**Resolution number: AC/II(22-23).3.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 the guidelines of National Education Policy 2020-Academic year 2023-24)**

**(Choice based Credit System)**

# Graduate Attributes

S. P. Mandali's Ramnarain Ruia Autonomous College has adopted the Outcome Based Education model to make its science graduates globally competent and capable of advancing in their careers. The Bachelors Program in Science also encourages students to reflect on the broader purpose of their education.

| GA | GA Description<br>**A student completing Bachelor's/Master's Degree in Science program will be able to:** |
|---|---|
| **GA 1** | 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. |
| **GA 2** | Critically evaluate, analyze and comprehend a scientific problem. Think creatively, experiment and generate a solution independently, check and validate it and modify if necessary. |
| **GA 3** | 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. |
| **GA 4** | Articulate scientific ideas, put forth a hypothesis, design and execute testing tools and draw relevant inferences. Communicate the research work in appropriate scientific language. |
| **GA 5** | 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. |
| **GA 6** | 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. |
| **GA 7** | 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. |
| **GA 8** | Understand cross disciplinary relevance of scientific developments and relearn and reskill so as to adapt to technological advancements. |

# PROGRAM OUTCOMES

| PO | Description<br><br>**A student completing Master's Degree in Science program in the subject of Bioanalytical Sciences will be able to:** |
|---|---|
| **PO 1** | Gain high quality science education in a vibrant academic ambience with the faculty of distinguished teachers and scientists. |
| **PO 2** | 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. |
| **PO 3** | 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 | RPSBAS301 | Molecular Biology and OMICS | - | 4 |
| | | RPSBAS302 | Modern Analytical Instrumentation | - | 4 |
| | | RPSBAS303 | Bioanalytical Techniques | - | 4 |
| | | RPSBASP301 | Practicals on RPSBAS301 | - | 2 |
| | | RPSBASP302 | Practicals on RPSBAS302 | - | 2 |
| | | RPSBASP303 | Practicals on RPSBAS303 | - | 2 |
| | | RPSBASP304 | Internship/Research Project | - | 6 |
| | | | | | |
| M.Sc. II | IV | RPSBAS401 | Clinical Research Industry | - | 4 |
| | | RPSBAS402 | Pharmaceutical Method Development and Validation | - | 4 |
| | | RPSBASE403 | Biopharmaceuticals & Biosimilars | - | 4 |
| | | RPSBASE404 | Xenobiotic Analysis | | |
| | | RPSBASP401 | Practicals on RPSBAS401 | - | 2 |
| | | RPSBASP402 | Practicals on RPSBAS402 | - | 2 |

| | | | | | |
|---|---|---|---|---|---|
| | | RPSBASEP403 | Practicals on RPSBASE403 | - | 2 |
| | | RPSBASEP404 | Practicals on RPSBASE404 | | |
| | | RPSBASP405 | Internship/Research Project | - | 6 |

## Course Code: RPSBASE403

## Course Title: Biopharmaceuticals & Biosimilars (Elective Course)
## Academic year 2023-24

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Give an account of Biopharmaceutical Industry |
| **CO 2** | Describe the development and regulations for Biopharmaceuticals & Biosimilars |
| **CO 3** | Explain the strategies involved in analysis of Biopharmaceuticals and Biosimilars |

### DETAILED SYLLABUS

| Paper Code | Semester IV- Paper III | Credits/ Hours |
|---|---|---|
| **RPSBASE403** | **Biopharmaceuticals & Biosimilars** | **4/60** |
| **403.1: Introduction to Biopharmaceuticals & Biosimilars** | | |
| 1. Therapeutics based on biotechnology<br>2. Current status of Biopharmaceutical Industry<br>3. Biopharmaceutics Classification System, Types of Biosimilars | | **15** |
| **403.2: Biopharmaceuticals : Development and Regulations** | | |
| 1. Development of Biopharmaceuticals<br>2. Pharmacology, Toxicology, Therapeutic Dosage Formulations, and Clinical Response<br>3. Regulatory Aspects ( United states & Japan) | | **15** |
| **403.3: Biosimilars: : Development and Regulations** | | |
| 1. Need for Biosimilar development<br>2. Understanding Small vs. Large Molecules<br>3. Scientific Factors in Biosimilar Product Development<br>4. Non clinical and Clinical studies<br>5. Biosimilar Regulatory Challenges | | **15** |
| **403.4: Analysis of Biopharmaceuticals and Biosimilars** | | |
| 1. Analytical methods for analysis of Biopharmaceuticals and Biosimilars<br>2. Structural and functional characterization of Biosimilars using chromatography and spectroscopy<br>3. Method Development and validation for Biosimilar and Biopharmaceutical Analysis<br>4. Bioanalysis of Biopharmaceuticals and Biosimilars | | **15** |

| **RPSBASEP403** | |
|---|---|
| 1. Study of biopharmaceuticals and Biosimilars (types and assays) 2. Analysis of a biosimilar using Capillary Electrophoresis<br>3. Protein purification and analysis<br>4. Shelf life, stability study of biopharmaceutical<br>5. Quality control tests for finished biopharmaceuticals | **1/30** |

**REFERENCES:**

1. Biopharmaceutics Applications in Drug Development: Rajesh Krishna & Lawrence Yu 2. Bioavailability and Bioequivalance in Pharmaceutical technology: T. K. Pal, P. K. Ganesan 3. Biopharmaceuticals: S.N. Jogdand
4. Biopharmaceuticals: Biochemistry and Biotechnology: Gary Walsh
5. Biopharmaceutics - From Fundamentals to Industrial Practice: In Hannah Batchelor 6. Biopharmaceutics & Pharmacokinetics: V Venkateswarlu
7. Biosimilars- Regulatory, Clinical, and Biopharmaceutical Development: In Hiten J. Gutka, Harry Yang, Shefali Kakar
8. Biosimilars: A New Generation of Biologics- Jean-Louis Prugnaud, Jean-Hugues Trouvin

## Course Code: RPSBASE404

## Course Title: Xenobiotic Analysis (Elective Course)
## Academic year 2023-24

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Give an account of Xenobiotics |
| **CO 2** | Describe the generation and identification of xenobiotic metabolites |
| **CO 3** | Explain the strategies involved in analysis of Xenobiotics from different matrices |

### DETAILED SYLLABUS

| Paper Code | Semester IV- Paper IV | Credits/ Hours |
|---|---|---|
| **RPSBASE404** | **Xenobiotic Analysis** | **4/60** |
| **404.1: Introduction to Xenobiotics** | | |
| 1. Xenobiotics and their types<br>2. Environmental impact of xenobiotics, bioremediation<br>3. Volatile organic compounds<br>4. Pharmaceutical Xenobiotics and their biotransformation- Phase reactions | | **15** |
| **404.2: Metabolites of pharmaceuticals** | | |
| 1. Methods for metabolite generation<br>2. Isolation and identification of drug metabolites<br>3. Structural elucidation of drug metabolites using NMR<br>4. Safety testing of Drug metabolites | | **15** |
| **404.3: Analysis of Xenobiotics in biological and environmental matrices** | | |
| 1. Application of accelerated solvent extraction and micro extraction techniques in the analysis of organic contaminants, bioactive and nutritional compounds<br>2. Analysis of small molecule drugs in Biological fluids<br>3. Capillary electrophoresis in the analysis of drug and drug products<br>4. Immunoassays in drug analysis. | | **15** |
| **404.4: Mass spectrometry of Xenobiotics** | | |
| 1. Quantitation of Biomarkers and Metabolites using LC-MS and LC MS/MS<br>2. Quantitation of Biomarkers and Metabolites using HPTLC-MS and GCMS 3. Impurity profiling of drug and drug products<br>4. Trends in pesticide and residual solvent analysis<br>5. Rapid analysis of pharmaceuticals and excreted xenobiotic and endogenous | | **15** |

| | |
|---|---|
| metabolites | |
| **RPSBASEP404** | |
| 1. Extraction and analysis of drug/metabolite from suitable body fluid<br>2. Detection of pesticide from plasma usinPg suitable chromatographic techniques<br>3. Analysis of residual solvents using GCMS<br>4. Analysis of a drug using Capillary Electrophoresis<br>5. Structural elucidation of a compound using IR, MS and NMR. | **1/30** |

**REFERENCES:**

1. Principles of Instrumental Analysis, Author: Skoog, Holler, Crouch
2. Environmental Xenobiotics: Mervyn Richardson
3. Advances in the Determination of Xenobiotics in Foods: Belen Gomara, Maria Luisa Marina
4. Method Development for the Analysis of Xenobiotics in Biological Matrix: Roberto Pérez Viera
5. Biotransformation and Metabolite Elucidation of Xenobiotics-Characterization and Identification: In Ala F. Nassar
6. Metabolism of Drugs and Other Xenobiotics: In Pavel Anzenbacher, Ulrich M. Zanger
7. Application of Mass Spectrometric Methods to Analysis of Xenobiotics in Biological Systems: M. L. Gross

# Modality of Assessment

**Sem III & IV**

**Theory Examination Pattern:**

**A) Internal Assessment- 40%- 40 Marks**

| Sr No | Evaluation type | Marks |
|---|---|---|
| 1. | Internal Examination | 20 |
| 2. | Assignment/Group Discussion/Presentation/Class Activity | 20 |
| | **TOTAL** | **40** |

**B) External Examination- 60%- 60 Marks**

**Semester End Theory Examination:**

1. Duration - These examinations shall be of **2.5 Hrs** duration.
2. Theory question paper pattern:

**Paper Pattern (except RPSBASP304):**

| Question | Options | Marks | Questions Based on |
|---|---|---|---|
| Q.1 Short answer questions (4 Marks each) | 3 out of 4 | 12 | Unit I |
| Q.2 Short Answer questions (4 Marks each) | 3 out of 4 | 12 | Unit II |
| Q.3 Short Answer questions (4 Marks each) | 3 out of 4 | 12 | Unit III |
| Q.4 Short Answer questions (4 Marks each) | 3 out of 4 | 12 | Unit IV |
| Q.5 Objective/short answer questions (3 Marks each) | 4 out of 6 | 12 | Combination of all units |
| | **TOTAL** | **60** | |

**Practical Examination Pattern:**

**A) Internal Examination: 40%- 40 Marks**

| **Particulars** | |
|---|---|
| Journal | 10 |
| Experimental tasks/Attendance | 10 |
| Small project/Class assignment/Presentation/Activity/Viva | 20 |
| **Total** | **40** |

**B) External Examination: 60%- 60 Marks**

**Semester End Practical Examination:**

| **Particulars** | **Paper** |
|---|---|
| Required Experiments Performed with appropriate principle, approach, Observations, Result, Demonstration of skills, Conclusion and Viva. | **60** |
| **Total** | **60** |