Resolution number: AC/II (23-24).2.RPS1

S. P. Mandali's

Ramnarain Ruia Autonomous College

(Affiliated to University of Mumbai)

Syllabus for

Program: M.Sc. in Bioanalytical Sciences

(Post-graduate syllabus)

Program Code: RPSBAS

As per guidelines of National Education Policy 2020-Academic Year 2024-25

(Choice Based Credit System)

GRADUATE ATTRIBUTES

GA	GA Description **A student completing Bachelor's/Master's Degree in Science program will be able to:**
GA1	Demonstrate in depth understanding in the relevant science discipline. Recall, explain, extrapolate and organize conceptual scientific knowledge for execution and application and also to evaluate its relevance.
GA2	Critically evaluate, analyze and comprehend a scientific problem. Think creatively, experiment and generate a solution independently, check and validate it and modify if necessary.
GA3	Access, evaluate, understand and compare digital information from various sources and apply it for scientific knowledge acquisition as well as scientific data analysis and presentation.
GA4	Articulate scientific ideas, put forth a hypothesis, design and execute testing tools and draw relevant inferences. Communicate the research work in appropriate scientific language.
GA5	Demonstrate initiative, competence and tenacity at the workplace. Successfully plan and execute tasks independently as well as with team members. Effectively communicate and present complex information accurately and appropriately to different groups.
GA6	Use an objective, unbiased and non-manipulative approach in collection and interpretation of scientific data and avoid plagiarism and violation of Intellectual Property Rights. Appreciate and be sensitive to environmental and sustainability issues and understand its scientific significance and global relevance.
GA7	Translate academic research into innovation and creatively design scientific solutions to problems. Exemplify project plans, use management skills and lead a team for planning and execution of a task.
GA8	Understand cross disciplinary relevance of scientific developments and relearn and reskill so as to adapt to technological advancements.

PROGRAM OUTCOMES

PO	Description **A student completing Integrated Master's Degree in Science program in the subject of Bioanalytical Sciences will be able to:**
PO1	Gain high quality science education in a vibrant academic ambience with the faculty of distinguished teachers and scientists.
PO2	Take up the challenge of doing quality research and teaching and also contribute to industrial production and R & D in the fields of Bioanalysis, Bioinformatics and Nutraceutical Sciences.
PO3	Amalgamate classical analytical chemical techniques with modern genomic and proteomic technologies of manufacturing and analysis to better characterize the products useful as medicines as well as nutraceuticals.

PROGRAM OUTLINE

YEAR	SEM	COURSE CODE	COURSE TITLE	Course Type	CREDITS
M.Sc. II	III	RPSBASO601/RPSINBASO601	OMICS	Discipline specific core course	3
		RPSBASO602/RPSINBASO602	Bioanalytical Techniques	Discipline specific core course	3
		RPSBASO603/RPSINBASO603	Modern Analytical Instrumentation	Discipline specific core course	3
		RPSEBASO604/RPSEINBASO604	Xenobiotic Analysis	Elective	3
		RPSEBASO605/RPSEINBASO605	Cancer Biology		
		RPSBASPO601/RPSINBASPO601	Practical based on RPSBASO601	Discipline specific core course	1
		RPSBASPO602/RPSINBASPO602	Practical based on RPSBASO602	Discipline specific core course	1
		RPSBASPO603/RPSINBASPO603	Practical based on RPSBASO603	Discipline specific core course	1
		RPSEBASPO604/RPSEINBASPO604	Practical based on RPSEBASO604	Elective	1
		RPSEBASPO605/RPSEINBASPO605	Practical based on RPSEBASO605		
		RPSRPBASO606/RPSRPINBASO606	Research Project		6
Total 22					
M.Sc. II	IV	RPSBASE611/RPSINBASE611	Clinical Research Industry	Discipline specific core course	3
		RPSBASE612/RPSINBASE612	Pharmaceutical Method Development and Validation	Discipline specific core course	3

		RPSEBASE613/RPSEINBASE613	Biopharmaceuticals & Biosimilars	Elective	3
		RPSEBASE614/RPSEINBASE614	Analytical Instrumentation in disease and disorder diagnostics		
		RPSBASPE611/RPSINBASPE611	Practical of RPSBASE611	Discipline specific core course	1
		RPSBASPE612/RPSINBASPE612	Practical of RPSBASE612	Discipline specific core course	1
		RPSBASPE613/RPSINBASPE613	Practical of RPSEBASE613	Elective	1
		RPSBASPE614/RPSINBASPE614	Practical of RPSEBASE614		
		RPSINTBASE615/RPSINTINBASE615	Internship	-	10

Course Code: RPSBASO601

Course Title: OMICS (Core Course)
Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Explain the applications of PCR techniques
CO2	Elaborate on the techniques involved in genome studies and also understand the significance of pharmacogenomic studies
CO3	Explain the techniques involved in transcriptome studies
CO4	Perform techniques involved in protein purification
CO5	Hands-on different methodologies used for proteomic and metabolomic studies

DETAILED SYLLABUS

Paper Code	Semester III- Paper I	Credits/ Hours
RPSBASO601	**OMICS**	**3/45**
601.1: Genomics 1. Introduction to genomics and its types. 2. Genome sequencing techniques- Sanger sequencing, Maxim Gilbert Sequencing, Next generation sequencing techniques (Illumina sequencing, 454 pyrosequencing, etc), Overview of whole genome sequencing 3. Types of SNPs and techniques to identify them (suitable examples of techniques based on restriction digestion, microarray, DNA conformation, and DNA sequencing). 4. Identification for SNPs for diseases- Haplotypes, Linkage disequilibrium, Genome wide association 5. Pharmacogenomics-. Correlation of SNPs with variations of ADME. (With suitable examples such as CYP gene variations), Variations in ethnic groups and races. 6. Introduction to epigenomics		**15**
601.2: Transcriptomics 1. Introduction to transcriptome, structure of eukaryotic m-RNA, exons, introns, splice variants. Types of non-coding RNAs 2. cDNA libraries and Expressed Sequence Tags (ESTs) 3. Techniques of gene expression analysis (Northern blot, in-situ hybridization, qRT-PCR, microarrays, RNA-seq, etc), Overview whole transcriptome sequencing 4. Transcriptomics biomarkers- mRNA and non-coding RNAs as biomarkers with suitable examples.		**15**

601.3: Proteomics and Metabolomics	
1. Protein extraction, separation, purification and identification 2. Types of Proteomics with suitable examples–, Functional Proteomics, Structural Proteomics, Post translational modifications, Protein-Protein interaction, Protein expression profiling, Proteome mining, Human Proteome Project 3. Protein fingerprinting techniques, De Novo sequencing of protein 4. Advanced techniques in proteomics: Co-immunoprecipitation, Yeast-2hybrid, Label free and label -based methods for protein quantification 5. Introduction to Peptidomics 6. Metabolomics- Lipidomics, Glycomics	**15**
RPSBASPO601 PRACTICALS	Credits/ Hours
1. Protein extraction, purification and quantitation from any biological source 2. Plasma protein profiling, plant protein profiling using SDS-PAGE 3. Plant DNA extraction and analysis using suitable method 4. Amplification of DNA by PCR 5. RFLP analysis 6. RT-PCR (demo)	1/30

References:

1. iGenetics A molecular Approach: Russell
2. Lehninger's Principle of Biochemistry : David Nelson, Michael Cox : Springer
3. Principles of Gene Manipulation and Genomics: Sandy B. Primrose, Richard Twyman
4. Genomics: Concepts and Applications: Caleb Elliot
5. Genomics and Proteomics- Functional and Computational Aspects: Sándor Suhai
6. Principles of Proteomics: Richard Twyman
7. Metabolomics: A Powerful Tool in Systems Biology
8. Omics in Clinical Practice- Genomics, Pharmacogenomics, Proteomics, and Transcriptomics in Clinical Research: Yu Liu

Course Code: RPSBASO602

Course Title: Bioanalytical Techniques (Core Course)

Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Explain different analytical techniques like XRD-XRF
CO2	Analyse and interpret mass spectrometric data for identification and quantification of analytes.
CO3	State and explain the principles and applications of NMR spectroscopy with special emphasis on Bioanalysis

DETAILED SYLLABUS

Paper Code	Semester III- Paper III	Credits/ Hours
RPSBASO602	**Bioanalytical Techniques**	**3/45**
602.1: XRD and XRF		**15**
1. Theory of XRD and XRF 2. Crystal structure of solids and concept of crystallography 3. Bragg's law of diffraction 4. Instrumentation of powdered XRD 5. Application in the determination of polymorphs in pharmaceutical compounds 6. Percent crystallinity, Single crystal XRD 7. Determination of the 3D structure 8. Wavelength dispersive (WD) and energy dispersive (ED) XRF 9. Instrumentation of WD and (ED)XRF 10. Applications of XRF for elemental analysis		
602.2 Mass Spectrometry(MS)		**15**

1. Evolution of MS and its importance as a detector 2. Components of Mass Spectrometer: a) Inlets b) Ion sources- GC-MS: EI,CI; LC-MS: ESI,API(APCI & APPI), FI,FD,FAB,TSP, MALDI c) Analyzers- QP,TOF, Ion trap, Magnetic sector, Hybrid analyzers d) Detectors 3. Importance of vacuum in MS system 4. Interfaces used in LC-MS & GC-MS 5. Sample preparation for MS 6. Introduction to MS/MS (tandem MS): GC/MS and GC/MS/MS; LC/MS and LC/MS/MS 7. Scan events in Triple Quadrupole and other tandem systems and hybrid Systems	
602.3: NMR and its applications in Bioanalysis	**15**
1. Basic Phenomenon of Nuclear Magnetic Resonance(NMR) Spectroscopy: Nuclear spin transition, magnetic dipole 2. Chemical Shielding 3. Chararacteristic ^{1}H, ^{13}C and ^{15}N chemical shifts 4. Factors affecting chemical shifts 5. Chemical shift dispersion and multi-dimensional NMR 6. Applications in Bioanalysis	
RPSBASPO602 PRACTICALS	Credits/Hours
1. HPLC analysis of modern drug from plasma 2. LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.) 3. GC/MS separation of plant essential oil 4. Mass Fingerprinting of peptides using a suitable sample 5. IR analysis of a purified compound 6. Structural elucidation of a compound on the basis of its FTIR, NMR and MS outputs.	1/30

REFERENCES:

1. Principles of Instrumental Analysis - Skoog, Holler, Crouch
2. Modern Practices in Gas-Chromatography- Robert L. Grob, Eugene F. Barry
3. Radioactive Tracer Techniques by George Keene Schweitzer
4. Handbook of Analytical Techniques, Vol I & II- Wiley Publications

Course Code: RPSBASO603

Course Title: Modern Analytical Instrumentation (Core Course)
Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Gain a comprehensive understanding of differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), differential thermal analysis (DTA), and other thermal analysis techniques, including their principles, instrumentation, and applications.
CO2	Recognize the fundamental principles of chiral chromatography, including the mechanisms of enantiomeric separation, types of chiral stationary phases, and selection criteria for appropriate chromatographic conditions.
CO3	Explain the principles and instrumentation of CD-ORD, including its application in analyzing the structural and conformational properties of chiral molecules.

DETAILED SYLLABUS

Paper Code	Semester III- Paper III	Credits/ Hours
RPSBASO603	**Modern Analytical Instrumentation**	**3/45**
603.1: Thermal Analysis		**15**
1. Principles of Thermal Analysis 2. Instrumentation Requirements 3. Sample preparation, Experimental conditions, Techniques in Thermal Analysis 4. Applications of Thermal Analysis 5. Thermal analysis of Bhasma preparations (Case studies e.g. Praval bhasma, Lohabhasma)		
603.2: Chiral Chromatography		**15**

1. Concept of chirality 2. Types of Chiral Chromatographic techniques (Direct and Indirect Chiral HPLC). 3. Principle of chiral separation using chiral liquid chromatography. 4. Chiral HPLC- Instrumentation 5. Classes and types of Chiral Stationary Phases (CSPs) – brush type, helical polymer type, cavity type, protein based, macrocyclic glycopeptide based; materials used for preparing them and their chemistry, mobile phases used in Chiral HPLC. 6. Special type of detectors used in Chiral HPLC. 7. Applications of chiral HPLC in analysis of pharmaceuticals, pesticides and natural products.	
603.3: CD-ORD	**15**
1. Molecular dissymmetry and chiroptical properties, nature of light – linearly and circularly polarised light 2. Circular Dichroism, CD Spectroscopy instrumentation and its application in analysis of proteins and nucleic acids. 3. Optical Rotary Dispersion, Circular birefringence and cotton effect 4. ORD Spectroscopy and its instrumentation. 5. Types of ORD curves and their applications. 6. Octant Rule and α –halo ketone rule with their applications. 7. Differences between CD and ORD.	
RPSBASPO603 PRACTICALS	Credits/Hours
1. Purification of a compound using preparative HPTLC/HPLC. 2. Simultaneous analysis of Iron by colorimetry and AAS 3. IR analysis of bhasma sample 4. HPTLC analysis of a drug from plasma. 5. Metabolic profiling using HPTLC	1/30

References:

1. Stereochemistry of Organic Compounds by D.Nasipuri
2. Chiral Analysis: Advances in Spectroscopy, Chromatography and Emerging Methods by Daniel W. Armstrong. (2nd edition)
3. Fundamentals of Analytical Chemistry by D.A Skoog, D.M. West, F.J. Holler.

Course Code: RPSRPBASO606

Course Title: Research Project

Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Formulate hypothesis, carry out literature survey, test hypothesis by designing experiments, and interpret the results
CO2	State the importance of proper documentation and present the research carried out.
CO3	Get trained to face the challenges of industry and acquire requisite skills in the field of Bioanalysis and research.

DETAILED SYLLABUS

Paper Code	Semester III- Paper VI	Credits/ Hours
RPSRPBASO606	**Research Project**	**6/180**
Research project 1. Students are required to complete a Research project for duration of 8-12 weeks. 2. Students are required to submit a report of the Research project in the format provided by the college/department. 3. A certificate of successful completion provided by the research institute should be attached in the submitted report. 4. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face *viva voce* based on the project work. Research Review: 1. Students should identify a topic for literature review 2. They should review at least 15 research articles for the review topic 3. Review article should be a detailed, comprehensive summary of the research articles in student's own words. 4. Final hardbound report as well as the soft copy report of the review article should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination 5. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on review article. Research based on Survey/Case study 1. Students should identify a topic for survey/case study 2. They should prepare an outline for data collection that can include questionnaire/interviews/referencing and present the same. Data collection can be done online, if required. 3. They should gather data for survey/case study in a stipulated time and keep record of the same. 4. After data, collection, students should analyze the data using appropriate statistical tests and write final conclusion of the study. 5. Final hardbound report as well as the soft copy of the survey/case study report should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination 6. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on survey/case study article.		

Course Code: RPSBASE611

Course Title: Clinical Research Industry (Core Course)

Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Give an account of the various aspects of clinical research.
CO2	Evaluate the case report format involved in BA/BE study.
CO3	Calculate pharmacokinetic parameters for the given drug.

DETAILED SYLLABUS

Paper Code	Semester IV- Paper I	Credits/Hours
RPSBASE611	**Clinical Research Industry**	**3/45**
611.1: Design and Conduct of Clinical Study		**15**
1. Clinical Trial Designs: Types 2. Preparing for clinical study 3. Study Initiation, Monitoring, Study closeouts 4. Overview of clinical audits 5. Regulatory compliance 6. Preparation and submission of clinical dossier		
611.2: Bioavailability and Bioequivalence		**15**
Bioavailability and Bioequivalence (8 L) 1. Concept of BA and BE 2. Parameters to evaluate BA and BE of a drug 3. Evaluating BA and BE of a drug 4. Design and conduct of a BA and BE study 5. Data record and reporting in BA and BE study 6. Regulatory requirements of BA and BE **Pharmacovigilance (4 L)** 1. Introduction to Pharmacovigilance 2. Significance and need for Pharmacovigilance 3. Indian scenario and the role of regulatory in Pharmacovigilance 4. Pharmacovigilance and safe use of medicines (with case studies) **Therapeutic Drug Monitoring (03 L)** 1. Purpose of therapeutic drug monitoring 2. Bioanalytical techniques in TDM 3. Analytical and practical issues of TDM 4. Pharmaco-economics of TDM		
611.3: Clinical Data Management		**15**

1. Introduction to CDM 2. Collection, Cleaning, and Management of subject data 3. Tools for CDM 4. Regulations, Guidelines, and Standards in CDM 5. The CDM Process 6. Review and finalization of study documents 7. Database designing, Data Collection 8. CRF tracking 9. Data entry & Validation, Medical Coding 10. Roles and Responsibilities in CDM	
RPSBASPE611 PRACTICALS	**Credits /Hours**
1. Calculation of AUC and bioequivalence from the given data (2 expts.) 2. Calculation of different Pharmacokinetic parameters like K_a, K_e, $t_{1/2}$, C_{max}, T_{max} and AUC from the given blood data. 3. Study of sample forms, checklists and logs of a clinical study 4. Evaluation of a BA/BE Report 5. Introduction to registry resources such as ct.gov 6. Introduction to medical writing	1 /30

References:

1. Principles of Good Clinical Practice: McGraw, George, Shearn, Hall and Thomas
2. Good Clinical Practice Standard Operating Procedures for Clinical Researchers: Graeme Scott, Josef Kolman, Paul Meng
3. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections: Vera Mihajlovic-Madzarevic
4. Design & Analysis of Bioavailability & Bioequivalence studies: Shein-Chung Chow & Jen-Pei Liu
5. Biopharmaceutics Applications in Drug Development: Rajesh Krishna & Lawrence Yu
6. Bioavailability and Bioequivalance in Pharmaceutical technology: T. K. Pal, P. K. Ganesan
7. Therapeutic Drug Monitoring: Newer Drugs and Biomarkers: Amitava Dasgupta
8. Therapeutic Drug Monitoring and Toxicology by Liquid Chromatography: Wong

Course Code: RPSBASE612

Course Title: Pharmaceutical Method Development and Validation (Core Course)

Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Perform method development and validation using analytical instruments.
CO2	Comprehend the additional issues of endogenous substances and biomarkers in Bioanalytical Method Development.
CO3	Perform method validation using sophisticated analytical instruments like HPLC or GC.

DETAILED SYLLABUS

Paper Code	Semester IV- Paper II	Credits/Hours
RPSBASE612	**Pharmaceutical Method Development and Validation**	**3/45**
612.1: Validation in Pharmaceuticals Industry 1. Types of validation in Pharma: Analytical, Process, Cleaning and Equipment 2. Process validation: Design, Qualification and verification 3. Cleaning validation and its significance 4. Types of Equipment validation-IQ, OQ, PQ 5. Study of Installation Qualification, Operational Qualification, Performance Qualification of any one analytical instrument.		**15**
612.2: Analytical Method Development (AMD) and Analytical Method Validation (AMV) 1. Concept of method development and validation, Parameters for Method Validation, ICH guidelines 2. Method Development and Validation in HPTLC, GC, GCMS, HPLC and LC-MS: Approach, Methodology and troubleshooting (with suitable examples)		**15**
612.3: Bioanalytical Method Development (BMD) and Bioanalytical Method Validation (BMV)		**15**

Bioanalytical Method Development (BMD) (07 L) 1. Strategies for Method development 2. Difference between AMD and BAMD, AMV and BAMV. 3. Regulatory requirements of validation **Bioanalytical Method Validation (BMV) (08L)** 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.	
RPSBASPE612 PRACTICALS	**Credits/Hours**
1. GC analysis of herbal raw material & ASU formulations 2. Analytical Method Validation (any one example) 3. Interpretation of GCMS spectra 4. Interpretation of LCMS spectra	1/30

References

1. Principles of Instrumental Analysis, Author: Skoog, Holler, Crouch
2. Method Validation in Pharmaceutical Analysis, Edited by: Ermer&Nethercote
3. Analytical chemistry by open learning- Mass spectrometry
4. Analytical Method Development And Validation: Swartz and Krull
5. Validation of Analytical Methods, Methodology and Statistics : Shrivastava and Saxena
6. Bioanalytical Method Validation: Waghulkar, Deshpande & Rathod

Course Code: RPSINTBASE615

Course Title: Project Work

Academic year 2024-25

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Student will be trained to face the challenges of industry and will acquire requisite skills in the field of Bioanalysis and research.
CO2	Students should understand the importance of proper documentation and should be able to present the research carried out.

DETAILED SYLLABUS

Paper Code	Semester IV- Paper V	Credits/Hours
RPSINTBASE615	**Industrial Training/Research Project**	**10/300**
Industrial Training 1. Students are required to complete an Industrial Training for duration of 8-12 weeks. 2. Students are required to submit a report of the Industrial Training in the format provided by the college/department. 3. A certificate of successful completion provided by the company/research institute should be attached in the submitted report. 4. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face viva voce based on the Training. **Research Project** 1. Students are expected to identify a research problem relevant to the subject 2. The topic of research should be interdisciplinary, and should involve statistical analysis. 3. Thorough literature review should be carried out by the students. 4. A project Proposal should be submitted by student and should get approval from mentor(s) allotted by the department. 5. Students should 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 should be prepared by the student as per the guidelines/ format provided by the institution & should 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 should face Viva voce based on the project work. **Research Review:** 1. Students should identify a topic for literature review 2. They should review at least 15 research articles for the review topic 3. Review article should be a detailed, comprehensive summary of the research articles in student's own words. 4. Final hardbound report as well as the soft copy report of the review article should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination 5. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on review article. **Research based on Survey/Case study** 1. Students should identify a topic for survey/case study 2. They should prepare an outline for data collection that can include questionnaire/interviews/referencing and present the same. Data collection can be done online, if required. 3. They should gather data for survey/case study in a stipulated time and keep record of the same. 4. After data, collection, students should analyze the data using appropriate statistical tests and write final conclusion of the study. 5. Final hardbound report as well as the soft copy of the survey/case study report should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination 6. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on survey/case study article.	