Resolution No.AC/II (18-19).2.RPS1

# Integrated M.Sc. In Bioanalytical Sciences

## Syllabus for Integrated M.Sc. I & II.

## Academic year 2019-20.

INTEGRATED M.SC DEGREE COURSE IN BIOANALYTICAL SCIENCES
*With the option of specialization in Bioanalysis or Bioinformatics or Nutraceuticals*

PREAMBLE:

OBJECTIVES:

1. To impart high quality science education in a vibrant academic ambience with the faculty of distinguished teachers and scientists.
2. To equip students for the future who will 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.
3. To 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.

PURPOSE:
There is very a rapid change in science and technology and it is affecting all walks of life across the globe. The application of science to real world problems is becoming more complex and it is no more possible to find a simple solution to real world problems as we need to adopt what is called as a multidisciplinary approach.
In this age of plurality, application of only pure science is sine qua non! A one dimensional approach is redundant and this holds true for myriad areas of scientific endeavour. Many fields of scientific study such as Astronomy, Biotechnology, Bioinformatics, Environmental Sciences, Forensic Sciences, Nanotechnology etc are rapidly expanding in terms of the knowledge generated and as a result in these areas the one dimensional approach doesn't work. The purpose of introducing five year integrated course is to teach the students the value of multidisciplinary approach right from the undergraduate days.

BACKGROUND:
A post graduate course in Bioanalytical Sciences is already being conducted in five colleges and the course has gained credence and acceptability amongst the student community. The industry has responded positively to this novel course by absorbing the pool of fresh talent generated in to the corporate domain. Similarly post graduate courses in bioinformatics and nutraceutical sciences have recently been introduced in 2 colleges and response has been very encouraging.

SALIENT FEATURES:
The uniqueness of this course dovetails a modular learning with credit based evaluation.
The program is designed by distinguished professionals and experts drawn from varied professional backgrounds. The team that has designed this integrated course consists of experienced people from the world of academia, research and industry.
The design of the course affirms the conviction that the students passing this course will help meet the demand for reliable and well informed Bioanalysts in the areas of Analytical Sciences, Biotechnology, Clinical Research, Immunology, Molecular Biology and Pharmaceutical industry.

BACK TO BASICS:
The program will encompass the basics of Biology, Chemistry and Computational Sciences together in the First Three years of the Five year Program.

## LEARNING OBJECTIVES FOR FOURTH YEAR:

*(Bridging year)*

RPSBAS701: Pharmaceutical Microbiology & Pharmaceutical Manufacturing

- To introduce the basic concept of microbiology.
- To be aware of microbiological aspect of pharmaceuticals, importance of microbes in food and pharmaceutical industry, source of contamination and regulatory microbial testing in pharmaceuticals products.
- To highlight the importance of good manufacturing practices in pharmaceutical industry.

RPSBAS702: Pharmacology & Toxicology

- To introduce the theory of toxicology and introduce the concept of regulatory toxicity.
- To make students realize the utmost need to follow regulatory standards of toxicology as survival of human subjects is directly dependent on it.
- Study the concepts of Pharmacokinetics & Pharmacodynamics.

RPSBAS 703: Sample handling and Isolation of analytes in Bioanalysis

- To get acquainted to different bio-matrices.
- To underline the extraction, separation and isolation methods for potential analytes present in the bio-matrices.
- To highlight advanced extraction and isolation techniques like SCFE, SCFC & electrophoresis.

RPSBAS 704: Different systems of Medicine & Regulations

- To study the principles & practices involved in traditional and modern medicinal systems with detailed account of the dosage forms & formulations of each system.
- To compare Ayurveda, Siddha and Unani system of medicine.
- To highlight the importance of standardization of traditional medicines as per modern regulatory standards.

RPSBAS 801: Molecular Biology & Tissue culture

- To study different tissue culture techniques and applications of molecular biology in pharmaceutical industries.
- To make students understand the fundamental concepts of polymerase chain reaction (PCR) and cell and gene therapy products.
- To underline the importance of cell and gene therapy as a modern and futuristic medicine.

RPSBAS 802: IPR, Drugs and Cosmetic Act & Regulations

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

- To enlighten the student about good manufacturing practices followed in pharmaceutical industry.

RPSBAS 803: Quality Management in Pharmaceutical Industry

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

RPSBAS 804: Pharmaceutical Testing and Proteomics

- To study proteomics and fingerprinting techniques.
- To introduce different Pharmacopoeia and its applications in Pharmaceutical evaluation of drugs and related substances.
- To alert about the possible challenges in biopharmaceutical testing.
- To illuminate about advances in Biopharmaceuticals and biosimilars.

## LEARNING OBJECTIVES FOR FIFTH YEAR

RPSBAS901: Research Methodology & Statistics

- To introduce the concept of research methodology and enlighten about the various research designs to evaluate biological data.
- To illuminate upon the area of descriptive statistics and its applications in research.
- To train students in regression analysis of data and its further treatment using test of significance.

RPSBAS902: Advances in Bioanalysis I

- To imbibe the theoretical principles of mass spectrometry with respect to ionization and fragmentation pattern.
- To instil analytical approach with respect to the correct choice of hyphenated technique as per the properties of analytes.
- To train students to interpret mass spectrometric data for identification and quantification of analytes.
- To study the applications of tracer techniques in recent medical treatments.

RPSBAS903: Automation & Data Management

- To focus on the need for Automation in chemical & clinical analysis.
- To make the student aware about electronic data validation and its regulatory requirements.
- Study the use of Reference genome sequence & integrated genomic maps in disease management.
- To introduce Clinical Data Management.

RPSBAS 904: Industrial Training

- To acquire enhanced skills in the field of Bioanalysis and research.
- To get the know-how of the function of an industry and understand its setup and norms.
- To imbibe professional qualities.

RPSBAS1001: Analytical Techniques and their Validation

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

RPSBAS1002: Advances in Bioanalysis II

- To learn the Qualitative & Quantitative applications of Mass Spectrometry.
- To emphasize the importance of analytical and bioanalytical method development and validation in the analysis of biological samples.

RPSBAS1003: Clinical Research & Ethics

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

RPSBAS 1004: Project work

- To make the student aware about recent research problems relevant to the subject, formulation of hypothesis, carrying out literature survey, effective analysis of the test material, interpretation of results and proper documentation and presentation of the research carried out.

Syllabus- Integrated M.Sc. I

*Syllabus at a Glance*

| Semester VII | Semester VIII |
|---|---|
| RPSBAS701: Pharmaceutical Microbiology & Pharmaceutical Manufacturing<br>701.1:Pharmaceutical Microbiology<br>701.2:Bioassays in Pharma evaluation<br>701.3: Immunoassays & Immunoinformatics<br>701.4: Pharmaceutical Manufacturing | RPSBAS 801: Molecular Biology & Tissue culture<br>801.1: Advances in Plant Tissue culture<br>801.2: Advances in Animal Tissue Culture<br>801.3: PCR & its application<br>801.4: Cell and Gene Therapy Products |
| RPSBAS702:Pharmacology & Toxicology<br>702.1: Basic Pharmacology<br>702.2: Pharmacokinetics & Pharmacodynamics<br>702.3: Basic Toxicology<br>702.4: Regulatory Toxicology | RPSBAS 802: IPR, Drugs and Cosmetic Act & Regulations<br>802.1: Intellectual Property Rights-I<br>802.2: Intellectual Property Rights -II<br>802.3: Drugs & Cosmetics Act and Guidelines<br>802.4: Good Manufacturing Practices |
| RPSBAS 703: Sample handling and Isolation of analytes in Bioanalysis<br>703.1: Sample handling and Biomatrices<br>703.2: Extraction & Isolation of Analytes<br>703.3: Super Critical Fluid Extraction & Super Critical Fluid Chromatography<br>703.4: Electrophoresis | RPSBAS 803: Quality Management in Pharmaceutical Industry<br>803.1: Good Laboratory Practices<br>803.2: Marketing of Pharmaceuticals<br>803.3: Packaging in Pharmaceutical Industry<br>803.4: Quality Control & Quality Assurance in Pharmaceuticals |
| RPSBAS 704: Different systems of Medicine & Regulations<br>704.1: Disease Management as per different medicinal systems<br>704.2: NCE & its Evolution into a drug molecule<br>704.3: Indian Systems of Medicine- Ayurveda, Siddha & Unani<br>704.4: Standardization aspects of Ayurveda, Siddha & Unani drugs | RPSBAS 804: Pharmaceutical Testing and Proteomics<br>804.1: Pharmacopoeial tests<br>804.2: Stability Studies<br>804.3: Biopharmaceuticals & Biosimilars<br>804.4: Proteomics |

| 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. Unit operations<br>3. Importance of Schedule M(D& C) in Pharmaceutical manufacturing process<br>4. Manufacturing of drugs- Tablets, Capsules, Syrups<br>5. Manufacturing of sterile drugs | 15 |
| RPSBASP701 | PRACTICALS | |

1. Bioassay of Penicillin
2. Bioassay of Vitamin $B_{12}$
3. Immunoassay for detection of Pregnancy
4. Immunoassays for detection of Hepatitis B/Dengue
5. Sterility testing of Pharmaceutical Dosage forms
6. Total Viable Count of microorganisms from herbal Raw materials and formulations
7. Screening of Pathogenic organisms from Food/herbal raw materials/formulations
8. Study of antibiotic producers

| 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: Basic 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 | 15 |
| | **702.4: 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)

| 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, Feces<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 |
| | **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. Extraction of Analyte from urine, fecal matter and saliva<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<br>7. Separation of a modern drug from plasma and its formulation/ peptides by Capillary Electrophoresis. | |

| 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.<br>5. 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. GC/HPLC Analysis of Eugenol from raw materials to finished drugs<br>5. Standardization of any one formulation using classical and modern analytical techniques | |

| 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 & labeling 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) | |

| 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.<br>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. | 15 |
| | **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 | |

| 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 | |
| | **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 | | |

| 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 Biosimilars & Biopharmaeuticals<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<br>6. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product | 15 |
| | **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/Biosimillars | | |

*Syllabus at a Glance*

| Semester IX | Semester X |
|---|---|
| RPSBAS901: Research Methodology & Statistics<br>901.1:Introduction to Research Methodology<br>901.2:Research design<br>901.3: Descriptive Statistics & Regression Analysis<br>901.4: Test of Significance | RPSBAS1001: Analytical Techniques and their Validation<br>1001.1: Thermal Analysis & XRD<br>1001.2: Chiral chromatography, Circular Dichroism – Optical Rotary Dispersion<br>1001.3: Analytical Method Validation<br>1001.4: Regulated Bioanalysis & Guidelines |
| RPSBAS902: Advances in Bioanalysis I<br>902.1: Introduction to Mass Spectrometry<br>902.2: Hyphenated Techniques<br>902.3: Application of Mass Spectroscopy<br>902.4: Application of Tracer techniques | RPSBAS1002: Advances in Bioanalysis II<br>1002.1: Qualitative applications of mass spectroscopy<br>1002.2: Quantitative applications of mass spectroscopy<br>1002.3: Bioanalytical Method Development<br>1002.4: Bioanalytical Method Validation |
| RPSBAS903: Automation & Data Management<br>903.1: Automation of sample preparation<br>903.2: Electronic Data Management<br>903.3: Bioinformatics in Disease Management<br>903.4: Introduction to Clinical Data Management | RPSBAS1003: Clinical Research & Ethics<br>1003.1: Good Clinical Practices & Ethics<br>1003.2: Pharmacovigilance<br>1003.3: Bioavailability & Bioequivalence Studies<br>1003.4: Therapeutic Drug Monitoring |
| RPSBAS 904: Industrial Training | RPSBAS 1004: Project work |

| Paper Code | Semester IX- Paper I | Lectures |
|---|---|---|
| RPSBAS901 | Research Methodology & Statistics | 60 |
| | **901.1: 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<br>a. Surveying, synthesizing, critical analysis, reading materials, reviewing, rethinking, critical evaluation, interpretation Research Purposes<br>5. Ethics in research – APA Ethics code. | 15 |
| | **901.2: 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 |
| | **901.3: 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 |
| | **901.4: 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 |

| RPSBASP901 | PRACTICALS |
|---|---|

1. Report writing
2. Case studies
3. Abstract writing
4. Research paper review
5. Questionnaire designing
6. Graphical Representation of a data
7. Problems based on statistics

| Paper Code | Semester IX- Paper II | No of lectures |
|---|---|---|
| RPSBAS902 | Advances in Bioanalysis I | 60 |
| | **902.1: Introduction to Mass Spectrometry(MS)**<br>1. Evolution of MS<br>2. Importance of MS as 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 eg, 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. Radio labelled 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 (eg. Mycopenolic acid, metabolite of Mycophenolatemofitil)<br>6. Mass Fingerprinting of peptides using a suitable sample | | |

| Paper Code | Semester IX- Paper III | No of lectures |
|---|---|---|
| RPSBAS903 | Automation & Data Management | 60 |
| | **903.1: 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 |
| | **903.2: 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 |
| | **903.3: Bioinformatics in Disease Management**<br>1. Basic concepts on identification of disease genes<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 |
| | **903.4: 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 |
| **RPSBASP903 Practicals** | | |
| 1. Problems based on Biostatistics<br>2. Tertiary structure and function prediction using homology modeling and *ab initio* method<br>3. Validation of Predicted structure<br>4. Visualization of 3D Protein structure using Rasmol, VMD<br>5. Docking: Using a docking software to study protein-ligand interaction | | |

| Paper Code | Semester IX- Paper IV | No of lectures |
|---|---|---|
| RPSBAS904 | Industrial Training | 120 |
| 1. Students are supposed to do internship of 8-12 weeks in an Industry. Students should submit the detailed report regarding the training. | | |

| Paper Code | Semester X- Paper I | No of 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 crystalanity, 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 M<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 to 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) | |

| Paper Code | Semester X- Paper II | No of lectures |
|---|---|---|
| RPSBAS1002 | Advances in Bioanalysis II | 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 | |

| Paper Code | Semester X- Paper III | No of 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 practice<br>5. Audit of GCP compliance<br>Ethics:<br>1. Origin of Ethical issues<br>2. Dealing with Ethical issues<br>3. Ensuring compliance to 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 & Bioequivalence 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**<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. | |

| Paper Code | Semester X- Paper IV | No of lectures |
|---|---|---|
| RPSBAS1004 | Project Work | 120 |

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 the student and should get the approval from the 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.

## LEARNING OUTCOMES

RPSBAS701: Pharmaceutical Microbiology & Pharmaceutical Manufacturing
This will highlight the applications of microbiology for testing quality of pharmaceutical products. Students will understand the norms required for manufacturing in pharmaceutical industry.

RPSBAS702: Pharmacology & Toxicology
This will highlight the importance of toxicological studies for ensuring safe administration of pharmaceuticals.

RPSBAS 703: Sample handling and Isolation of analytes in Bioanalysis
This will help the student in dealing with different bio-matrices. Student will be able to choose appropriate method for extraction and isolation of analytes when varied bio-matrices are subjected to bioanalysis.

RPSBAS 704: Different systems of Medicine & Regulations
This will underline the importance of bioanalytical techniques for standardization of traditional medicines.

RPSBAS 801: Molecular Biology & Tissue culture
This will facilitate the student in understanding different tissue culture techniques and studying its applications. Student will also understand the significance of cell and gene therapy as a potent futuristic medicine.

RPSBAS 802: IPR, Drugs and Cosmetic Act & Regulations
This will familiarize students with the current legal scenario regarding intellectual property rights. Students will understand the importance of Drug act and the need for regulations in Bioanalysis.

RPSBAS 803: Quality Management in Pharmaceutical Industry
This will give an insight into the good practices followed in industry operations. Students will realize the importance of documentation and strict adherence to protocol in bioanalytical industries.

RPSBAS 804: Pharmaceutical Testing and Proteomics
This will enable the student to make effective use of Pharmacopoeia in evaluation of drugs and related substances. Student will also learn to deal with possible challenges in biopharmaceutical testing.

RPSBAS901: Research Methodology & Statistics
This will convey the importance of research methodology and research designs in all fields of research. Student will also be able to use descriptive statistics and test of significance for accurate statistical calculations in research.

RPSBAS902: Advances in Bioanalysis I
This will highlight the importance of hyphenated techniques and enable the students to analyze and interpret mass spectrometric data for identification and quantification of analytes.

RPSBAS903: Automation & Data Management
Student will be aware about the need for Automation in analysis. This will convey the importance of electronic data management system. Student will also be able to absorb the concepts of clinical data management.

RPSBAS 904: Industrial Training
Student will be trained to face the challenges of industry and will acquire requisite skills in the field of Bioanalysis and research.

RPSBAS1001: Analytical Techniques and their Validation
This will train students to interpret spectral data of IR, NMR and LC-MS for structural elucidation of analytes. Students will understand applications of these techniques with special emphasis on bioanalysis.

RPSBAS1002: Advances in Bioanalysis II
This will enable the students to use mass spectrometry for qualitative and quantitative analysis of data and conduct method development and validation on analytical instruments.

RPSBAS1003: Clinical Research & Ethics
Students will be enlightened about the various aspects of clinical research. They will get a brief idea regarding the case report format involved in BA/BE study.

RPSBAS 1004: Project work
Student will be aware about how to formulate hypothesis, carry out literature survey, effectively analyze the test material, interpret results and properly document and present the research carried out.