**Resolution number: AC/I(21-22).2(II). 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

**(Choice Based Credit System for the academic year 2022-23)**

# GRADUATE ATTRIBUTES

| 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 Integrated 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 |
|---|---|---|---|---|---|
| I.M.Sc. I | VII | RPSBAS701 | Modern Pharmaceutical Industry | CC | 4 |
| | | RPSBAS702 | Pharmacology, Toxicology & Bioassays | CC | 4 |
| | | RPSBAS703 | Advances in Spectroscopy & Chromatography | CC | 4 |
| | | RPSBAS704 | Extraction methodologies in Biological Analysis | SEC | 4 |
| | | RPSBAS705 | Resume Building & Soft Skills | AEC | 2 |
| | | RPSBASP701 | Practical I | - | 2 |
| | | RPSBASP702 | Practical II | - | 2 |
| | | RPSBASP703 | Practical III | - | 2 |
| | | RPSBASP704 | Practical IV | - | 2 |
| I.M.Sc. I | VIII | RPSBAS801 | Practices in Pharmaceutical Industry | CC | 4 |
| | | RPSBAS802 | Process of Drug Discovery & Development | CC | 4 |
| | | RPSBAS803 | Medicinal Systems & Standardization of Herbal Drugs | CC | 4 |
| | | RPSBAS804 | Bioinformatics & Biostatistics | SEC | 4 |
| | | RPSBAS805 | Research Methodology & Scientific Communication | AEC | 2 |
| | | RPSBAS801 | Practical I | - | 2 |
| | | RPSBASP802 | Practical II | - | 2 |
| | | RPSBASP803 | Practical III | - | 2 |

| | | | | | |
|---|---|---|---|---|---|
| | | RPSBASP804 | Practical IV | - | 2 |
| I.M.Sc. II | IX | RPSBAS901 | Fundamentals of Clinical Research Industry | - | 4 |
| | | RPSBAS902 | Modern Analytical Instrumentation | - | 4 |
| | | RPSBAS903 | Research methodology and Biostatistics | - | 4 |
| | | RPSBAS904 | Internship/Research Project | - | 8 |
| | | RPSBASP901 | Practical I | - | 2 |
| | | RPSBASP902 | Practical II | - | 2 |
| I.M.Sc. II | X | RPSBAS1001 | Method validation in pharmaceutical analysis | - | 4 |
| | | RPSBAS1002 | Biopharmaceuticals & Biosimilars | - | 4 |
| | | RPSBAS1003 | Xenobiotic Analysis | - | 4 |
| | | RPSBAS1004 | Internship/Research Project | - | 8 |
| | | RPSBASP1001 | Practical I | - | 2 |
| | | RPSBASP1002 | Practical II | - | 2 |

# Course Code: RPSBAS701 (Core Course)
# Course Title: Modern Pharmaceutical Industry

## Academic year 2022-23

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will learn the applications of microbiology for testing quality of pharmaceutical products. |
| **CO 2** | Students will understand the norms required for manufacturing in pharmaceutical industry. |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper I | Lectures |
|---|---|---|
| **RPSBAS701** | **Modern Pharmaceutical Industry** | **60** |
| **701.1: Pharmaceutical Manufacturing & Pharmaceutical Microbiology** | | |
| **Pharmaceutical Manufacturing (07 lectures)**<br>1. Asepsis, Disinfection and Sterilization, Concept of death curve of microbial population, Aseptic filling in Pharmaceutical Industry, Classification of Clean Rooms/ Clean areas, Quality Control and Quality Assurance in Pharmaceutical Industry<br>2. Important microbes for Food and drug industry, Pathogenic organisms in Food and Pharmaceutical Industry.<br>3. Sources of Contamination, Microbial Contamination in Ayurveda, Siddha & Unani (ASU) preparations.<br>4. Regulatory microbiological testing in pharmaceuticals<br>5. Microbiological assays for pharmaceutical products<br><br>**Pharmaceutical Microbiology (08 Lectures)**<br>1. Overview of Pharmaceutical manufacturing<br>2. Importance of Schedule M (D& C) in Pharmaceutical manufacturing process<br>3. Regulatory requirements in pharmaceutical manufacturing process<br>Unit operations and advances in: Manufacturing of oral solid dosage forms, oral liquid dosage forms, sterile injectables and topical dosage forms | | **15** |
| **701.2: Packaging of Pharmaceutical Products** | | |
| 1. Introduction to Packaging<br>2. Fundamentals of Distribution<br>3. Packaging Forms & their Significance<br>4. Packaging Materials<br>5. Paper, Paper Board and CFB Glass, metals, Basic Polymer based materials, Polymer based composite materials<br>6. Ancillary Mats<br>7. Package Material Testing<br>8. Compatibility & Migration Studies<br>9. Packaging Validation<br>10. Packaging Laws and regulatory compliance | | **15** |

| **701.3: Marketing of Pharmaceuticals** | |
|---|---|
| 1. Stages leading to marketing Authorization<br>2. Marketing authorization in EU and India<br>3. Unlicensed indication<br>4. Advertising of Pharmaceuticals<br>a. FDA<br>b. Direct to Consumer Advertising<br>i. Disclaimer<br>ii. Perception of Risk<br>5. Medical representatives & Promotional activities<br>6. Ethics | **15** |
| **701.4: Nutraceuticals** | |
| 1. Organizational elements<br>2. Classification of nutraceuticals, dietary supplements, fortified foods, functional foods and phytonutracuticals.<br>3. Scope involved in the industry, Indian and global scenario.<br>4. Nutraceuticals of plant and animal origin:<br>a. Plant secondary metabolites- classification and sub-classification - Alkaloids, phenols, Terpenoids. Extraction and purification, applications with specific examples with reference to skin, hair, eye, bone, muscle, heart, brain, liver, kidney, general health and stimulants. Concept of cosmoceuticals and aquaceuticals.<br>b. Animal metabolites - Sources and extraction of nutraceuticals of animal origin. Examples: chitin, chitosan, glucosamine, chondroitin sulphate and other polysaccharides of animal origin, uses and applications in preventive medicine and treatment.<br>c. Microbial and algal nutraceuticals Concept of prebiotics and probiotics - principle, mechanism, production and technology involved, applications - examples of bacteria used as probiotics, use of prebiotics in maintaining the useful microflora - extraction from plant sources. Synbiotics for maintaining good health. Algae as source of omega - 3 fatty acids, antioxidants and minerals - extraction and enrichment.<br>5. Basis of claims for a compound as a nutraceuticals.<br>6. Regulatory issues for nutraceuticals including CODEX role of nutraceuticals/functional foods<br>7. Clinical testing of nutraceuticals and health foods | **15** |
| **RPSBASP701: PRACTICAL I** | |
| 1. Total Viable Count of microorganisms from herbal Raw materials and formulations<br>2. Study of MIC of a pharmaceutical product<br>3. Study of Hardness and Friability of a tablet<br>4. Study of Disintegration and Dissolution of a tablet as per IP/USP (uncoated)<br>5. Study of compatibility of container (primary/secondary packaging) with the drug<br>6. Evaluation of a nutraceutical production as per corresponding standard protocols | |

**References:**

1. Pharmaceutical Manufacturing Handbook, Production and Processes, Edited by: Shayne Cox Gad
2. Hugo and Russell's Pharmaceutical Microbiology
3. Prescott, Harley and Klein's Microbiology: Willey, Sherwood and Woolverton

4. Remington The Science and Practice of Pharmacy- Lippincott Wiliams & Wilkins
5. Pharmaceutical Packaging Handbook: Edward Bauer
6. Remington, Essentials of Pharmaceutics: Linda Felton

# Course Code: RPSBAS702 (Core Course)

# Course Title: Pharmacology, Toxicology & Bioassays

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will be able to design and perform bioassays. |
| **CO 2** | Students will realize the importance of toxicological studies for ensuring safe administration of pharmaceuticals. |
| **CO3** | Students will get hands-on training in toxicological assays. |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper II | Lectures |
|---|---|---|
| **RPSBAS702** | **Pharmacology, Toxicology & Bioassays** | **60** |
| **702.1: Pharmacology** | | |
| 1. Scope of Pharmacology<br>2. Routes of Drug Administration<br>3. Dose- Response Relationship<br>4. Factors influencing drug dosage and drug action.<br>5. Drug disposition & Pharmacokinetics<br>6. Drug Metabolism: Introduction, Absorption, Distribution, Bio-transformation, Excretion<br>7. Mechanisms of Drug Action- Pharmacodynamics<br>8. Different Pharmacokinetic & Pharmacodynamics parameters and their meanings and basic techniques to evaluate the parameters<br>9. Basic types of models in Pharmacokinetics & Pharmacodynamics | | **15** |
| **702.2: Toxicology** | | |
| 1. Introduction, History, Scope and types of toxicological studies<br>2. Toxicants and their classification<br>3. Mode of action of Toxicants (Toxicokinetics and Toxicdynamics)<br>4. Dose Toxicity Relationship<br>5. Adverse drug reaction & treatment of Poisoning<br>6. Concept of LC 50, LD50, ED50<br>7. Applications of Toxicology<br>8. Introduction to Regulatory Toxicology<br>9. Types of toxicity tests<br>10. OECD Guidelines on Toxicological studies- Design considerations, Evaluation of results, Extrapolation to man<br>11. Risk analysis of Food & Drug related substances<br>12. Environmental impact assessment | | **15** |
| **702.3: Bioassays** | | |

| | |
|---|---|
| 1. General idea about bioassay systems used in pharmaceutical evaluations<br>2. *Invitro* assays and *invivo* assays<br>3. Ethical issues involved in animal assay systems<br>4. Alternatives to animal assays – one or two examples | **15** |
| **702.4: Immunoassays** | |
| 1. Introduction<br>2. Requirements for immunoassay<br>3. Principles and instrumentation in immunoassay<br>4. Types of Detection systems in immunoassay<br>5. Applications of immunoassay<br>6. Advantages & Disadvantages of immunoassay | **15** |
| **RPSBASP702: PRACTICAL II** | |
| 1. Calculation of different pharmacokinetic parameters like $K_a$, $K_e$, $t_{1/2}$, $C_{max}$, $T_{max}$ and AUC from the given blood data<br>2. $LC_{50}$ evaluation using a suitable model (Daphnia/Rice weevils/*Chyronomous larvae*)<br>3. Study of Hepatoprotective action of a herbal drug against $CCl_4$ liver dysfunction in rats (an experimental comparison using suitable groups of controls, natural recovery & treatment with known hepatoprotectants to be carried out)<br>4. Immunoassays for detection of Hepatitis B/Dengue<br>5. Bioassay of Penicillin<br>6. Bioassay of Vitamin $B_{12}$ | |

**References:**

1. Essentials of Medical Pharmacology: K.D.Tripathi, Jaypee Publications
2. Pharmacology: George M. Brenner, Craig Stevens:
3. Casarett & Doull's Toxicology, The basic Sciences of Poisons: Dr. Curtis Klaassen
4. Fundamentals of toxicology: Pandey, Shukla, Trivedi
5. Fundamentals of Pharmacognosy and Phytochemistry: Heinrich, Barnes, Gibbons and Williamson
6. Text book of Pharmacognosy: G.E. Trease, W.C. Evans
7. Pharmacognosy: Chandrakant Kokate
8. Herbal Drug Technology: Agrawal, Paridhavi
9. Pharmacognosy: Tyler, Brody, Robbers
10. Pharmacogenomics: Challenges and Opportunities in Therapeutic Implementation- Yui-Wing Francis Lam & Stuart Scott
11. Principles of Pharmacogenetics and Pharmacogenomics- Altman, Flockhart & Goldstein
12. Immunology: Essential and Fundamental- Palan and Pathak
13. Kuby Immunology: Kindt, Goldsby & Osborna

# Course Code: RPSBAS703 (Core Course)

# Course Title: Advances in Spectroscopy & Chromatography

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | This course will highlight the importance of Electromagnetic spectrum and introduce the students to components of optical instruments. |
| **CO 2** | Students will be well versed with atomic absorption as well as atomic emission spectroscopy. |
| **CO 3** | Students will also learn the Principles and applications of different molecular spectroscopy techniques. |
| **CO 4** | Students will learn the principle, and applications of spectroscopic techniques based on light scattering. |
| **CO 5** | Students will be able to perform and compare modern analytical techniques such as HPTLC, HPLC, UV-Vis spectroscopy for standardization of pharmaceutical products. |
| **CO 6** | In the practicals, students will get hands-on different techniques like Nephelometry, Turbidometry, IR spectroscopy. |
| **CO 7** | Students will also learn to analyze samples using Flame Photometry and Atomic Absorption Spectroscopy. |



## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper III | Lectures |
|---|---|---|
| **RPSBAS703** | **Advances in Spectroscopy & Chromatography** | **60** |
| **703.1: Atomic Spectroscopy** | | |
| 1. Components of optical instruments<br>2. Instrumentation, Sample preparation and Applications of Atomic Absorption Spectroscopy, Atomic Emission Spectroscopy and Inductively Coupled Plasma (ICP-AES & ICP-OES). | | **15** |

| | |
|---|---|
| **703.2: Molecular Spectroscopy** | |
| Principle, Instrumentation, precautions for sample preparation and applications of :<br>1. UV-Visible and fluorescence spectroscopy: Derivative spectroscopy (Zero order, First order and Second order)<br>2. IR spectroscopy: Principles of Diffuse Reflectance Spectroscopy and Attenuated Total Reflectance<br>3. Difference between Raman and IR spectroscopy | **15** |
| **703.3: Advances in Chromatography** | |
| 1. Specialized columns & detectors in HPLC and GC<br>2. Ultra Performance Liquid Chromatography (UPLC)<br>3. Preparative HPTLC & HPLC<br>4. 2D-HPLC | **15** |
| **703.4: Other Techniques of analysis** | |
| Principles, Instrumentation, Sample preparations and Applications of:<br>1. Nephelometry & Turbidimetry<br>2. Particle Size Analyzer<br>3. Size exclusion chromatography & Affinity chromatography for protein separation<br>4. Ion exchange chromatography<br>5. Electrophoresis( Agarose, SDS-PAGE, IEF & Capillary Electrophoresis) | **15** |
| **RPSBASP703: PRACTICAL III** | |
| 1. Turbidimetric & Nephelometric analysis of Pharmaceutical Products<br>2. Flame Photometric estimation of metals with special emphasis on interference<br>3. Sample Preparation for AAS & analysis of pharmaceutical products/Crude drugs for their metal content using AAS<br>4. Qualitative analysis of organic solids using IR spectroscopy<br>5. IR analysis of modern drug (any one example)<br>6. HPTLC analysis of modern drug from plasma<br>7. HPTLC analysis of modern drug from formulations | |

**References:**

1. Introduction to Molecular Spectroscopy: Gordon M. Barrow
2. Molecular Luminescence Spectroscopy Methods and Applications: John Wiley and sons
3. Concept Instrumentation and techniques in Atomic Absorption Spectroscopy: Pekin-Elmer
4. Principles of instrumental analysis: Douglas a. Skoog
5. Introduction to Spectroscopy: Donald L. Pavia

# Course Code: RPSBAS704 (Skill Enhancement Course)

# Course Title: Extraction methodologies in Biological Analysis

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will be able to safely handle different biomatrices. |
| **CO 2** | Student should be able to choose and perform appropriate method for extraction and isolation of analytes in varied biomatrices. |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper IV | Lectures |
|---|---|---|
| **RPSBAS704** | **Extraction methodologies in Biological Analysis** | **60** |
| **704.1: Sample handling and Biomatrices** | | |
| 1. Introduction to Bio-matrices-Microbial, Plant & Animal<br>2. Collection and storage of Biological samples<br>3. Microbes-Bacteria, Algae, Fungi, Protozoans<br>4. Plants- different parts & stages of growth<br>5. Animals & Humans-<br>a. Blood, or whole blood, Plasma and serum<br>b. Urine, Faeces<br>c. Saliva<br>d. Cerebrospinal Fluid, Synovial fluid<br>e. Hair and Nails<br>f. Tissue (Biopsies) | | **15** |
| **704.2: Phytochemical Extraction and Analysis** | | |

| | |
|---|---|
| 1. Extraction of phytoconstituents<br>2. Choice of solvent for extraction<br>3. Classical and modern methods of extraction<br>a. Percolation & Maceration<br>b. Soxhlet extraction<br>c. Steam Distillation & Rotary vacuum evaporator<br>d. Liquid- Liquid & Solid Phase Extraction<br>e. Ultrasonication<br>f. Microwave Assisted Extraction<br>4. Supercritical Fluid extraction<br>5. Classical methods of analysis (Gravimetric & Titrimetric)<br>6. Chromatographic & Spectroscopic analysis of phytoconstituents<br>7. Chromatographic fingerprints<br>8. Phytochemical variations in plants<br>9. Analysis of herbal formulations<br>10. Effect of drying on phytoconstituents | **15** |
| **704.3: Extraction, Isolation & Purification of analytes from Biological Matrices** | |
| 1. Physico-chemical properties of drugs and solvents<br>2. Concept of partition & Partition Coefficient<br>3. Solvent properties<br>4. Introduction to Liquid-liquid Extraction & Liquid-Liquid Micro-extraction, Solid Phase extraction & Solid Phase Micro-Extraction Techniques<br>5. Ionization and its effect on the extraction of drugs<br>6. Matrix components & analyte isolation<br>a. Concentration of extracts<br>b. Isolations of fractions<br>7. Purification of isolate | **15** |
| **704.4: Super Critical Fluid Extraction (SCFE) & Super Critical Fluid Chromatography (SCFC)** | |
| 1. The concept of SCFE & SCFC<br>2. Instrumentation of SCFE & SCFC<br>3. Factors affecting SCFE & SCFC<br>4. Benefits of SCFE & SCFC<br>5. Application of SCFE for natural products and Application of SCFC | **15** |
| **RPSBASP704: PRACTICAL IV** | |
| 1. Bioanalysis of Urine<br>2. Liquid-Liquid Extraction of a modern drug<br>3. Solid Phase Extraction (SPE) of a drug from Plasma<br>4. Protein precipitation techniques<br>5. TLC for essential oils<br>6. Analysis of betalains by UV visible spectroscopy<br>7. Extraction of phytoconstituents by classical and modern methods<br>8. Microscopic evaluation of sections and powders with adulteration and formulation comparison of the medicinal plants (any5) | |



## References:

1. Fundamentals of pharmacognosy and Phytochemistry: Heinrich, Barnes, Gibbons and Williamson
2. Phytochemical methods: A guide to modern techniques of plant analysis: Harborne
3. Phytochemical extraction, separation and analysis: Dr. Deep Panhekar, Ms.Trupti P. Sawant and Dr.D.P. Gogle

4. Fundamentals of Phytochemical analysis: Mr.Vishnu Balamurugan
5. Herbal Drg Technology: Agrawal, Paridhavi
6. Pharmacognosy: Tyler, Brody, Robbers
7. Textbook of Pharmacognosy: G.E. Trease and W.C. Evans
8. Pharmacognosy: Chandrakant Kokate
9. High Performance Liquid Chromatoraphy in Phytochemical analysis(Chromatographic Science Series): Monika Waksmundzka-Hajnos, Joseph Sherma
10. Solvent extraction: Classical and Modern Approaches- Vladimir K. Kislik
11. Analytical Supercritical Fluid Extraction Techniques - E.D. Ramsey

# Course Code: RPSBAS705 (Ability Enhancement Course)

# Course Title: Resume Building & Soft Skills

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO 1 | |
| CO 2 | |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper IV | Lectures |
|---|---|---|
| RPSBAS705 | Resume Building & Soft Skills | 30 |
| 705.1 | | |
| | | 15 |
| 705.2 | | |
| | | 15 |

**References:**

# Modality of Assessment

## Sem VII

**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:**

| 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/shortanswer questions (3Marks 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** |

**Overall Examination & Marks Distribution Pattern**

**Semester VII**

| Course | 701 | | | 702 | | | 703 | | | 704 | | | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Internal | External | Total | Internal | External | Total | Internal | External | Total | Internal | External | Total | |
| Theory | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |
| Practicals | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |

External Examination- 60%- 60 Marks

Semester End Theory Examination: (Deviation from the usual modality)

Owing to the pandemic situation prevailing in 2020 and continuing in 2021, the external examinations (Semester End) may be conducted online as per the instructions/circulars received from the University of Mumbai and Maharashtra State notifications from time to time. The conventional mode of external examination will commence again only after the declaration of normalcy by the Government authorities.

# Course Code: RPSBAS801(Core Course)

# Course Title: Practices in Pharmaceutical Industry

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will understand the importance of Drug act and the need for regulations in Bioanalysis. |
| **CO2** | Students will get an insight into the good practices followed in industrial operations. |
| **CO 3** | Students will realize the importance of documentation and strict adherence to protocol in bioanalytical industries. |

## DETAILED SYLLABUS

| Paper Code | Semester VIII - Paper I | Lectures |
|---|---|---|
| **RPSBAS801** | **Practices in Pharmaceutical Industry** | **60** |
| **801.1: Drug Act & Regulations in Pharma** | | |
| 1. Indian Drugs and Cosmetics Act with respect to Schedule 1,2 and Schedule A, H, M, S, T, X, & Y<br>2. Introduction to foreign guidelines (for import of drugs) with respect to US, EU, Australia & Japan<br>3. Introduction to 21 CFR Part 11 | | **15** |
| **801.2: Good Laboratory Practices & Good Manufacturing Practices** | | |

| | |
|---|---|
| **Good Laboratory Practices (07 Lectures)**<br>1. What is GLP?<br>2. Practicing GLP<br>3. Guidelines to GLP<br>4. Documentation of Laboratory work<br>5. Preparation of SOPs<br>6. Calibration records<br>7. Significance of validation in GLP<br>8. Transfer of methods<br>9. Documentation of results<br>**Good Manufacturing Practices (08 Lectures)**<br>1. Introduction to GMP<br>2. Requirements of GMP implementation<br>3. Documentation of GMP practices<br>4. Regulatory certification of GMP<br>5. GMP in production of ASU drugs<br>6. Harmonization of SOP of manufacture<br>7. Audit for GMP compliances | **15** |
| **801.3: Quality Assurance & Stability studies** | |
| **Quality Assurance (07 Lectures)**<br>1. Introduction to QC & QA<br>2. Requirements for implementing QA<br>3. QA concepts in ASU drugs<br>4. Standardizing an Analytical method<br>5. Factors affecting standardization<br>6. Support work & documentation, Validation<br>7. Audit requirements, audits and audit reports<br>8. Personnel Responsibility in QA<br>**Stability Studies (08 Lectures)**<br>1. Types of Stability studies<br>2. Stability Chambers<br>3. Regulatory requirements for stability studies<br>4. Factors affecting stability of Products<br>5. Predicting shelf life of a finished product<br>6. Guidelines for Stability studies | **15** |
| **801.4: IPR in Pharma** | |

| | |
|---|---|
| 1. Concept of IPR<br>2. Types of IPR<br>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.<br>4. International Agreements related to IPR & patents - Paris Convention, PCT.<br>5. Indian Patent Act -<br>a. Criteria to be fulfilled for Patentability, introduction to WIPO<br>b. Non-patentable subject matter<br>c. Concept of Mailbox and EMR<br>d. Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, servicing of patents.<br>e. Provisional Patents, Divisional Patents & Patents of Addition.<br>f. Patent infringement<br>6. IPR as a strategic tool -<br>a. Concepts of piracy, reverse engineering and knowledge worker.<br>7. IP clearance – Precautions before launching of product anywhere in the world<br>8. Putting IPR related disclaimers while advertising product list or selling products. | **15** |
| **RPSBASP801 PRACTICAL I** | |
| 1. Patent Claim Drafting, Patent Evaluation<br>2. Preparation of Standard Operating Procedure (SOP) for any one analytical instrument<br>3. Study of Certificate of Analysis (COA)<br>4. Study of Shelf life of herbal drugs<br>5. Stability studies of drugs (API & Formulation) with respect to the effect of pH, Temperature, Moisture and Light (any 4 experiments) | |

**References:**


1. Drugs and Cosmetics Act 1940 and Rules 1945
2. Remington, Essentials of Pharmaceutics: Linda Felton
3. Intellectual property rights: N. Pandey, K. Dharni
4. Indian Patent Law and Practice: K.C. Kankanala
5. GLP Essentials: A Concise guide to Good Laboratory Practice, 2nd Edition: Milton A. Anderson
6. The Certified Pharmaceutical GMP Professional Handbook, Second Edition: Mark Allen Durivage
7. Good Laboratory Practice Regulations: Sandy Weinberg
8. Handbook of Stability tasting in pharmaceutical development: regulations, methodologies and best practices: Springer

# Course Code: RPSBAS802(Core Course)

# Course Title: Process of Drug Discovery & Development

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Student will learn the importance of preclinical research. |
| **CO2** | Student will learn the different stages of clinical trials and understand the regulatory norms for conduct of clinical trials. |
| **CO3** | Students will learn about the concept of new chemical entity and get an idea about the entire process of new drug development |
| **CO4** | Students will understand the ethical issues to be addressed while conducting a clinical trial |

## DETAILED SYLLABUS

| Paper Code | Semester VIII - Paper II | Lectures |
|---|---|---|
| **RPSBAS802** | **Process of Drug Discovery & Development** | **60** |
| **802.1: Drug discovery and development process** | | |
| 1. Introduction to Drug Discovery, Design and Development<br>2. Target identification<br>3. Discovery of a Lead compound: Screening, drug metabolism studies and clinical observation.<br>4. Concept of New Chemical Entity (NCE)<br>5. Stages in the development of NCE<br>6. Current Status | | **15** |
| **802.2: Preclinical Research** | | |
| 1. Importance of preclinical studies<br>2. Types of preclinical studies<br>3. Design of animal trial in compliance with CPCSEA guidelines<br>4. Ethical considerations in animal testing<br>5. Model organisms used in drug testing studies<br>6. Extrapolation of data to humans | | **15** |
| **802.3: Basics of Clinical Trials** | | |
| 1. Importance of clinical trials<br>2. Phases involved in clinical trials<br>3. Types of clinical trials<br>4. Regulatory requirements for clinical trials<br>5. Schedule Y compliance | | **15** |
| **802.4: Ethical guidelines in Clinical Trials and GCP** | | |

| | |
|---|---|
| **Ethics (08 Lectures)**<br>1. Origin of Ethical issues<br>2. Dealing with Ethical issues<br>3. Ensuring compliance of ethical issues<br>4. Ethical committees & their setup<br>5. Regulatory powers of ethical committees<br>6. Compliance to ethical guidelines<br>7. Dealing with Ethical issues (subject compensation and subject rights)<br>8. Compliance to current ethical guidelines<br><br>**Good Clinical Practices ( 07 Lectures)**<br>1. Origin of GCP & Earlier Guidelines for GCP<br>2. GCP Guidelines of ICH<br>3. Ensuring GCP Compliance<br>4. Documentation of GCP<br>5. Audit of GCP compliance | **15** |
| **RPSBASP802 PRACTICAL II** | |
| 1. $LC_{50}$ evaluation using a suitable model (Daphnia/Rice weevils/*Chyronomous larvae*)<br>2. Study of Hepatoprotective action of a herbal drug against $CCl_4$ liver dysfunction in rats (an experimental comparison using suitable groups of controls, natural recovery & treatment with known hepatoprotectants to be carried out)<br>3. Study of Disintegration and Dissolution of a tablet as per IP/USP (enteric coated)<br>4. Study of an Informed consent form | |

## 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.

# Course Code: RPSBAS803 (Core Course)

# Course Title: Medicinal Systems & Standardization of Herbal Drugs

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will also be introduced to Modern system of Medicine and management of diseases using modern medicine |
| **CO 2** | Students will also be introduced to Indian Systems of Medicine and regulatory aspects of ASU drugs. |
| **CO 3** | The course will underline the importance of Bioanalytical techniques for standardization of traditional medicines. |
| **CO 4** | In the practical paper, students will learn to carry out microscopic evaluation of Ayurveda, Siddha and Unani Drugs in compliance to Pharmacopoeia. |

## DETAILED SYLLABUS

| Paper Code | Semester VIII - Paper III | Lectures |
|---|---|---|
| **RPSBAS803** | **Medicinal Systems & Standardization of Herbal Drugs** | **60** |
| **803.1: Modern Medicine** | | |
| 1. History of Modern Medicine<br>2. Concept of disease, types of diseases<br>3. Treatment of Infections (With special emphasis on Covid)<br>4. Management of endocrine disorders- Polycystic ovarian syndrome, Diabetes<br>5. Management of vascular disorders- Cardiovascular disorders | | **15** |
| **803.2: Indian Medicinal Systems** | | |
| 1. Principles and practices of ASU systems of medicine<br>2. Diagnosis & treatment as per Ayurveda (Special emphasis on Panchakarma)<br>3. Types of Drug formulations as per ASU systems<br>4. Dosage forms as per ASU system<br>5. Mode of action of drugs according to Ayurveda | | **15** |
| **803.3: Standardization of ASU drugs** | | |
| 1. Need of standardization of Ayurvedic, Siddha & Unani drugs<br>2. Sources of Raw materials & Finished products as per ASU drugs<br>3. Methods of manufacture-raw materials to finished products<br>4. Quality control of ASU drugs in India<br>5. Shelf-life studies on finished products<br>6. Analytical tools for standardization<br>7. Clinical studies in Standardization | | **15** |

| **803.4: Regulatory Aspects of ASU Drugs** | |
|---|---|
| 1. Herbal pharmacopoeia and Ayurvedic Formulary of India<br>2. Shelf life studies on finished products.<br>3. Analytical tools for standardization<br>4. Need for standardization and approaches to developing standardized QC methods<br>5. Clinical studies in standardization<br>6. QC for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon, etc.)<br>7. Organizational setup in India for the regulation of herbal drugs, Regulatory laws in India for herbal drugs<br>8. Import & Manufacture of herbal drugs, Conditions for the manufacture of herbal drugs<br>9. Administrative agencies regarding the regulation of herbal drugs<br>10. Regulatory aspects of herbal drugs in India & other countries. | **15** |
| **RPSBASP803 PRACTICAL III** | |
| 1. Standardization of any one formulation using classical and modern analytical techniques<br>2. HPLC analysis of modern drugs from plasma, formulations and combination formulations<br>3. High Performance Liquid Chromatography (HPLC) separation of herbal raw material from its formulation (any one example)<br>4. Comparative estimation of caffeine by using UV-Visible spectrophotometer, HPTLC & HPLC. | |

**References:**

1. Indian Herbal Pharmacopoeia
2. Drugs and Cosmetics Act 1940 and Rules 1945
3. Database on medicinal plant used in Ayurveda: Sharma, Yelne and Dennis
4. Globalisation of Ayurvedic & Herbal products, challenges and strategies
5. Disease Management: A Guide to Clinical Pharmacology- M. Randall & K.Neil

# Course Code: RPSBAS804 (Skill Enhancement Course)

# Course Title: Bioinformatics & Biostatistics

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | This course will introduce students with field bioinformatics and its use in drug designing. |
| **CO 2** | Students will be able to understand role of bioinformatics in disease analysis. |
| **CO 3** | Students will be able to visualize protein tertiary structure using Bioinformatic tools. |
| **CO 4** | Students will gain knowledge about data types and its collection methods in biostatistics. |
| **CO5** | Students will be able to analyse biological samples in a regulated manner and apply suitable statistical tests to extrapolate the observations to relevant results. |

## DETAILED SYLLABUS

| **Paper Code** | **Semester VIII - Paper IV** | **Lectures** |
|---|---|---|
| **RPSBAS804** | **Bioinformatics & Biostatistics** | **60** |
| **804.1: Bionformatics: Methods in Drug Design** | | |
| 1. Enzymes as drug targets<br>2. ADME characteristics and routes of drug administration<br>3. Handling chemical structures, SMILES<br>4. In silico lead identification and screening using Pharmacophore<br>5. QSAR, database searches<br>6. Lead optimization<br>7. Bioisosteric replacement<br>8. Conformation restriction. | | **15** |
| **804.2: Bioinformatics in disease management** | | |
| 1. Basic concepts on identification of genes responsible for diseases<br>2. Role of bioinformatics in human disease analysis<br>3. OMIM database<br>4. Reference genome sequence & integrated genomic maps<br>5. Gene expression profiling | | **15** |

| **804.3: Descriptive Statistics & Regression Analysis** | |
|---|---|
| 1. Concepts: Population, Sample, sample size, Normal distribution, Level of significance, Confident limits, Power of test<br>2. Sampling Design:<br>a. Different Types of Sampling Design: Simple Random Sampling Stratified Random Sampling, Systematic Sampling, Cluster Sampling, Area Sampling, Multistage Sampling.<br>b. Steps in sample design<br>3. Data Collection<br>a. Primary Data collection through Questionnaire & Schedules<br>b. Collection of Secondary Data<br>4. Data Analysis:<br>a. Measures of central tendency (mean, median, mode)<br>b. Measures of dispersion (range, sample deviation, variance, CoV)<br>5. Introduction to correlation & regression analysis | **15** |
| **804.4: Test of Significance** | |
| 1. Introduction to hypothesis testing & Errors in Testing<br>2. Introduction to parametric tests- Z-test, t-test, Chi-Square test, F-test, ANOVA (One way and Two way).<br>3. Introduction to non-parametric test- Mann–Whitney U test, Kruskal-Wallis test<br>4. Design of experiments: Block designs (CRD, RBD), Latin square design<br>5. Introduction to statistical packages for data analysis | **15** |
| **RPSBASP804 PRACTICAL IV** | |
| 1. Tertiary structure and function prediction using homology modeling and *ab initio* method<br>2. Validation of Predicted structure<br>3. Visualization of 3D Protein structure using Rasmol, VMD<br>4. Docking: Using a docking software to study protein-ligand interaction<br>5. Problems based on Biostatistics | |

## References:


1. Bioinformatics for Diagnosis, Prognosis and Treatment of Complex Diseases
2. Methods in Biostatistics: B.K. Mahajan
3. Basic Concepts of Biostatistics: Arumugam
4. Biostatistics, Basic concepts and Methodology for the Health Sciences: Daniel & Cross
5. Fundamentals of Applied Statistics: Gupta and Kapoor: S. Chand and sons
6. Introduction to Biostatistics and Research Methods: Rao and Richard

# Course Code: RPSBAS805 (Ability Enhancement Course)

# Course Title: Research Methodology & Scientific Communication

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO 1 | |
| CO2 | |
| CO3 | |

## DETAILED SYLLABUS

| Paper Code | Semester VIII - Paper IV | Lectures |
|---|---|---|
| RPSBAS805 | Research Methodology & Scientific Communication | 30 |
| 805.1 | | |
| 1. | | 15 |
| 805.2: | | |
| | | 15 |

**References:**

1.

# Modality of Assessment

**Sem VIII**

**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:**

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

**Overall Examination & Marks Distribution Pattern**

**Semester VIII**

| Course | 801 | | | 802 | | | 803 | | | 804 | | | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Internal | External | Total | Internal | External | Total | Internal | External | Total | Internal | External | Total | |
| Theory | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |
| Practicals | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |

External Examination- 60%- 60 Marks

Semester End Theory Examination: (Deviation from the usual modality)

Owing to the pandemic situation prevailing in 2020 and continuing in 2021, the external examinations (Semester End) may be conducted online as per the instructions/circulars received from the University of Mumbai and Maharashtra State notifications from time to time. The conventional mode of external examination will commence again only after the declaration of normalcy by the Government authorities.

# Course Code: RPSBAS901

# Course Title: Fundamentals of Clinical Research Industry
# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |
| CO2 | |
| CO3 | |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper I | Lectures |
|---|---|---|
| RPSBAS901 | Fundamentals of Clinical Research Industry | 60 |
| **901.1: Functioning of CRO** | | 15 |
| 1. | | |
| **901.2: Bioavailability-Bioequivalence studies** | | 15 |
| | | |
| **901.3: Therapeutic Drug Monitoring and Pharmacovigilance** | | 15 |
| | | |
| **901.4: Clinical Data Management** | | 15 |
| 1. | | |
| **RPSBASP901 PRACTICALS** | | Practical |
| | | |

**References:**

# Course Code: RPSBAS902

# Course Title: Modern Analytical Instrumentation
# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |
| CO2 | |
| CO3 | |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper II | Lectures |
|---|---|---|
| RPSBAS902 | Modern Analytical Instrumentation | 60 |
| **902.1: CD, ORD & Chiral Chromatography** | | 15 |
| **902.2: NMR Spectroscopy** | | 15 |
| 1. | | |
| **902.3: Mass Spectroscopy Basics** | | 15 |
| 1. | | |

| | |
|---|---|
| **902.4: Applied Mass Spectrometry** | **15** |
| 1. | |
| **RPSBASP902 PRACTICALS** | |
| | |

**References:**

# Course Code: RPSBAS903

# Course Title: Research Methodology & Biostatistics

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |
| CO2 | |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper III | Lectures |
|---|---|---|
| RPSBAS903 | Research Methodology & Biostatistics | 60 |
| 903.1: Introduction to Research methodology | | 15 |
| 903.2: Research design | | 15 |
| 903.3: Descriptive statistics and Regression analysis | | 15 |
| 903.4: Test of Significance | | 15 |
| RPSBASP903 PRACTICALS | | |
| | | |

**References:**

# Course Code: RPSBASP904

## Course Title: Internship/Research Project

## Academic year 2022-23

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper IV | Lectures |
|---|---|---|
| **RPSBASP904** | **Internship/Research Project** | **120** |
| Industrial Training, and/or research project/ Online training (Swayam/Coursera/NPTEL/MOOC, etc.)/Online internship<br><br>1. Students should submit the detailed report regarding of the above-mentioned course.<br>2. Students should consult the teacher mentor allotted by the department and HOD for taking up modules from the course.<br>3. After getting approval from the mentor/HOD, student should provide the weekly update to the mentor over email.<br>4. For internal component students are required to present the learning outcome(s) of the module twice in a semester and submit necessary assignments given by the mentor. | | |

# Modality of Assessment

## Sem IX

### 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 RPSBASP904):**

| 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** |

**Overall Examination & Marks Distribution Pattern**

**Semester IX**

| Course | 901 | | | 902 | | | 903 | | | 904 | | | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Internal | External | Total | Internal | External | Total | Internal | External | Total | Internal | External | Total | |
| Theory | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |
| Practicals | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |

External Examination- 60%- 60 Marks

Semester End Theory Examination: (Deviation from the usual modality)
Owing to the pandemic situation prevailing in 2020 and continuing in 2021, the external examinations (Semester End) may be conducted online as per the instructions / circulars received from the University of Mumbai and Maharashtra State notifications from time to time. The conventional mode of external examination will commence again only after the declaration of normalcy by the Government authorities.

# Course Code: RPSBAS1001

# Course Title: Method validation in pharmaceutical analysis

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |
| CO2 | |
| CO3 | |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper I | Lectures |
|---|---|---|
| RPSBAS1001 | Method validation in pharmaceutical analysis | 60 |
| **1001.1: Fundamentals of Method Validation** | | 15 |
| 1. | | |
| **1001.2: Life cycle of Method Validation in Pharmaceutical Environment** | | 15 |
| 1. | | |
| **1001.3: Bioanalytical Method development** | | 15 |
| 1. | | |
| **1001.4: Bioanalytical Method validation** | | 15 |
| 1. | | |
| **RPSBASP1001 PRACTICALS** | | |
| 1. | | |

**References:**

# Course Code: RPSBAS1002

# Course Title: Biopharmaceuticals & Biosimilars

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper II | Lectures |
|---|---|---|
| RPSBAS1002 | Biopharmaceuticals & Biosimilars | 60 |
| **1002.1: Introduction to Biopharmaceuticals and Biosimilars**<br>1. | | 15 |
| **1002.2: Development of Biopharmaceuticals and Biosimilars**<br>1. | | 15 |
| **1002.3: Characterization of Biopharmaceuticals and Biosimilars**<br>1. | | 15 |
| **1002.4: Regulatory framework for biopharmaceuticals and biosimilars** | | 15 |
| **RPSBASP1001 PRACTICALS** | | |
| | | |

**References**

# Course Code: RPSBAS1003

# Course Title: Xenobiotic Analysis

# Academic year 2022-23

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |
| CO2 | |
| CO3 | |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper III | Lectures |
|---|---|---|
| RPSBAS1003 | Xenobiotic Analysis | 60 |
| **1003.1: Xenobiotic compounds and their metabolism- I** | | 15 |
| 1. | | |
| **1003.2: Xenobiotic compounds and their metabolism -II** | | 15 |
| | | |
| **1003.3: Detection of Xenobiotic compounds** | | 15 |
| | | |
| **1003.4: Characterization of Xenobiotics by spectroscopic techniques** | | 15 |
| | | |
| **RPSBASP1003: PRACTICALS** | | |
| 1. | | |



**References**

## Course Code: RPSBASP1004

## Course Title: Project Work

## Academic year 2022-23

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| CO1 | |
| CO2 | |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper IV | Lectures |
|---|---|---|
| RPSBASP1004 | Internship/Research Project | 120 |

Industrial Training, and/or research project/Online training/Online internship

Industrial Training, and/or research project/ Online training (Swayam/Coursera/NPTEL/MOOC, etc.)/Online internship

1. Students should submit the detailed report regarding of the above-mentioned course.
2. Students should consult the teacher mentor allotted by the department and HOD for taking up modules from the course.
3. After getting approval from the mentor/HOD, student should provide the weekly update to the mentor over email.
4. For internal component students are required to present the learning outcome(s) of the module twice in a semester and submit necessary assignments given by the mentor.

**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 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.

# Modality of Assessment

**Sem X**

**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 RPSBASP1004):**

| Question | Options | Marks | Questions Based on |
|---|---|---|---|
| Q.1 Short answer question (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 question (3Marks 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** |

**Overall Examination & Marks Distribution Pattern**

**Semester X**

| Course | 1001 | | | 1002 | | | 1003 | | | 1004 | | | Grand Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Internal | External | Total | Internal | External | Total | Internal | External | Total | Internal | External | Total | |
| Theory | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |
| Practicals | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 40 | 60 | 100 | 400 |

External Examination- 60%- 60 Marks

Semester End Theory Examination: (Deviation from the usual modality)
Owing to the pandemic situation prevailing in 2020 and continuing in 2021, the external examinations (Semester End) may be conducted online as per the instructions / circulars received from the University of Mumbai and Maharashtra State notifications from time to time. The conventional mode of external examination will commence again only after the declaration of normalcy by the Government authorities.