Resolution number: AC/II (20-21).2. RPS1

# S. P. Mandali's

# Ramnarain Ruia Autonomous College

**(Affiliated to University of Mumbai)**

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## Syllabus for

## Integrated M.Sc. in Bioanalytical Sciences

## (Post-graduate syllabus)

## Program Code: RPSBAS

(Credit Based Semester and Grading System
for academic year 2020–2021)

# PROGRAM OUTCOMES

| PO | PO Description<br>**A student completing Bachelor's/Master's Degree in Science program will be able to:** |
|---|---|
| **PO 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. |
| **PO 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. |
| **PO 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. |
| **PO 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. |
| **PO 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. |
| **PO 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. |
| **PO 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. |
| **PO 8** | Understand cross disciplinary relevance of scientific developments and relearn and reskill so as to adapt to technological advancements. |

# PROGRAM SPECIFIC OUTCOMES

| PSO | Description<br><br>**A student completing Integrated Master's Degree in Science program in the subject of Bioanalytical Sciences will be able to:** |
|---|---|
| **PSO 1** | Gain high quality science education in a vibrant academic ambience with the faculty of distinguished teachers and scientists. |
| **PSO 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. |
| **PSO 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 | CREDITS |
|---|---|---|---|---|
| I. M.Sc. I | VII | RPSBAS701 | Pharmaceutical Microbiology & Pharmaceutical Manufacturing | 4 |
| | | RPSBASP701 | Practical | 2 |
| | | RPSBAS702 | Pharmacology & Toxicology | 4 |
| | | RPSBASP702 | Practical | 2 |
| | | RPSBAS703 | Extraction, Separation and Isolation of Analytes from biological matrices | 4 |
| | | RPSBASP703 | Practical | 2 |
| | | RPSBAS704 | Different systems of Medicine & Regulations | 4 |
| | | RPSBASP704 | Practical | 2 |
| I. M.Sc. I | VIII | RPSBAS801 | Molecular Biology & Tissue Culture | 4 |
| | | RPSBASP801 | Practical | 2 |
| | | RPSBAS802 | IPR, Drugs and Cosmetic Act & Regulations | 4 |
| | | RPSBASP802 | Practical | 2 |
| | | RPSBAS803 | Quality Management in Pharmaceutical Industry | 4 |

| | | | | |
|---|---|---|---|---|
| | | **RPSBASP803** | **Practical** | **2** |
| | | **RPSBAS804** | **Pharmaceutical Testing & Proteomics** | **4** |
| | | **RPSBASP804** | **Practical** | **2** |
| **I. M.Sc. II** | **IX** | **RPSBAS901** | **Automation and Data Management** | **4** |
| | | **RPSBASP901** | **Practical** | **2** |
| | | **RPSBAS902** | **Bioanalytical Techniques** | **4** |
| | | **RPSBASP902** | **Practical** | **2** |
| | | **RPSBAS903** | **Research Methodology and Biostatistics** | **4** |
| | | **RPSBASP903** | **Practical** | **2** |
| | | **RPSBASP904** | **Internship** | **6** |
| **I. M.Sc. II** | **X** | **RPSBAS1001** | **Analytical Techniques and their Validation** | **4** |
| | | **RPSBASP1001** | **Practical** | **2** |
| | | **RPSBAS1002** | **Advances in Bioanalysis** | **4** |
| | | **RPSBASP1002** | **Practical** | **2** |
| | | **RPSBAS1003** | **Clinical Research & Ethics** | **4** |
| | | **RPSBASP1003** | **Practical** | **2** |
| | | **RPSBASP1004** | **Project Work** | **6** |

# Course Code: RPSBAS701

# Course Title: Pharmaceutical Microbiology & Pharmaceutical Manufacturing

# Academic year 2020-21

## 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. |
| **CO3** | Students will be able to design and perform bioassays. |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper I | Lectures |
|---|---|---|
| **RPSBAS701** | **Pharmaceutical Microbiology & Pharmaceutical Manufacturing** | **60** |
| | **701.1:** Pharmaceutical Microbiology<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. | **15** |
| | **701.2:** Bioassays in Pharma Evaluation<br>1. General idea about bioassay systems used in pharmaceutical evaluations<br>2. In vitro assays and in vivo assays<br>3. Ethical issues of using animal assay systems<br>4. Alternatives to animal assays – one or two examples | **15** |

| | | |
|---|---|---|
| | **701.3:** Immunoassays & Immunoinformatics<br>1. Introduction to Immune system<br>2. Introduction to Immunoassay and its types<br>3. Requirements for immunoassay<br>4. Standardization of Immunoassay<br>5. Advantages and Disadvantages of immunoassay<br>6. Integrated scenario of Immunoinformatics & research areas<br>7. Immunomics & databases- CED, IEDB, Epitome<br>8. Applications of Immunoinformatics | **15** |
| | **701.4:** Pharmaceutical Manufacturing<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>4. Unit operations and advances in: Manufacturing of oral solid dosage forms, oral liquid dosage forms, sterile injectables and topical dosage forms | **15** |
| **RPSBASP701** | **PRACTICALS** | |

1. Bioassay of Penicillin
2. Bioassay of Vitamin $B_{12}$
3. Immunoassays for detection of Hepatitis B/Dengue
4. Total Viable Count of microorganisms from herbal Raw materials and formulations
5. Screening of Pathogenic organisms from Food/herbal raw materials/formulations
6. Study of antibiotic producers
7. Study of MIC of a pharmaceutical product

**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. Immunology: Essential and Fundamental- Palan and Pathak
6. Kuby Immunology: Kindt, Goldsby& Osborna
7. Immunoinformatics, Methods in Molecular Biology: Namrata Tomar: Springer
8. Principle and practice of Bioanalysis: Richard F. Venn
9. Essential Bioinformatics: Jin Xiong

# Course Code: RPSBAS702

# Course Title: Pharmacology & Toxicology

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will realize the importance of toxicological studies for ensuring safe administration of pharmaceuticals. |
| **CO 2** | Students will get hands-on training in toxicological assays. |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper II | Lectures |
|---|---|---|
| **RPSBAS702** | **Pharmacology & Toxicology** | **60** |
| | **702.1:** Basic Pharmacology<br>1. Scope of Pharmacology<br>2. Sources, Nature and Nomenclature of Drugs<br>3. Dosage Forms and Routes of Drug Administration<br>4. Dose-Response Relationship | **15** |
| | **702.2:** Pharmacokinetics & Pharmacodynamics<br>1. Basic concepts of Pharmacokinetics & Pharmacodynamics<br>2. Different Pharmacokinetic & Pharmacodynamics parameters and their meanings<br>3. Basic techniques of evaluating Pharmacokinetic & Pharmacodynamics parameters<br>4. Basic types of models in Pharmacokinetics & Pharmacodynamics | **15** |
| | **702.3:** Pharmacogenomics<br>1. Introduction to pharmacogenetics and Pharmacogenomics, benefits and practical applications of Pharmacogenomics, Personalized medicines.<br>2. Human Genetic variation- e.g. CYP gene variations leading to variable metabolism of drugs<br>3. Distribution of variation<br>4. Mutation and its kinds<br>5. Natural selection<br>6. Variation in ethnic groups, races. | **15** |

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|---|---|---|
| | **702.4:** Toxicology<br>1. Introduction, History, Scope and types of toxicological studies<br>2. Toxicants and their classification<br>3.Mode of action of Toxicants (Toxicokinetics and Toxicodynamics)<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>**Regulatory Toxicology**<br>1. Introduction to Regulatory Toxicology<br>2. Types of toxicity tests<br>3.OECD Guidelines on Toxicological studies- Design considerations, Evaluation of results, Extrapolation to man<br>4. Risk analysis of Food & Drug related substances<br>5. Environmental impact assessment | **15** |
| **RPSBASP702** | **PRACTICALS** | |

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
2. pK of a drug using UV-Vis Spectrophotometer
3. $LC_{50}$ evaluation using a suitable model (Daphnia/Rice weevils/*Chyronomous larvae*)
4. 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)

## 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

# Course Code: RPSBAS703

# Course Title: Extraction, Separation and Isolation of Analytes from biological matrices

## Academic year 2020-21

### 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 III | Lectures |
|---|---|---|
| **RPSBAS703** | **Extraction, Separation and Isolation of Analytes from biological matrices** | **60** |
| | **703.1:** Sample handling and Biomatrices<br>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** |
| | **703.2:** Extraction & Isolation of Analytes<br>1. Physico-chemical properties of drugs and solvents<br>2. Concept of partition & Partition Coefficient, Solvent properties<br>3. Introduction to Liquid-liquid Extraction & Liquid-Liquid Micro-extraction, Solid Phase extraction & Solid Phase Micro-Extraction Techniques<br>4. Ionization and its effect on the extraction of drugs<br>5. The 'First law of drug metabolism'<br>6. Matrix components & analyte isolation<br>a. Concentration of extracts<br>b. Isolations of fractions<br>7. Purification of isolate | **15** |

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|---|---|---|
| | **703.3** Super Critical Fluid Extraction (SCFE) & Super Critical Fluid Chromatography (SCFC)<br>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<br>6. Conclusions and future perspectives | **15** |
| | **703.4:** Electrophoresis<br>1. Principles of electrophoretic separation<br>2. Equipment and process in electrophoresis<br>3. Types of Electrophoresis<br>4. Standardization of electrophoretic techniques<br>5. Troubleshooting in Electrophoresis<br>6. Applications of Electrophoresis<br>7. Advantages and Disadvantages of Electrophoresis | **15** |
| **RPSBASP703** | **PRACTICALS** | |
| 1. Bioanalysis of Urine, blood and serum sample<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. Analysis of Plant/ Animal/ Microbial proteins by SDS PAGE<br>6. 2- dimensional Gel Electrophoresis of proteins (demo)<br>7. Separation of a modern drug from plasma and its formulation/ peptides by Capillary Electrophoresis. | | |

## References:

1. Solvent extraction: Classical and Modern Approaches- Vladimir K. Kislik
2. Analytical Supercritical Fluid Extraction Techniques - E.D. Ramsey
3. Bioanalysis of Pharmaceuticals- Wiley
4. Principles and Practices of Bioanalysis- Richard Venn
5. Electrophoresis: Theory and Practice- Budin Michov
6. Gel Electrophoresis: Basic concepts and Principles- Jill Clark
7. Capillary Electrophoresis: Theory & Practices- Grossman & Colburn

# Course Code: RPSBAS704

# Course Title: Different Systems of Medicine & Regulations

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will realize the importance of bioanalytical techniques for standardization of traditional medicines. |
| **CO 2** | Students will be able to perform and compare modern analytical techniques such as HPTLC, HPLC, UV-Vis spectroscopy for standardization of pharmaceutical products. |

## DETAILED SYLLABUS

| Paper Code | Semester VII- Paper IV | Lectures |
|---|---|---|
| **RPSBAS704** | **Different Systems of Medicine & Regulations** | **60** |
| | **704.1:** Disease Management as per different medicinal systems<br>1. History of Modern Medicine<br>2. Concept of disease, types of diseases<br>3. Patient: Signs & symptoms, clinical laboratory tests, lifestyle advice, Herbal medicine & homeopathy<br>4. Treatment: Infections, Endocrine disorders- Polycystic, diabetes, thyroid, Cardiovascular disorders | **15** |
| | **704.2:** New Chemical Entity (NCE) & its Evolution into a drug molecule<br>1. What is NCE?<br>2. Stages in the development of NCE<br>3. Preclinical studies on NCE<br>4. Schedule Y<br>5. Current Status | **15** |
| | **704.3:** Indian systems of medicine- Ayurveda, Siddha & Unani<br>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** |

| | | |
|---|---|---|
| | **704.4:** Standardization aspects of Ayurveda, Siddha & Unani drugs<br>1. Need of standardization of Ayurvedic, Siddha & Unani drugs<br>2. Approaches to standardization<br>3. Sources of Raw materials & Finished products as per ASU drugs<br>4. Methods of manufacture-raw materials to finished products<br>5. Quality control of ASU drugs in India<br>6. Developing standardized QC methods<br>7. Shelf life studies on finished products<br>8. Bioanalytical tools for standardization<br>9. Clinical studies in Standardization<br>10. Regulatory Aspects | **15** |
| **RPSBASP704** | **PRACTICALS** | |
| 1. Microscopic evaluation of Ayurvedic drugs (e.g. Triphala Churna/Avipattikar Churna)<br>2. High Performance Liquid Chromatography (HPLC) separation of herbal raw material from its formulation (any one example)<br>3. HPLC analysis of modern drugs from plasma, formulations and combination formulations<br>4. Standardization of any one formulation using classical and modern analytical techniques<br>5. 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

# 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/short answer 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 |

# Course Code: RPSBAS801

*To be revised for academic year 2020-2021*

# Course Title: Molecular Biology & Tissue culture

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will learn different tissue culture techniques and their applications. |
| **CO2** | Student will understand the significance of cell and gene therapy as a potent futuristic medicine. |
| **CO 3** | Students will be trained in molecular biology techniques such as PCR, RFLP, and DNA purification |

## DETAILED SYLLABUS

| Paper Code | Semester VIII- Paper I | Lectures |
|---|---|---|
| **RPSBAS801** | **Molecular Biology & Tissue culture** | **60** |
| | **801.1:** Advances in Plant tissue culture<br>1. Media and role of plant hormones (Natural and synthetic media)<br>2. Callus Production<br>3. Shooting and rooting<br>4. Hardening and further propagation<br>5. Design and requirements of green house/polyhouse<br>6. Production of Secondary Metabolites using PTC, Commercial aspects with examples | **15** |
| | **801.2:** Advances in Animal Tissue Culture<br>1. Media and role of serum (Natural and synthetic media)<br>2. Primary and secondary cell lines, Established cell lines<br>3. Trypsinization, evaluation of viability and maintenance of cell lines, $CO_2$ incubator<br>4. Specialized cell lines-HeLa cell line, Mouse cell line, CHK cell Lines, etc. | **15** |

| | | |
|---|---|---|
| | **801.3:** PCR & its application<br>1. Introduction to Polymerase Chain Reaction<br>2. Types of PCR: Conventional Qualitative PCR, Hot start PCR, Colony PCR, Nested PCR, Realtime PCR, Reverse transcriptase PCR, Touchdown PCR, Mulitplex PCR, Assembly PCR, Methylation specific PCR, LAMP assay<br>3. PCR instrumentation: Principle of thermal cycler<br>4. PCR standardization<br>5. Primer designing: Primers for Qualitative PCR, Primers for Epitope tag, Mutagenesis primers<br>6. Applications of PCR: Gene expression analysis, Cloning, RFLP-PCR, AFLP, RAPD, SNP genotyping, Diagnostics, DNA sequencing. | **15** |
| | **801.4:** Cell and Gene Therapy Products<br>1. Meaning of gene therapy, Viral & non-viral methods for gene delivery<br>2. Gene editing techniques: RNAi, ShRNA, Crispr/Cas9<br>3. Stem cell therapy<br>4. Manufacture, storage, shipping & labelling of cell & gene therapy products | **15** |
| **RPSBASP801** | **PRACTICALS** | |
| 1. Plant DNA extraction and separation using agarose gel electrophoresis and purity assessment by 260/280 ratio.<br>2. Plasmid isolation and RFLP analysis of the same.<br>3. Elution of DNA from gel<br>4. Primer designing for given DNA sequence<br>5. Amplification of DNA using PCR<br>6. Identification of Genetically Modified Organism (GMO) using a suitable technique<br>7. DNA fingerprinting via RFLP analysis<br>8. DNA sequencing (Demo) | | |

## References:

1. Principles and Practice of Animal Tissue Culture: Sudha Gangal
2. I-Genetics: A Molecular Approach: Peter J. Russell
3. US Pharmacopoeia: Chapter 1046 and 1047.
4. Introduction to Plant Tissue Culture- M. K. Razdan

# Course Code: RPSBAS802

*To be revised for academic year 2020-2021*

# Course Title: Intellectual Property Rights, Drugs and Cosmetic Act & Regulations

## Academic year 2020-21

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO 1** | Students will be familiarized with the current legal scenario regarding intellectual property rights. |
| **CO2** | Students will understand the importance of Drug act and the need for regulations in Bioanalysis. |
| **CO3** | Students will be able to perform stability studies for pharmaceuticals. |

## DETAILED SYLLABUS

| Paper Code | Semester VIII- Paper III | Lectures |
|---|---|---|
| **RPSBAS802** | **Intellectual Property Rights, Drugs and Cosmetic Act & Regulations** | **60** |
| | **802.1:** Intellectual Property Rights-I<br>1. Concept of IPR - Understanding IPR & its significance in knowledge-based economy.<br>2. Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, Geographical indications, Protection of New Plant Varieties, Copyright.<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. | **15** |
| | **802.2:** Intellectual Property Rights-II<br>1. **Indian Patent Act -**<br>a) Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step, useful/capable of industrial application.<br>b) Non-patentable subject matter - what is not patentable.<br>c) Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance.<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. | **15** |

| | | |
|---|---|---|
| | 2. **IPR as a strategic tool -**<br>a) Concepts of piracy, reverse engineering and knowledge worker.<br>b) Benefits of creating and/or owning patents and other IPR.<br>c) How India has leveraged the flexibilities provided by TRIPS to safeguard the industry and prevent ever-greening of patents.<br>3. **IP clearance – Precautions before launching of product anywhere in the world**<br>a) Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check<br>b) Other IPR checks like trademarks, copyrights (for printed data on leaflets, packages etc.)<br>4. Putting IPR related disclaimers while advertising product list or selling products. | |
| | **802.3:** Drugs & Cosmetics Act and Regulation<br>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** |
| | **802.4:** Good Manufacturing Practices (GMP)<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** |
| **RPSBASP802** | **PRACTICALS** | |
| 1. Patent Claim Drafting, Patent Evaluation<br>2. HPTLC and HPLC analysis of herbal raw material & ASU formulations (3 Examples)<br>3. Stability studies of drugs (API & Formulation) with respect to the effect of pH, Temperature, Moisture and Light (any 4 experiments) | | |

## References:


1. Intellectual property rights: N. Pandey, K. Dharni
2. Indian Patent Law and Practice: K.C. Kankanala
3. Drugs and Cosmetics Act 1940 and Rules 1945
4. The Certified Pharmaceutical GMP Professional Handbook, Second Edition: Mark Allen Durivage
5. Law Relating to Intellectual Property- Dr. B.L.Wadehra

# Course Code: RPSBAS803

*To be revised for academic year 2020-2021*

# Course Title: Quality Management in Pharmaceutical Industry

# Academic year 2020-21

## COURSE OUTCOMES

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

## DETAILED SYLLABUS

| Paper Code | Semester VIII- Paper III | Lectures |
|---|---|---|
| **RPSBAS803** | Quality Management in Pharmaceutical Industry | **60** |
| | **803.1:** Good Laboratory Practices<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 | **15** |
| | **803.2:** Marketing of Pharmaceuticals<br>1. Stages leading to marketing Authorization<br>2. Unlicensed indication<br>3. Advertising of Pharmaceuticals<br>a. FDA<br>b. Direct to Consumer Advertising<br>i. Disclaimer<br>ii. Perception of Risk<br>4. Medical representatives & Promotional activities<br>5. Ethics | **15** |

| | | |
|---|---|---|
| | **803.3:** Packaging in Pharmaceutical Industry<br>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** |
| | **803.4:** Quality Control & Quality Assurance in Pharmaceuticals<br>1. Introduction to QC & QA<br>2. Requirements for implementing QC & QA<br>3. QC & 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 | **15** |
| **RPSBASP803** | **PRACTICALS** | |
| 1. Study of compatibility of container (primary/secondary packaging) with the drug<br>2. Study of Certificate of Analysis (COA)<br>3. Preparation of Standard Operating Procedure (SOP) for any one analytical instrument<br>4. Study of Shelf life of herbal drugs<br>5. Determination of percentage purity of $CaCO_3$/ $MgCO_3$ by Complexometric titration<br>6. Chemical assay of an API/Formulation in compliance with Pharmacopoeia | | |

## References:

1. GLP Essentials: A Concise guide to Good Laboratory Practice, 2nd Edition: Milton A. Anderson
2. Good Laboratory Practice Regulations: Sandy Weinberg
3. The Certified Pharmaceutical GMP Professional Handbook, Second Edition: Mark Allen Durivage
4. Pharmaceutical Packaging Handbook: Edward Bauer
5. Remington, Essentials of Pharmaceutics: Linda Felton

# Course Code: RPSBAS804

*To be revised for academic year 2020-2021*

# Course Title: Pharmaceutical Testing and Proteomics

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Students will be enabled to make effective use of Pharmacopoeia in evaluation of drugs and related substances. |
| **CO2** | Student will learn to deal with possible challenges in biopharmaceutical testing. |
| **CO3** | Students will be able to perform pharmacopeial assays for active pharmaceutical ingredient and tablet properties. |

## DETAILED SYLLABUS

| Paper Code | Semester VIII- Paper IV | Lectures |
|---|---|---|
| **RPSBAS804** | **Pharmaceutical Testing and Proteomics** | **60** |
| | **804.1: Pharmacopoeial tests**<br>1. Introduction to World Health Organization (WHO)<br>2. Introduction to Pharmacopoeial Indian Pharmacopoeia (IP) , British Pharmacopoeia(BP), United States Pharmacopoeia (USP), (Japanese Pharmacopoeia(JP), European Pharmacopoeia (EP), Australian Pharmacopoeia(AP) where ever applicable)<br>3. Specified test in Monographs with respect to liquid formulation (injectible) and solid dosage form (USP, EP, BP, IP)<br>4. AP, Indian Herbal Pharmacopoeia (IHP) and Ayurvedic Formulary of India(AFI) (wherever applicable) | **15** |
| | **804.2: Stability Studies**<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** |
| | **804.3: Biopharmaceuticals & Biosimilars**<br>1. Introduction to Biopharmaeuticals & Biosimilars<br>2. Sources of Biopharmaceuticals (*E. coli*, Animal cells, Additional systems)<br>3. Upstream & Downstream Processing<br>4. Therapeutic Hormones, Recombinant blood products & Therapeutic Enzymes<br>5. Biosimilars Development, Review & Approval | **15** |

| | | |
|---|---|---|
| | 6. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product | |
| | **804.4: Proteomics**<br>1. Protein extraction, separation, purification and identification<br>2. Protein fingerprinting techniques<br>3. Endogenous peptides and concepts of post translational modifications<br>4. Chemical modification of proteins | **15** |
| **RPSBASP804 PRACTICALS** | | |
| 1. Turbidity analysis of a liquid formulation<br>2. Study of Pharmaceutical Preparation: Chemical assay as per IP<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 Disintegration and Dissolution of a tablet as per IP/USP (enteric coated)<br>6. Analysis of Biopharmaceuticals/Biosimilars | | |

## References:

1. Indian Pharmacopoeia
2. U.S. Pharmacopoeia
3. British Pharmacopoeia
4. Indian Herbal Pharmacopoeia
5. Biosimilars: Regulatory, Clinical, and Biopharmaceutical Development: Hiten G., Harry Yang., Shefali Kakar
6. Introduction to Proteomics: Tools for the new Biology: Daniel C. Lieber.
7. Handbook of Stability tasting in pharmaceutical development: regulations, methodologies and best practices: Springer

# 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 |

# Course Code: RPSBAS901

# Course Title: Automation & Data Management
# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Student will be aware about the need for Automation in analysis. |
| **CO2** | Students will realize the importance of clinical data management and electronic data management |
| **CO3** | Student will be able to visualize protein tertiary structures using bioinformatics tools |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper I | Lectures |
|---|---|---|
| **RPSBAS901** | **Automation & Data Management** | **60** |
| | **901.1:** Automation of sample preparation<br>1. Introduction to Automation<br>2. Need for Automation in chemical, clinical analysis<br>3. Approaches to Automation: Solid phase extraction, Protein precipitation methods, Multi-well plate technology, Liquid handling procedures avoiding evaporation<br>4. Importance of automation in Bioanalysis | **15** |
| | **901.2:** Electronic Data Management<br>1. Electronic Acquisition of data<br>2. Management of data in Computers<br>3. Electronic Data Validation and regulatory requirements<br>4. Electronic signatures & its regulation<br>5. Generating reports using computers<br>6. Regulatory requirements of Data evaluation | **15** |
| | **901.3:** Bioinformatics in Disease Management<br>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** |

| | | |
|---|---|---|
| | 901.4: Introduction to Clinical Data Management<br>1. Introduction to CDM<br>2. Collection, Cleaning, and Management of subject data<br>3. Tools for CDM<br>4. Regulations, Guidelines, and Standards in CDM<br>5. The CDM Process<br>6. Review and finalization of study documents<br>7. Database designing, Data Collection<br>8. CRF tracking<br>9. Data entry & Validation, Medical Coding<br>10. Roles and Responsibilities in CDM | **15** |
| **RPSBASP901** | | **Practical** |
| 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 | | |

## References:


1. USFDA 21 CFR Part 11 Web resource: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application
2. Bioinformatics for Diagnosis, Prognosis and Treatment of Complex Diseases
3. Practical Guide to Clinical Data Management: Susanne Prokscha
4. Principles and Practice of Bioanalysis- Richard Venn
5. High throughput Bioanalytical Sample Preparation: Methods and Automation Strategies- David Wells
6. Experiences with Automated Sample Preparation in Bioanalysis-Picot and McDowall
7. Introduction to Electronic Data Management system- B.Lusia
8. Introduction to Electronic Data Management system- W. Green
9. Guidance for Industry Part, Electronic Records; Electronic Signatures- Scope and Application

# Course Code: RPSBAS902

# Course Title: Bioanalytical techniques
# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Students will be able to understand the importance of hyphenated techniques. |
| **CO2** | Students will be able to analyse and interpret mass spectrometric data for identification and quantification of analytes. |
| **CO3** | Students will get hands-on training on HPLC. |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper II | Lectures |
|---|---|---|
| **RPSBAS902** | **Bioanalytical techniques** | **60** |
| | **902.1:** Introduction to Mass Spectrometry (MS)<br>1. Evolution of MS<br>2. Importance of MS as a detector<br>3. Interfaces used in LC-MS & GC-MS<br>4. Sample preparations of MS<br>5. Components of Mass Spectrometer:<br>a) Inlets<br>b) Ion sources- GC-MS: EI, CI; LC-MS: ESI,API(APCI & APPI), FI,FD,FAB,TSP, MALDI<br>c) Analyzers- QP, TOF, Ion trap, Magnetic sector, Hybrid analyzers<br>d) Detectors<br>6. Importance of vacuum in MS system<br>7. Sample preparation for MS | **15** |
| | **902.2:** Hyphenated Techniques in Bioanalysis<br>1. Introduction to MS/MS (tandem MS)<br>2. GC/MS and GC/MS/MS<br>3. LC/MS and LC/MS/MS<br>4. Scan events in Triple Quadrupole and other tandem systems and hybrid systems | **15** |
| | **902.3:** Applications and Advances of Mass Spectroscopy<br>1. Introduction to ICP-MS and its industrial applications.<br>2. Introduction to advances in the field of mass spectroscopy e.g. Headspace Gas chromatography, Thin Layer Chromatography-Mass Spectroscopy | **15** |

| | | |
|---|---|---|
| | **902.4:** Application of Tracer techniques<br>1. Concept of Radioactivity & Half life<br>2. ∝, β, γ emitters and their biological applications<br>3. Using tracers in assays<br>4. Detectors and counters<br>5. Concept of autoradiography<br>6. Radiolabeled probes and their uses | **15** |
| **RPSBASP902 PRACTICALS** | | |
| 1. HPLC analysis of modern drug from plasma<br>2. LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.)<br>3. GC/MS separation of plant essential oil (Demonstration)<br>4. LC/MS/MS quantitation of a modern drug from plasma (e.g. Diclofenac Sodium)<br>5. LC/MS/MS quantitation of metabolite of a modern drug from plasma (e.g. Mycopenolic acid, metabolite of Mycophenolatemofitil).<br>6. Mass Fingerprinting of peptides using a suitable sample | | |

## 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: RPSBAS903

# Course Title: Research Methodology & Biostatistics

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Student will understand the importance of research methodology and research designs in all fields of research. |
| **CO2** | Students will also be able to use descriptive statistics and test of significance for accurate statistical calculations in research. |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper III | Lectures |
|---|---|---|
| **RPSBAS903** | **Research Methodology & Biostatistics** | **60** |
| | **903.1:** Introduction to Research Methodology<br>1. Meaning, objectives and motivation of Research<br>2. Various Types of Research:<br>a) Descriptive v/s Analytical<br>b) Applied v/s Fundamental<br>c) Quantitative v/s Qualitative<br>d) Conceptual v/s Emperical<br>3. Overview & flowchart of research process.<br>4. Literature review: Surveying, synthesizing, critical analysis, reading materials, reviewing, rethinking, critical evaluation, interpretation Research Purposes<br>5. Ethics in research – APA Ethics code. | **15** |
| | **903.2:** Research design<br>1. Definition of research design & its importance<br>2. Features of Good Research Design<br>3. Important Concepts regarding Research Design:<br>a) Dependent, Independent, Extraneous variables<br>b) Importance of control<br>c) Research hypothesis, experimental & non-experimental hypothesis testing<br>d) Treatment, experimental & experimental units<br>4. Research designs: Exploratory research, Descriptive & diagnostic research, Hypothesis testing research<br>5. Informal experimental design: Before & after without control, After- only without control, Before & after with control | **15** |

| | | |
|---|---|---|
| | **903.3:** Descriptive Statistics & Regression Analysis<br>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>c. Introduction to correlation & regression analysis | **15** |
| | **903.4:** Test of Significance<br>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** |
| **RPSBASP903** | | **PRACTICALS** |
| 1. Report writing<br>2. Case studies<br>3. Abstract writing<br>4. Research paper review<br>5. Questionnaire designing<br>6. Graphical Representation of a data<br>7. Problems based on Biostatistics | | |

## References:


1. Research Methodology: Methods and Techniques: C. R. Kothari
2. Essentials of research design and methodology: Geoffrey R. Marczyk
3. Fundamental of Research Methodology and Statistics: Y.K. Singh
4. Research Methodology: A Step-by-step Guide for Beginners: Ranjit Kumar
5. Methods in Biostatistics: B.K. Mahajan
6. Basic Concepts of Biostatistics: Arumugam
7. Biostatistics, Basic concepts and Methodology for the Health Sciences: Daniel & Cross
8. Fundamentals of Applied Statistics: Gupta and Kapoor: S. Chand and sons
9. Introduction to Biostatistics and Research Methods: Rao and Richard

# Course Code: RPSBASP904

# Course Title: Internship

# Academic year 2020-21

## 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. |

## DETAILED SYLLABUS

| Paper Code | Semester IX- Paper IV | Lectures |
|---|---|---|
| **RPSBASP904** | **Internship** | **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 |

# Course Code: RPSBAS1001

*To be revised for academic year 2020-2021*

## Course Title: Analytical Techniques and their Validation

## Academic year 2020-21

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Students will be trained to interpret spectral data of IR, NMR and LC-MS for structural elucidation of analytes. |
| **CO2** | Students will understand applications of these techniques with special emphasis on bioanalysis. |
| **CO3** | Students will be able to perform IQ/OQ/PQ for analytical instruments. |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper I | Lectures |
|---|---|---|
| **RPSBAS1001** | **Analytical Techniques and their Validation** | **60** |
| | **1001.1:** Thermal Analysis & XRD<br>1. Principles of Thermal Analysis<br>2. Instrumentation Requirements<br>3. Applications of Thermal Analysis<br>4. Thermal analysis of Bhasma preparations<br>5. Thermal Analysis Techniques<br>6. Theory of XRD and XRF<br>7. Crystal structure of solids and concept of crystallography<br>8. Bragg's law of diffraction<br>9. Instrumentation of powdered XRD<br>10. Application in the determination of polymorphs in pharmaceutical compounds<br>11. Percent crystallinity, Single crystal XRD<br>12. Determination of the 3D structure<br>13. Wavelength dispersive (WD) and energy dispersive (ED) XRF<br>14. Instrumentation of WD and (ED)XRF<br>15. Applications of XRF for elemental analysis | **15** |
| | **1001.2:** Chiral chromatography, Circular Dichroism-Optical Rotatory Dispersion<br>1. Chiral Chromatography:<br>2. Concept of chirality, Chiral HPLC, Column chemistry and column conditions in chiral HPLC, Applications of chiral HPLC<br>3. Theory and Applications of Circular Dichroism & Optical Rotary Dispersion | **15** |

| | | |
|---|---|---|
| | **1001.3:** Analytical Method Validation<br>1. Concept of method validation<br>2. Regulatory requirements of validation<br>3. System suitability, Parameters for Method Validation<br>4. Use of Reference standards<br>5. Issues of Method transfer<br>6. Intra lab validation and Inter lab validation<br>7. Sampling | **15** |
| | **1001.4:** Regulated Bioanalysis & Guidelines<br>1. Introduction<br>2. Evolution of Regulated Bioanalysis<br>3. Bioanalytical method validation<br>4. Pre-study Validation<br>5. In-study validation<br>6. Documentation<br>7. Regulatory requirements of Bioanalysis<br>8. Quality systems in Regulated Bioanalysis | **15** |
| **RPSBASP1001** | | **PRACTICALS** |
| 1. GC analysis of herbal raw material & ASU formulations<br>2. Analytical run design<br>3. Study of Installation Qualification, Operational Qualification, Performance Qualification of any one analytical instrument.<br>4. Analytical Method Validation (any one example) | | |

## References:


1. Handbook of Analytical Techniques, Vol I & II
2. Chiral Chromatography by Beesley & Scott
3. Principles of Instrumental Analysis - Skoog, Holler, Crouch
4. Regulated Bioanalysis: Fundamentals and Practice: Rocci Jr., Mario L., Lowes, Stephen
5. Analytical Method Development And Validation: Swartz and Krull
6. Validation of Analytical Methods, Methodology and Statistics: Shrivastava and Saxena
7. Introduction to Spectroscopy: Donald L. Pavia
8. Principles of instrumental analysis: Douglas a. Skoog
9. Ord and Cd in Chemistry and Biochemistry: Pierre Crabbe
10. Chiral Chromatography: Beesley & Scott

# Course Code: RPSBAS1002

*To be revised for academic year 2020-2021*

# Course Title: Advances in Bioanalysis

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Student shall be enabled to use mass spectrometry for qualitative and quantitative analysis of data and conduct method development and validation on analytical instruments. |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper II | Lectures |
|---|---|---|
| **RPSBAS1002** | **Advances in Bioanalysis** | **60** |
| | **1002.1:** Qualitative applications of mass spectroscopy<br>1. Structural elucidation by MS, Rules of fragmentation<br>2. Interpretation of MS spectra<br>3. Analysis of essential oils, pesticides<br>4. Peptide mapping, peptide mass fingerprinting | **15** |
| | **1002.2:** Quantitative applications of mass spectroscopy<br>1. Impurity profiling in drugs and drug products (sample Preparation and characterization)<br>2. Macromolecule quantitation<br>3. Small Molecule (SM) quantitation<br>4. Applications in proteomics<br>5. Pesticide residue analysis from different sample matrices<br>6. Technique of generating drug metabolites<br>7. Metabolite Identification & Metabolite quantitation | **15** |
| | **1002.3:** Bioanalytical Method Development<br>1. Strategies for Method development<br>2. What and Why of method validation<br>3. Regulatory requirements of validation<br>4. Intra and inter lab – Validation<br>5. IQ, OQ and PQ of analytical instruments (practicals for this are already done in part one as per the new syllabus)<br>6. Use of Reference standards<br>7. Issues of Method transfer | **15** |

| | | |
|---|---|---|
| | **1002.4:** Bioanalytical Method Validation<br>1. Pre- study Validation.<br>2. Selectivity, Accuracy, Precision, Recovery, Calibration Curve, Sensitivity, Reproducibility, Stability Incurred sample re-analysis (ISR).<br>3. Documentation and Additional issues like Endogenous substances & Biomarkers etc.<br>4. In-Study Validation. | **15** |
| **RPSBASP1002** | | **PRACTICALS** |
| 1. Impurity profiling of Modern Drug by HPTLC/HPLC.<br>2. Content Uniformity analysis of drugs by HPTLC/ HPLC.<br>3. IR patterns of an Ayurvedic Bhasma preparation (e.g. comparison of calcium from Shankha Bhasma – with pure $CaCO_3$ and other modern Calcium supplement)<br>4. AAS/Redox/ Colorimetric analysis of Lohabhasma.<br>5. Metabolite preparation, Identification, quantitation by LC-MS-MS<br>6. Comparative interpretation of IR, NMR and Mass spectra | | |

## 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: RPSBAS1003

*To be revised for academic year 2020-2021*

# Course Title: Clinical Research & Ethics

# Academic year 2020-21

## COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Student will learn the various aspects of clinical research. |
| **CO2** | Student will get an overview of BA/BE studies and Therapeutic Drug Monitoring (TDM) |
| **CO3** | Students will be able to calculate pharmacokinetic parameters for the given drug |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper III | Lectures |
|---|---|---|
| **RPSBAS1003** | **Clinical Research & Ethics** | **60** |
| | **1003.1:** Good Clinical Practices & Ethics<br>**Good Clinical Practices:**<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<br>**Ethics:**<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 | **15** |

| | | |
|---|---|---|
| | **1003.2:** Pharmacovigilance<br>1. Introduction to Pharmacovigilance<br>2. Significance and need for Pharmacovigilance<br>3. Indian scenario and the role of regulatory in Pharmacovigilance<br>4. Pharmacovigilance and safe use of medicines (with case studies) | **15** |
| | **1003.3:** Bioavailability (BA) & Bioequivalence (BE) Studies<br>1. Concept of BA and BE<br>2. Parameters to evaluate BA and BE of a drug<br>3. Factors that influence BA and BE of a drug<br>4. Evaluating BA and BE of a drug<br>5. Estimating BA and BE parameters of a drug<br>6. Design of a BA and BE study<br>7. Conduct of a BA and BE study<br>8. Data record and evaluation in BA and BE study<br>9. Reporting a BA study<br>10. Regulatory requirements of BA and BE | **15** |
| | 1003.4 Therapeutic Drug Monitoring (TDM)<br>1. Purpose of therapeutic drug monitoring<br>2. Bioanalytical techniques in TDM<br>3. Analytical and practical issues of TDM<br>4. Pharmaco-economics of TDM | **15** |
| RPSBASP1003 | | **PRACTICALS** |
| 1. Calculation of AUC and bioequivalence from the given data (2 expts.)<br>2. Evaluation of a BA/BE Report<br>3. Calculation of different Pharmacokinetic parameters like Ka, Ke, t½, C max, $T_{max}$ and AUC from the given blood data.<br>4. Study of matrix effect by IR<br>5. Use of IR spectroscopy as a quantitative tool<br>6. Structural elucidation of compound by IR, NMR & MS. | | |

## 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: RPSBASP1004

*To be revised for academic year 2020-2021*

## Course Title: Project Work

## Academic year 2020-21

### COURSE OUTCOMES

| COURSE OUTCOME | DESCRIPTION |
|---|---|
| **CO1** | Students will learn how to formulate hypothesis, carry out literature survey, test hypothesis by designing experiments, and interpret results |
| **CO2** | Students should understand the importance of proper documentation and should be able to present the research carried out. |

## DETAILED SYLLABUS

| Paper Code | Semester X- Paper IV | Lectures |
|---|---|---|
| **RPSBASP1004** | **Project work** | **120** |
| | Industrial Training, and/or research project/Online training/Online internship<br>Industrial Training, and/or research project/ Online training (Swayam/Coursera/NPTEL/MOOC, etc.)/Online internship<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.<br>**Research Project**<br>1. Students are expected to identify a research problem relevant to the subject<br>2. The topic of research should be interdisciplinary, and should involve statistical analysis.<br>3. Thorough literature review should be carried out by the students.<br>4. A project Proposal should be submitted by student and should get approval from mentor allotted by the department.<br>5. Students should report and update the allotted mentor regarding the project work.<br>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<br>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.<br>**Research Review:**<br>1. Students should identify a topic for literature review<br>2. They should review at least 15 research articles for the review topic<br>3. Review article should be a detailed, comprehensive summary of the research articles in student's own words.<br>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<br>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.<br>**Research based on Survey/Case study**<br>1. Students should identify a topic for survey/case study<br>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.<br>3. They should gather data for survey/case study in a stipulated time and keep record of the same.<br>4. After data, collection, students should analyze the data using appropriate statistical tests and write final conclusion of the study.<br>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<br>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 |