues of TDM 4. Pharmacoeconomics of TDM	**15**
	403.4: Pharmacovigilance	
	1. Basic concepts in PV 2. Types and sources of data, The process of Pharmacovigilance 3. Significance and need for Pharmacovigilance 4. Indian scenario and the role of regulatory in Pharmacovigilance	**15**
RUSBASP403	**PRACTICALS**	

1. Calculation of AUC and bioequivalence from the given data (2 expts.)
2. Evaluation of a BA/BE Report
3. Calculation of different Pharmacokinetic parameters like Ka, Ke, t½, C max, T_{max} and AUC from the given blood data.
4. Interpretation of IR, NMR and Mass Spectra of a given compound
5. Practicals based on Therapeutic drug monitoring using HPLC

Paper Code	Semester IV- Paper IV		Lectures
RPSBAS04	**Modern Analytical Techniques**		**60**
	404.1:	Thermal Analysis & X-ray Diffraction-X-ray Fluorescence	
		1. Principles of Thermal Analysis 2. Instrumentation Requirements 3. Applications of Thermal Analysis 4. Thermal analysis of Bhasma preparations 5. Thermal Analysis Techniques 6. Theory of XRD and XRF 7. Crystal structure of solids and concept of crystallography 8. Bragg's law of diffraction 9. Instrumentation of powdered XRD 10.Application in the determination of polymorphs in pharmaceutical compounds 11. Percent crystalanity, Single crystal XRD 12. Determination of the 3D structure 13. Wavelength dispersive (WD) and energy dispersive (ED) XRF 14. Instrumentation of WD and (ED)XRF 15. Applications of XRF for elemental analysis	**15**
	404.2:	Nuclear Magnetic Resonance Spectroscopy	
		1. General Introduction 2. Theory of NMR, Chemical shift, H-H coupling 3. Instrumentation and concept of FT-NMR 4. Applications to Biological and organic compounds 5. Concepts of 2D and 3D NMR 6. Structural elucidation using proton NMR 7. Theory of EPR, Para magnetism and absorption of radiation, 8. Instrumentation, 9. Use of free radicals as probe 10. Advances in NMR, Applications of 2D & 3D NMR.	**15**
	404.3:	Tracer techniques	
		1. Concept of Radioactivity & Half life 2. ∝, β, γ emitters and their biological applications 3. Using tracers in assays 4. Detectors and counters 5. Concept of autoradiography 6. Radio labelled probes and their uses	**15**
	404.4:	Chiral Chromatography & Circular Dichroism and Optical Rotatory Dispersion	
		1. Chiral Chromatography: a. Concept of Chirality b. Chiral HPLC, column chemistry and column conditions in Chiral HPLC c. Applications of chiral HPLC 2. Theory and Applications of: a. Circular Dichroism b. Optical Rotary Dispersion	**15**

RUSBASP404	PRACTICALS	120

Research Project:

1. Students are expected to identify a research problem relevant to the subject
2. The topic of research will be interdisciplinary, and will involve statistical analysis.
3. Thorough literature review will be carried out by the students.
4. A project Proposal will be submitted by the student and will get the approval from the mentor allotted by the department.
5. Students will report and update the allotted mentor regarding the project work.
6. Students are expected to support detailed report of the project work such as Laboratory notebooks
7. Final hardbound report as well as the soft copy report of the project work will be prepared by the student as per the guidelines/ format provided by the institution & will submit the same to the department before the examination
8. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and will face Viva voce based on the project work.

Learning Outcomes for M.Sc. in Bioanalytical Sciences

RPSBAS101 Principles of Bioanalysis

This will develop curiosity and interest in the field of Bioanalysis. Students will get acquainted with different bio- matrices, and extraction of analytes from the same.

RPSBAS201 Pharmacognosy and Phytochemistry

Students will be able to appreciate the therapeutic properties of plants and effectively use modern methods for extraction and analysis of phytoconstituents.

RPSBAS102 Spectroscopic techniques

This will enable students to use spectroscopic techniques like UV-Visible spectrophotometery, colorimetry, Turbidometry, to analyze different biological samples.

RPSBAS202 Chromatographic techniques

This will inculcate analytical approach regarding correct choice of analytical method and troubleshooting involved in different chromatographic techniques. The students will be able to effectively use chromatographs for analysis of samples and interpret the results.

RPSBAS103 Introduction to pharmacy

This will empower the student with the knowledge of pharmacopoeias. The student will be able to critically analyze drugs and dosage forms for different pharmacokinetic parameters.

RPSBAS203 Practices in Pharmaceutical Industry

This will give an insight into the good practices followed in industry operations. Students will realize the importance of documentation and strict adherence to protocol in bioanalytical industries.

RPSBAS104 Applied Biology

This will train students on analytical techniques like SDS-PAGE and immunoassays. Students will get acquainted with advances in the fields of genomics and proteomics.

RPSBAS204 IPR, Drug act and Regulations

This will familiarize students with the current legal scenario regarding intellectual property rights. Students will understand the importance of Drug act and the need for regulations in Bioanalysis.

RPSBAS301 Standardization of Ayurveda, Siddha &Unani Medicine

This will underline the importance of Bioanalytical techniques for standardization of traditional medicines. The project work introduced in the syllabus will inculcate the habit of innovative thinking, meticulous work and good laboratory practices.

RPSBAS401 Pharmaceutical Biotechnology & Pharmaceutical Manufacturing

This will train students to use appropriate Bioanalytical technique to assess the stability of pharmaceuticals. Students will understand the norms required for manufacturing in pharmaceutical industry.

RPSBAS302 Bioanalytical Techniques I

This will highlight the importance of hyphenated techniques and enable the students to analyze and interpret mass spectrometric data for identification and quantification of analytes. Students will also be able to run bioassays for pharmaceutical samples.

RPSBAS402 Bioanalytical techniques II

This will enable the students to use mass spectrometry for qualitative and quantitative analysis of data and conduct method development and validation on analytical instruments.

RPSBAS303 Applied Microbiology & Toxicology

This will empower the students to employ antimicrobial agents in an effective way. This will also highlight the importance of toxicological studies for ensuring safe administration of pharmaceuticals.

RPSBAS403 Fundamentals of Clinical Research

Students will be enlightened about the various aspects of clinical research. They will get a brief idea regarding the case report format involved in BA/BE study.

RPSBAS304 Bioanalytical Data Handling

Students will be able to analyze biological samples in a regulated manner and apply suitable statistical tests to extrapolate the observations to relevant results.

RPSBAS404 Modern Analytical Techniques

This will train students to interpret spectral data of IR, NMR and LC-MS for structural elucidation of analytes.