Resolution number:

S. P. Mandali's

Ramnarain Ruia Autonomous College

(Affiliated to University of Mumbai)

Syllabus for

M.Sc. in Bioanalytical Sciences

(Post Graduate Syllabus)

Program Code: RPSBAS

(Credit Based Semester and Grading System
for academic year 2021–2022)

PROGRAM OUTCOMES

PO	PO Description **A student completing Masters in Science program offered by the institution 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 **A student completing Master's Degree in Bioanalytical Sciences program in the subject of Bioanalytical Sciences will be able to:**
PSO 1	Develop skills in the field of Bio-analytical Sciences with specific emphasis for exploitation of ASU system of medicine as well as its need for changing trends of modern pharmaceutical Industries.
PSO 2	Amalgamate traditional analytical chemical techniques with modern genomic and proteomic technologies of manufacturing and analysis.
PSO 3	It will also introduce the powerful tools of informatics in routine use at manufacturing, QC and research.
PSO 4	It will further expose to National & International regulatory affairs with reference to drugs.

PROGRAM OUTLINE

YEAR	SEM	COURSE CODE	COURSE TITLE	CREDITS
M. Sc. I	I	RPSBAS101	Principles of Bioanalysis	4
		RPSBASP101	Practical	2
		RPSBAS102	Spectroscopic Techniques	4
		RPSBASP102	Practical	2
		RPSBAS103	Introduction to Pharmacy	4
		RPSBASP103	Practical	2
		RPSBAS104	Applied Biology	4
		RPSBASP104	Practical	2
M. Sc. I	II	RPSBAS201	Pharmacognosy & Phytochemistry	4
		RPSBASP201	Practical	2
		RPSBAS202	Chromatographic Techniques	4
		RPSBASP202	Practical	2
		RPSBAS203	Practices In Pharmaceutical Industry	4
		RPSBASP203	Practical	2
		RPSBAS204	IPR, Drug Act & Regulations	4
		RPSBASP204	Practical	2

M. Sc. II	**III**	**RPSBAS301**	**Microbiology, Toxicology, and Standardization of Ayurveda, Siddha & Unani (ASU) Medicine**	**4**
		RPSBASP301	**Practical**	**2**
		RPSBAS302	**Bioanalytical Techniques and Clinical Data Management (CDM)**	**4**
		RPSBASP302	**Practical**	**2**
		RPSBAS303	**Research Methodology and Biostatistics**	**4**
		RPSBASP303	**Practical**	**2**
		RPSBAS304	**Internship**	**4**
		RPSBASP304	**Practical**	**2**
M. Sc. II	**IV**	**RPSBAS401**	**Pharmaceutical Biotechnology & Modern Analytical Techniques**	**4**
		RPSBASP401	**Practical**	**2**
		RPSBAS402	**Advances in Bioanalysis**	**4**
		RPSBASP402	**Practical**	**2**
		RPSBAS403	**Fundamentals of Clinical Research**	**4**
		RPSBASP403	**Practical**	**2**
		RPSBAS404	**Research project**	**4**
		RPSBASP404	**Practical**	**2**

Course Code: RPSBAS101

Course Title: Principles of Bioanalysis

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	Students will develop curiosity and interestin the field of Bioanalysis.
CO 2	Students will get acquainted with intricacies of dilutions, concepts of weight, volume and density for different samples and chemical solutions.
CO 3	Students will also learn about the composition and storage of different bio-matrices.
CO 4	In the practical paper, students will learn the preparation of analytical standard solutions along with extraction and analysis of biomolecules.
CO 5	Students will also learn the skill of Liquid-Liquid Extraction and Solid Phase Extraction of modern drug from complex biomatrix like plasma.

DETAILED SYLLABUS

Paper Code	**Semester I- Paper I**	**Lectures**
RPSBAS101	**Principles of Bioanalysis**	**60**
101.1: Introduction of Bioanalytical Sciences		
1. Concepts in Bioanalysis 2. Purpose of Bioanalysis 3. Bioanalysis in Pharmaceutical industry, Hospital laboratories, Forensic toxicology laboratories, Doping control laboratories. 4. Challenges in Bioanalysis 5. Various Tools used in Bioanalysis		**15**
101.2: Analysis of Biomolecules		
1. Importance of accurate determination of biomolecules 2. Major methods to detect and quantify biomolecules 3. Understanding mass, weight, volume and density 4. Understanding moles and molarity 5. Understanding solubility and dilutions		**15**
101.3: Composition, Storage and properties of Biological Samples		
1. Introduction to Bio-matrices- Microbial, Plant & Animal 2. Collection and storage of Biological samples 3. Microbes- Bacteria, Algae, Fungi, Protozoans		**15**

4. Plants- different parts & stages of growth 5. Animals & Humans: a. Blood, or whole blood, Plasma and serum b. Urine, faeces c. Saliva d. Cerebrospinal Fluid, Synovial fluid e. Hair and Nails f. Tissue (Biopsies)	
101.4: Extraction Techniques for Bioanalysis	
1. Physico-chemical properties of drugs and solvents 2. Concept of partition & Partition Coefficient 3. Solvent properties 4. Introduction to Liquid-liquid Extraction & Liquid-Liquid Micro-extraction, Solid Phase extraction & Solid Phase Micro-Extraction Techniques 5. Ionization and its effect on the extraction of drugs 6. Matrix components & analyte isolation a. Concentration of extracts b. Isolations of fractions 7. Purification of isolate	**15**
RPSBASP101 PRACTICALS	
1. Preparation of analytical standard solutions 2. Extraction and Analysis of Carbohydrates, proteins and lipids from biological sample (Microbe, Plant & animal) 3. Bioanalysis of Urine 4. Liquid – liquid extraction of a modern drug from plasma and formulations 5. Solid Phase extraction of a drug from plasma	

References:

1. Storage Carbohydrates in Vascular Plants:Distribution, Physiology, and Metabolism: David Hopkin Lewis
2. Lehninger's Principle of Biochemistry: David Nelson, Michael Cox: Springer
3. Basic concept in Biochemistry:Hiram.F.Gilbert: Mac Grow Hill
4. Color Atlas of Biochemistry: 2nd edition:J Koolman, K.H. Roehm :Theime Publication
5. Modern Analytical Chemistry:DandHarvey:Mc Grow Hill Publishers
6. Principle and practice of Bioanalysis:Richard F. Venn
7. High Throughput Bioanalytical Sample Preparation, Volume 5, 1st Edition, Methods and Automation Strategies:David Wells: Elsevier Science
8. Bioanalysis of Pharmaceuticals, Sample preparation, Separation technique and Mass Spectrometry: Steen Honore Hansen &Stig Pedersen- Bjergaard

Course Code:RPSBAS102

Course Title:Spectroscopic Techniques

Academic year 2021-22

COURSE OUTCOMES:

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

DETAILED SYLLABUS

Paper Code	**Semester I- Paper II**	**Lectures**
RPSBAS102	**Spectroscopic Techniques**	**60**
102.1: Introduction to Spectroscopy		
1. General properties of Electromagnetic Radiation 2. The electromagnetic spectrum 3. Components of optical instruments 4. Introduction to optical atomic spectroscopy 5. Atomic & Molecular spectroscopy		**15**
102.2: Techniques in Atomic Spectroscopy		
1. Atomic Absorption Spectroscopy a. Principles & Instrumentation b. Applications 2. Atomic Emission Spectroscopy		

a. Principles & Instrumentation (Atomic Emission Spectrophotometer, Flame Photometer &Inductively Coupled Plasma- Atomic Emission Spectroscopy, Inductively Coupled Plasma- Optical Emission Spectroscopy) 3. Applications	
102.3: Techniques in Molecular Spectroscopy	
Principles, Instrumentation and Applications of: 1. UV -Visible and fluorescence Spectroscopy 2. IR Spectroscopy 3. Raman Spectroscopy 4. NMR spectroscopy	**15**
102.4: Spectroscopic Techniques based on Light Scattering	
Principles, Instrumentation and Applications of: 1. Nephelometry 2. Turbidimetry 3. Particle Size Analyzer 4. Refractometer	**15**
RPSBASP102 PRACTICALS	
1. Turbidimetric & Nephelometric analysis of Pharmaceutical Products 2. Flame Photometric estimation of metals with special emphasis on interference 3. Sample Preparation for AAS & analysis of pharmaceutical products/Crude drugs for their metal content using AAS 4. Turbidimetric & Nephelometric analysis of Pharmaceutical Products 5. Qualitative analysis of organic solids using IR spectroscopy 6. IR analysis of modern drug (any one example.)	

References:

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

Course Code RPSBAS103

Course Title: Introduction to Pharmacy

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	Students will be introduced to the concept of Drug, its formulations and drug metabolism.
CO 2	Students will be studying the mechanism of drug action.
CO 3	Students will also learn about the concept of new chemical entity and get an idea about the entire process of new drug development.
CO 4	Students will also study the different pharmacopoeias and will be able to understand the significance of each pharmacopoeia.
CO 5	In the practical paper, the student will carry out tablet testing for different parameters like hardness, friability, disintegration and dissolution of the tablet.
CO 6	Students will also practise advanced titrations like complexometric titrations.

DETAILED SYLLABUS

Paper Code	Semester I- Paper III	Lectures
RPSBAS103	**Introduction to Pharmacy**	**60**
103.1: Basic Pharmaceutical Chemistry		
1. Definition of a drug, Requirements of an ideal drug, Classification of drugs (based on therapeutic action) 2. Nomenclature of drugs: Generic name, Brand name, Systematic name 3. Definition of the following medicinal terms: Pharmacon, Pharmacophore, Prodrug, Half-life efficiency, LD50, ED50, Therapeutic Index. 4. Brief idea of the following terms: Receptors, Drug-receptor interaction, Drug Potency, Bioavailability, Drug toxicity, Drug addiction, Spurious Drugs, Misbranded Drugs, Adulterated Drugs, Pharmacopoeia. 5. Formulations, Different dosage forms (emphasis on sustained release formulations.) 6. Drug development from Natural Sources: Anti-infective agents, Anti-cancer agents, CNS agent		**15**

7. Development of drug: The Pharmacophore identification, modification of structure or functional group. 8. Different types of chemical transformation of drugs with specific examples.	
103.2: Basic Pharmacology	
1. Scope of Pharmacology 2. Sources, Nature & Nomenclature of Drugs 3. Dosage forms & Routes of Drug Administration 4. Dose- Response Relationship 5. Factors influencing drug dosage and drug action. 6. Drug disposition & Pharmacokinetics 7. Drug Metabolism: Introduction, Absorption, Distribution, Bio-transformation, Excretion 8. Mechanisms of Drug Action- Pharmacodynamics 9. Different Pharmacokinetic & Pharmacodynamics parameters and their meanings and basic techniques to evaluate the parameters 10. Basic types of models in Pharmacokinetics & Pharmacodynamics	**15**
103.3: New Drug Development	
1. Introduction to Drug Discovery, Design and Development 2. Target identification 3. Discovery of a Lead compound: Screening, drug metabolism studies and clinical observation. 4. Concept of New Chemical Entity (NCE) 5. Stages in the development of NCE 6. Preclinical studies on NCE 7. Clinical trials & introduction to schedule Y 8. Enzymes in drug discovery	**15**
103.4: Pharmacopoeia and its uses	
1. Introduction to World Health Organisation guidelines 2. Introduction to Pharmacopoeias IP, BP, USP (JP, EP, AP where ever applicable) 3. Specified test in Monographs with respect to liquid formulation (injectable) and solid dosage form (USP, EP, BP, IP) 4. AP, Indian HP and AFI (wherever applicable)	**15**
RPSBASP103 PRACTICALS	
1. Study of different dosage forms and classification of drugs (Assignment) 2. Use of Pharmacopoeia (Indian and US Pharmacopoeia) 3. Study of Hardness and Friability of a tablet 4. Study of Disintegration and Dissolution of a tablet as per IP/USP (uncoated) 5. Study of Disintegration and Dissolution of a tablet as per IP/USP (enteric coated) 6. Determination of percentage of $CaCO_3$/$MgCO_3$ from formulation(s) by Complexometric titration	

References:

1. Pharmaceutical Analysis:David Lee
2. Excipients and Delivery Systems of Pharmaceutical formulations:Karsa,Stephenson
3. Remington: Essential of pharmaceutics: Linda Felton
4. George M. Brenner, Craig Stevens: Pharmacology
5. Biopharmaceutics and Pharmacokinetics: A Treatise: Brahmankar, Jaiswal: Pharma Dost
6. Essentials of Pharmacotherapeutics: F S K Barar.
7. Essentials of Medical Pharmacology: K.D.Tripathi, Jaypee Publications

Course Code: RPSBAS104

Course Title: Applied Biology

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This course will introduce students with advances in the fields of genomics and proteomics.
CO 2	Students will also learn about enzymes,their kinetics and multi-enzyme complexes& their applications.
CO 3	Students will get an idea about the vast field of Immunoassays and Immunoinformatics.
CO 4	Students will also be enlightened about Electrophoresis technique and its applications.
CO 5	The practical paper will train students on analytical techniques like SDS-PAGE and immunoassays.
CO 6	The students will also get a hands-on experience on various Bioinformatics tools.

DETAILED SYLLABUS

Paper Code	Semester I- Paper IV	Lectures
RPSBAS104	**Applied Biology**	**60**
104.1: Genomics & Proteomics		
1. **Genomics:** Nucleic acid chemistry, Principles of DNA sequencing, DNA & RNA probes, Concepts of Gene manipulation, Restriction enzymes & their uses, Vectors & their uses, Producing Transgenic organisms, Hybridoma technology, cDNA production & applications, Gene libraries & applications 2. **Proteomics:** Protein extraction, separation, purification and identification, Protein fingerprinting techniques, Types of Proteomics with suitable examples–, Functional Proteomics, Structural Proteomics, Post translational modifications, Protein-Protein interaction, Protein expression profiling, Proteome mining, Human Proteome Project		**15**
104.2: Applied Enzymology		
1. General review of enzyme and properties including multi-enzyme complexes.		**15**

2. The relation of structure and kinetics mechanisms of enzymatic catalysis; studies of specific enzyme and enzyme systems, steady-state enzyme kinetics, transient kinetic methods, chemistry of enzyme catalysis. 3. Regulatory enzymes, Molecular models for allosterism. Regulation of enzyme activity. 4. Criteria for determining purity of enzymes 5. Recent advances in Enzymology.	
104.3: Immunoassays & Immunoinformatics	
1. Introduction 2. Requirements for immunoassay 3. Practical aspects 4. Advantages & Disadvantages of immunoassay 5. Principles and instrumentation in immunoassay 6. Applications of immunoassay 7. Types of Detection systems in immunoassay 8. Immunoinformatics, Immunomics& databases: IMGT, CED, IEDB, Bcipep, Syfpeithi and Applications of Immunoinformatics	**15**
104.4: Electrophoresis	
1. Basic Protein Chemistry 2. Principles of electrophoretic separation 3. Equipment and process in electrophoresis 4. Types of Electrophoresis 5. Advantages and Disadvantages of Electrophoresis 6. Applications of Electrophoresis 7. Standardization of electrophoretic techniques 8. Troubleshooting in Electrophoresis	**15**
RPSBASP104 PRACTICALS	
1. Separation of proteins using SDS-PAGE (3 practicals) 2. Separation of proteins using 2D gel electrophoresis 3. Protein profiling of plant seed sample by SDS-PAGE 4. Separation of a modern drug from plasma and its formulation/ peptides by Capillary Electrophoresis 5. Immunoassay for detection of pregnancy 6. Immunoassay for detection of Hepatitis B/Dengue 7. Bioinformatics: INSDC, UniProt, GenBank, BLAST & its variants, Clustal O, Rasmol, MarvinSketch- Marvin View & Docking. 8. Immunomic databases: CED, BCIPEP, IMGT, IEDB, Epitome	

References:

1. Enzyme, 2nd edition: Robert Copeland: Wiley publication
2. Catalysis in Chemistry and Enzymology: William P. Jencks: Courier Dover Publications
3. Introduction to Enzyme and Coenzyme Chemistry, 2nd Edition: Tim Bugg: Blackwill publication
4. Kuby Immunology: Kindt, Goldsby&Osborna
5. Immunology Essentials and Fundamentals: Palan and Pathak
6. Immunoinformatics, Methods in Molecular Biology: Namrata Tomar: Springer
7. Lehninger's Principle of Biochemistry: David Nelson, Michael Cox: Springer
8. Principle and practice of Bioanalysis:Richard F. Venn
9. Essential Bioinformatics: JinXiong

Semester I

Modality of Assessment

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) External Examination: 50 Marks

Semester End Practical Examination:

Particulars	Paper
Required Experiments Performed with appropriate principle, approach, Observations, Result, Demonstration of skills, Conclusion and Viva.	50
Total	**50**

Overall Examination & Marks Distribution Pattern

Course	101			102			103			104			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	—	50	50	—	50	50	—	50	50	—	50	50	200

Course Code: RPSBAS201

Course Title: Pharmacognosy & Phytochemistry

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This course will introduce the students to the field of Pharmacognosy, ethnobotany and ethnomedicine.
CO 2	Students will be able to appreciate the therapeutic properties of plants.
CO 3	Students will learn phytochemistry and significance of different phytoconstituents along with its chemistry.
CO 4	Students will be able to effectively use modern methods for extraction and analysis of phytoconstituents
CO 5	In the Practical paper, students will learn to analyze secondary metabolites and carry out evaluation of crude drugs.
CO 6	Students will also get a hands-on experience for Herbaria preparation of a plant and its microscopic study.

DETAILED SYLLABUS

Paper Code	Semester II- Paper I	Lectures
RPSBAS201	**Pharmacognosy & Phytochemistry**	**60**
201.1: Pharmacognosy		
1. Introduction, Plants and their medicinal uses example of one plant to be given 2. Concepts of ethanobotany, ethno medicines and pharmacology 3. Herbaria evaluation to include Plant collection, Authentication, storage and drying techniques. 4. Evaluation of Crude drugs 5. Concepts of GAP and GHP for medicinal plants (only introduction)		**15**
201.2: Phytochemistry		
1. Primary and secondary metabolites from plants 2. Classification of Plant Secondary metabolites 3. Functions of Plant Secondary Metabolites 4. Chemistry of Phenolics, Terpenoids, Alkaloids 5. Phytochemicals as Drugs 6. Key factors affecting synthesis of secondary metabolites		**15**

201.3: Extraction Technologies for Phytochemicals	
1. Extraction of phytoconstituents 2. Choice of solvent for extraction 3. Classical and modern methods of extraction a. Percolation & Maceration b. Soxhlet extraction c. Steam Distillation & Rotary vacuum evaporator d. Liquid- Liquid & Solid Phase Extraction e. Ultrasonication f. Microwave Assisted Extraction g. Supercritical Fluid extraction	**15**
201.4: Phytochemical analysis	
1. Classical methods of analysis (Gravimetric & Titrimetric) 2. Chromatographic & Spectroscopic analysis of phytoconstituents 3. Chromatographic fingerprints 4. Phytochemical variations in plants 5. Analysis of herbal formulations 6. Effect of drying on phytoconstituents	**15**
RPSBASP201 PRACTICALS	
1. Microscopic evaluation of sections and powders with adulteration and formulation comparison of the medicinal plants (Any 5) 2. Qualitative (TLC) tests for secondary metabolites 3. Qualitative and Quantitative (gravimetric) detection of secondary metabolites 4. Herbaria preparation & Evaluation of any one annual plant available locally 5. Standardization of solvent and Phytochemical extraction by classical & modern methods 6. Proximate evaluation of crude drugs	

References:

1. Fundamentals of Pharmacognosy and Phytochemistry: Heinrich, Barnes, Gibbons and Williamson
2. Text book of Pharmacognosy:G.E. Trease,W.C. Evans
3. Pharmacognosy: Chandrakant Kokate
4. Herbal Drug Technology:Agrawal,Paridhavi
5. Pharmacognosy:Tyler,Brody,Robbers
6. Phytochemicals Extraction, Separation & Analysis : Dr. Deep Panhekar, Ms. Trupti P. Sawant & Dr. D. P. Gogle
7. Fundamentals of Phytochemical Analysis: Mr Vishnu Balamurugan
8. High Performance Liquid Chromatography in Phytochemical Analysis (Chromatographic Science Series) : by Monika Waksmundzka-Hajnos , Joseph Sherma
9. Phytochemical Methods: A guide to modern techniques of plant analysis: Harborne

Course Code: RPSBAS202

Course Title: Chromatographic Techniques

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This course will inculcate analytical approach regarding correct choice of analytical method and introduce to basic principles of chromatography.
CO 2	Students will learn the different techniques of Planar Chromatography.
CO 3	Students will also get familiarized with instrumentation and applications of Gas Chromatography and will be able to effectively use chromatographs for analysis of samples and interpret the results.
CO 4	Students will get an insight into recent advances and troubleshooting involved in High Performance Liquid Chromatography.
CO 5	In the practical paper, students will learn the importance of standardization in various experimental conditions.
CO 6	Students will be able to carry out simultaneous analysis of Phytoconstituents using sophisticated analytical techniques like HPTLC and GC.

DETAILED SYLLABUS

Paper Code	**Semester II- Paper II**	**Lectures**
RPSBAS202	**Chromatographic Techniques**	**60**
202.1: Principles of Chromatography		
1. Principles of chromatographic separation 2. Classification of Chromatographic methods 3. Elution in Column Chromatography, The chromatogram 4. Migration rates of solutes a. Distribution constant b. Retention time c. Retention factor d. Selectivity factor 5. Band Broadening and column efficiency 6. Optimization of Column Performance		15

202.2: Planar chromatography	
1. Paper Chromatography & Thin Layer Chromatography (TLC) a. Principles and Practice b. Significance of mobile phase c. Applications d. Derivatization 2. High Performance Thin Layer Chromatography (HPTLC) a. TLC vs HPTLC b. *In Situ* Densitometric scanning c. Troubleshooting d. HPTLC Fingerprinting and other applications 3. Preparative HPTLC	15
202.3: Gas Chromatography (GC)	
1. Principles and Instrumentation 2. Factors that affect the chromatographic separation (Temperature, Type of column etc.) 3. GC techniques 4. Types of columns and their application 5. Selection of liquid stationary phases (Packed and capillary columns) 6. GC hardware a. Introduction to flow and pressure controllers b. Injection techniques- on column injection, large volume injection, split -split less, PTV and various auto injectors- gas sampling as well as liquid sampling c. Column Oven- temperature programming, (High /cryogenic oven temperature) 7. Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD) 8. Derivatization for GC 9. GC strategy for analysis involving biological matrices 10. Troubleshooting 11. Applications	15
202.4: High Performance Liquid Chromatography (HPLC)	
1. Principles and Instrumentation 2. Column chemistry, Column switching in HPLC, Column condition 3. System parameters 4. Automation in HPLC 5. Types of HPLC a. Reverse-Phase HPLC b. Gradient reverse-phase HPLC c. Ion-pair HPLC d. Ion-exchange HPLC e. Normal-phase HPLC f. Affinity Chromatography g. Gel permeation Chromatography 6. HPLC detectors 7. Data Processing: Manual and Electronic 8. Applications of HPLC 9. Recent advances (Fast LC, online extractions, add on pumps, online Derivatization, multi-dimensional LC) 10. Troubleshooting	15
RPSBASP202 PRACTICALS	

1. Standardization of mobile phase for Separation of plant pigments using paper chromatography 2. TLC analysis of Modern drugs 3. Gas Chromatographic separation of solvent mixtures or Analysis of Formulations by GC 4. HPLC separation of herbal raw material from its formulation (any one example) 5. HPTLC analysis of modern drug from plasma 6. HPTLC analysis of modern drug from formulations 7. Simultaneous Analysis of Phytoconstituents by HPTLC & GC 8. Simultaneous Analysis of Caffeine by HPTLC, HPLC & GC	

References:

1. Principles and Practice of Chromatography:B.Ravindranath
2. Chromatography: Concepts and Contrasts: James M Miller
3. High performance liquid chromatography in biotechnology: William S. Hancook
4. Principle and practice of Bioanalysis:Richard F. Venn
5. Principles of instrumental analysis:Douglas a. Skoog
6. Basic Gas Chromatography: Mc Nair & Miller

Course Code:RPSBAS203

Course Title: Practices in Pharmaceutical Industry

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	In this course, students will be trained for Good Lab Practices.
CO 2	The course will also give an insight into the good manufacturing practices followed in industry operations.
CO 3	Students will realize the importance of documentation and strict adherence to protocol in bioanalytical industries.
CO 4	Students will understand the issues related to stability of raw material and its formulations.
CO 5	In the Practical paper, students will understand the importance of shelf-life and stability studies of Pharmaceutical Preparations.
CO 6	Students will also learn to use HPLC as a separation tool for evaluation of modern drug and its formulations from plasma.

DETAILED SYLLABUS

Paper Code	**Semester II- Paper III**	**Lectures**
RPSBAS203	**Practices in Pharmaceutical Industry**	**60**
203.1: Good Laboratory Practices (GLP)		
1. What is GLP? 2. Practicing GLP 3. Guidelines to GLP 4. Documentation of Laboratory work 5. Preparation of SOPs 6. Calibration records 7. significance of validation in GLP 8. Transfer of methods 9. Documentation of results		**15**
203.2: Good Manufacturing Practices (GMP)		
1. Concept of GMP 2. Requirements of GMP implementation 3. Documentation of GMP practices 4. Regulatory certification of GMP		**15**

5. GMP in production of ASU drugs 6. Harmonization of SOP of manufacture 7. Audit for GMP compliances	
203.3: Quality Assurance (QA)-QualityControl (QC) in Food & Pharmaceutical Industry	
1. Introduction to QC & QA 2. Requirements for implementing QC & QA 3. QC & QA concepts in ASU drugs 4. Standardizing an Analytical method 5. Factors affecting standardization 6. Support work & documentation 7. Validation 8. Audit requirements, audits and audit reports 9. Personnel Responsibility in QA	**15**
203.4: Stability Studies of Pharmaceutical Products	
1. Types of stability studies 2. Stability chambers 3. Regulatory requirements for stability studies (Modern and Traditional) 4. Factors affecting stability of drug products (Modern and Traditional) 5. Predicting shelf-life of a finished product 6. Stability issues of raw materials and finished products (Modern and Traditional)	**15**
RPSBASP203 PRACTICALS	
1. Preparation of Standard Operating Procedure, for any one analytical Instrument 2. Study of Pharmaceutical Preparation: Chemical Assay as per IP 3. Stability studies of drugs (API & formulation Dosage form) with respect to effect of pH, Temperature, Pressure, Moisture and Light 4. Study of(on) compatibility of container (primary/secondary packaging) with the drug 5. Study of Shelf life of herbal drugs 6. HPLC separation of a modern drug from plasma 7. HPLC separation of a modern drug from formulations	

References:

1. Remington, Essentials of Pharmaceutics: Linda Felton
2. GLP Essentials: A Concise guide to Good Laboratory Practice, 2nd Edition: Milton A. Anderson
3. The Certified Pharmaceutical GMP Professional Handbook, Second Edition: Mark Allen Durivage
4. Good Laboratory Practice Regulations: Sandy Weinberg
5. Handbook of Stability tasting in pharmaceutical development: regulations, methodologies and best practices: Springer
6. Pharmaceutical Packaging Handbook – Edward Bauer

Course Code: RPSBAS204
Course Title: IPR, Drug Act & Regulations

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This will familiarize students with the current legal scenario regarding intellectual property rights.
CO 2	Students will also learn the importance of different Acts and treaties made for Intellectual Property Rights.
CO 3	Students will understand the importance of Drug& Cosmetics act and regulations.
CO 4	Students will also get an insight into regulated bioanalysis, its evolution and quality systems in regulated bioanalysis.
CO 5	In the practical paper, students will be able to review research papers and learn the art of abstract writing and patent claim drafting.
CO 6	Students will also get a chance to summarize present their learning outcomes of industrial visits in the current semester.

DETAILED SYLLABUS

Paper Code	Semester II- Paper IV	Lectures
RPSBAS204	**IPR, Drug Act & Regulations**	**60**
204.1: Intellectual Property Rights-I		
1. Concept of IPR - Understanding IPR & its significance in knowledge-based economy. 2. Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, Geographical indications, Protection of New Plant Varieties, Copyright. 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. 4. International Agreements related to IPR & patents - Paris Convention, PCT.		**15**
204.2: Intellectual Property Rights-II		
1. Indian Patent Act - a. Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step, useful/capable of industrial application. b. Non-patentable subject matter - what is not patentable.		**15**

c. Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance. d. Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, servicing of patents. e. Provisional Patents, Divisional Patents & Patents of Addition. 2. IPR as a strategic tool - a. Concepts of piracy, reverse engineering and knowledge worker. b. Benefits of creating and/or owning patents and other IPR. c. How India has leveraged the flexibilities provided by TRIPS to safeguard the industry and prevent ever-greening of patents. 3. IP clearance – Precautions before launching of product anywhere in the world - a. Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check b. Other IPR checks like trademarks, copyrights (for printed data on leaflets, packages etc.), 4. Putting IPR related disclaimers while advertising product list or selling products.	
204.3: Drug Act & Regulations	
1. Indian Drugs and Cosmetics Act with respect to Schedule1,2 and Schedule A, H M, S, T, X, Y 2. Introduction to foreign guidelines (for import of drugs) with respect to US, EU, Australia & Japan 3. Introduction to 21 CFR Part 11	**15**
204.4: Regulated Bioanalysis & Guidelines	
1. Introduction 2. The Evolution of Regulated Bioanalysis 3. Bioanalytical Method Validation 4. Pre-study Validation 5. In- study Validation 6. Documentation 7. Regulatory Requirements to Bioanalysis 8. Quality systems in Regulated Bioanalysis	**15**
RPSBASP204 PRACTICALS	
1. Report writing 2. Case studies 3. Abstract writing 4. Research paper review 5. Questionnaire designing 6. Graphical Representation of a data 7. Students must submit a Field visit notebook, comprehensive Report of the Industrial Visits including a PowerPoint Presentation on any one Visit.	

References:

1. Intellectual property rights: N. Pandey, K. Dharni
2. Law relating to Intellectual Property: Dr.Wadehra
3. Indian Patent Law and Practice: K.C. Kankanala
4. Regulated Bioanalysis: Fundamentals and Practice: Rocci Jr., Mario L., Lowes, Stephen
5. Drugs and Cosmetics Act 1940 and Rules 1945
6. Remington, Essentials of Pharmaceutics: Linda Felton

Semester II
Modality of Assessment

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:

3. Duration - These examinations shall be of **2.5 Hrs** duration.
4. 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) External Examination: 50 Marks

Semester End Practical Examination:

Particulars	Paper
Required Experiments Performed with appropriate principle, approach, Observations, Result, Demonstration of skills, Conclusion and Viva.	50
Total	**50**

Overall Examination & Marks Distribution Pattern

Course	201			202			203			204			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	—	50	50	—	50	50	—	50	50	—	50	50	200

External Examination- 60%- 60 Marks

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

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

Course Code: RPSBAS301

Course Title: Microbiology, Toxicology and Standardization of Ayurveda, Siddha & Unani (ASU) Medicine

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	The course will underline the importance of Bioanalytical techniques for standardization of traditional medicines.
CO 2	This will empower the students to employ antimicrobial agents in an effective way.
CO 3	This course will also highlight the importance of toxicological studies for ensuring safe administration of pharmaceuticals
CO 4	Students will also be introduced to Indian Systems of Medicine and regulatory aspects of ASU drugs.
CO 5	In the practical paper, students will learn to carry out microscopic evaluation of Ayurveda, Siddha and Unani Drugs in compliance to Pharmacopoeia.
CO 6	Students will also get hands-on different microbiological techniques like gram staining, sterility testing and total viable count as an application to herbal raw material and its formulations.

DETAILED SYLLABUS

Paper Code	Semester III – Paper I	Lectures
RPSBAS301	**Microbiology, Toxicology, and Standardization of Ayurveda, Siddha & Unani (ASU) Medicine**	**60**
301.1	**Microbiology**	
	1. Introduction to Microbes & their significance 2. Visualization of Microorganisms: Staining & microscopic techniques 3. Nutritional Requirements, Different types of media 4. Methods to study growth, preservation, maintenance of microorganisms 5. Commercially important Microbes (food and Pharmaceutical industry) 6. Microbial contaminants in food and Pharmaceutical products) 7. Asepsis, Disinfection and Sterilization, Aseptic filling in pharmaceutical industry, Classification of Clean rooms / Clean areas, QA and QC in Microbiology Laboratory 8. Important Microbes for Food & Drug Industry, Pathogenic organisms in Food & Pharma Industry 9. Sources of contamination, Microbial Contamination in ASU preparations 10. Regulatory Microbiological testing in pharmaceuticals 11. Microbiological Assays for pharmaceutical products	**15**
301.2	Toxicology	
	1. Introduction, History, Scope and types of toxicological studies 2. Toxicants and their classification 3. Mode of action of Toxicants (Toxicokinetics and Toxicdynamics) 4. Dose Toxicity Relationship 5. Adverse drug reaction & treatment of Poisoning 6. Concept of LC 50, LD50, ED50 7. Applications of Toxicology 8. Introduction to Regulatory Toxicology 9. Types of toxicity tests 10. OECD Guidelines on Toxicological studies- Design considerations, Evaluation of results, Extrapolation to man 11. Risk analysis of Food & Drug related substances 12. Environmental impact assessment	**15**
301.3	Indian Systems of Medicine	
	1. Principles and practices of ASU systems of medicine 2. Diagnosis & treatment as per Ayurveda (Special emphasis on Panchakarma) 3. Types of Drug formulations as per ASU systems 4. Dosage forms as per ASU system 5. Mode of action of drugs according to Ayurveda. 6. Sources of Raw materials & Finished products as per ASU drugs 7. Methods of manufacture-raw materials to finished products	**15**
301.4	Regulatory aspects of ASU Drugs	
	1. Herbal pharmacopoeia and Ayurvedic Formulary of India 2. Shelf life studies on finished products. 3. Analytical tools for standardization 4. Need for standardization and approaches to developing standardized QC methods 5. Clinical studies in standardization	**15**

	6. QC for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon, etc.) 7. Organizational setup in India for the regulation of herbal drugs,Regulatory laws in India for herbal drugs 8. Import & Manufacture of herbal drugs,Conditions for the manufacture of herbal drugs 9. Administrative agencies regarding the regulation of herbal drugs 10. Regulatory aspects of herbal drugs in India & other countries.	
RPSBASP301	**PRACTICALS**	
1. Microscopic Analysis of ASU formulation 2. Study of Hepatoprotective action of a herbal drug against CCl_4 liver dysfunction in rats and using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out) 3. Gram staining of bacteria and mounting of filamentous and non-filamentous fungi 4. Sterility testing of Pharmaceutical Dosage form. 5. Total Viable count of microorganisms from herbal raw materials and formulations.		

References:

1. Prescott, Harley and Klein's Microbiology: Willey, Sherwood and Woolverton
2. Casarett&Doull's Toxicology, The basic Sciences of Poisons: Dr. Curtis Klaassen
3. Fundamentals of toxicology: Pandey, Shukla, Trivedi
4. Database on medicinal plant used in Ayurveda: Sharma, Yelne and Dennis
5. Globalisation of Ayurvedic &Herbal products, challenges and strategies
6. Industrial Microbiology- An introduction: Waites, Morgan, Rockey and Hington
7. Ananthanarayan and Paniker's Microbiology: Reba Kanungo
8. Btock Biology of Microorganisms: Madigan

Course Code: RPSBAS302

Course Title: Bioanalytical Techniques & Clinical Data Management (CDM)

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This will highlight the importance of hyphenated techniques.
CO 2	It will enable the students to analyze and interpret mass spectrometric data for identification and quantification of analytes.
CO 3	Students will obtain a knowhow of in-vitro and in-vivo bioassays.
CO 4	Students will be benefited with the guidelines and regulations in Clinical Data Management.
CO 5	In the practical paper, students will gain an in-depth knowledge of applications of IR-Spectroscopy for variety of samples.
CO 6	Students will also be able to run bioassaysfor pharmaceutical samplesand toxicity study assays.

DETAILED SYLLABUS

Paper Code	Semester III- Paper II	Lectures
RPSBAS302	**Bioanalytical Techniques and Clinical Data Management (CDM)**	**60**
302.1	Introduction to Mass Spectrometry (MS)	
	1. Evolution of MS 2. Importance of MS as detector 3. Interfaces used in LC-MS & GC-MS 4. Sample preparations of MS 5. Components of Mass Spectrometer: a) Inlets b) Ion sources- i) GC-MS: EI, CI ii) LC-MS: ESI, API (APCI & APPI), FI, FD, FAB, TSP, MALDI c) Analyzers- QP, TOF, Ion trap, Magnetic sector, hybrid analyzers d) Detectors e) Vacuum system & its significance f) Applications of MS g) Introduction to MS/MS (Tandem MS)	**15**
302.2	Hyphenated Techniques in Bioanalysis	
	1. LC/MS and LC/MS/MS 2. GC/MS and GC/MS/MS 3. Scan events in TQ and other tandem systems and hybrid systems	**15**

	4. Introduction to ICP/MS and its applications in pharmaceuticals and food 5. Introduction to advances in the field of mass spectrometry E.g. Headspace GC and GC-MS TLC-MS	
302.3	Bioassays	**15**
	1. General idea about bioassay systems used in pharmaceutical evaluations 2. In vitro assays and in vivo assays 3. Ethical issues involved in animal assay systems 4. Alternatives to animal assays – one or two examples	
302.4	Clinical Data Management	**15**
	1. Introduction to CDM 2. Collection, Cleaning, and Management of subject data 3. Tools for CDM 4. Regulations, Guidelines, and Standards in CDM 5. The CDM Process 6. Review and finalization of study documents 7. Database designing, Data Collection 8. CRF tracking 9. Data entry & Validation, Medical Coding 10. Roles and Responsibilities in CDM	
RPSBASP302	**PRACTICALS**	
1. Bioassay of Penicillin and Vitamin B12 2. Simultaneous Analysis of iron from a given sample / sample solution by a. Redox titration b. Colorimetry c. Atomic Absorption Spectroscopy 3. LC 50 evaluation using a suitable model (e.g. Daphnia / rice weevil, Chyronomous larvae) 4. Analysis of Ayurvedic oil: Refractive Index, Viscosity & IR Spectroscopy 5. Study of matrix effect on IR spectra of API 6. Use of IR spectroscopy as a quantitative tool		

References:

1. Modern Practice of Gas Chromatography- Robert L. Grob, Eugene F. Barry
2. Principles of Instrumental Analysis- Skoog, Holler, Crouch
3. Bioassay Techniques for Drug Development: Atta-ur-Rahman, M. Iqbal Choudhary, and William J. Thomsen
4. Statistical Techniques in Bioassay: Z. Govindarajulu
5. Pharmaceutical Bioassays: Methods and Applications: Ming Zhao and Shiqi Peng
6. Bioassay Methods in Natural Product Research and Drug Development: Bohlin and Bruhn
7. Practical Guide to Clinical Data Management: Susanne Prokscha

Course Code: RPSBAS303

Course Title: Research Methodology and Biostatistics

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	Students will be able to employ the strategies of research methodology while undertaking any research.
CO 2	Students will learn the types of research and various research designs along with ethics in research.
CO 3	Students will gain knowledge about data types and its collection methods in biostatistics.
CO 4	Students will be able to analyse biological samples in a regulated manner and apply suitable statistical tests to extrapolate the observations to relevant results.
CO 5	Industrial training experience will imbibe the Industrial practices in students.

DETAILED SYLLABUS

Paper Code	Semester III- Paper III	Lectures
RPSBAS303	**Research Methodology and Biostatistics**	**60**
303.1 Introduction to Research Methodology		
1. Meaning, objectives and motivation of Research 2. Various Types of Research: a. Descriptive v/s Analytical b. Applied v/s Fundamental c. Quantitative v/s Qualitative d. Conceptual v/s Empirical 3. Overview & flowchart of research process. 4. Literature review a. Surveying, synthesizing, critical analysis, reading materials, reviewing, rethinking, critical evaluation, interpretation Research Purposes 5. Ethics in research – APA Ethics code.		**15**

303.2 Research design	
1. Definition of research design & its importance 2. Features of Good Research Design 3. Important Concepts regarding research Design: a) Dependent, Independent, Extraneous variables b) Importance of control c) Research hypothesis, experimental & non-experimental hypothesis testing d) Treatment, experimental & experimental units 4. Research designs: Exploratory research, Descriptive & diagnostic research, Hypothesis testing research 5. Informal experimental design: Before & after without control, After- only without control, Before & after with control	**15**
303.3 Biostatistics I	
1. Concepts: Population, sample, sample size, Normal distribution, level of significance, confident limits, power of test 2. Sampling Design: a. Different Types of Sampling Design: Simple Random Sampling Stratified Random Sampling, Systematic Sampling, Cluster Sampling, Area Sampling, Multistage Sampling. b. Steps in sample design 3. Data Collection a. Primary Data collection through Questionnaire & Schedules b. Collection of Secondary Data 4. Data Analysis a. Measures of central tendency (mean, median, mode) b. Measures of dispersion (range, Sample deviation, variance, CoV) c. Introduction to Parametric & Non-Parametric tests d. Introduction to correlation & regression analysis.	**15**
303.4 Biostatistics II	
1. Introduction to hypothesis testing & Errors in Testing 2. Z-test, t- test, Chi-Square test, F-test, ANOVA (One way and Two way). 3. Design of experiments: Block designs (CRD, RBD), Latin square design 4. Introduction to statistical packages for data analysis	**15**
RPSBASP303 **PRACTICALS**	
1. Case studies on Biostatistics 2. Internship: Industrial Training, and/or research project/Online training(Swayam/Coursera/NPTEL/Swayam MOOC, etc) /Online internship a) Students should submit the detailed report regarding of the above-mentioned course. b) Students should consult the teacher mentor allotted by the department and HOD for taking up modules from the course. c) After getting approval from the mentor/HOD, student should provide the weekly update to the mentor over email. d) 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.	

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: RPSBASP304

Course Title: Internship

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	Students will get to know the functionality and working setup and norms of Industry.
CO 2	Industrial training will impart all types of professional qualities in students along with enhancing their skills in the Industrial research.
CO 3	This will also familiarize students with current research trends and job roles in the Pharmaceutical and allied industries.
CO 4	Additionally, the students will be able to interpret case studies and problems in Biostatistics.

DETAILED SYLLABUS

Paper Code	Semester III- Paper IV	Lectures
RPSBASP304	**Internship**	**120**
	Industrial Training, and/or research project/Online training (Swayam/Coursera/NPTEL/Swayam MOOC, etc.) /Online internship 1. Students should submit the detailed report regarding of the above-mentioned course. 2. Students should consult the teacher mentor allotted by the department and HOD for taking up modules from the course. 3. After getting approval from the mentor/HOD, student should provide the weekly update to the mentor over email. 4. For internal component students are required to present the learning outcome(s) of the module twice in a semester and submit necessary assignments given by the mentor.	

Semester III

Modality of Assessment

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:

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

Paper Pattern (except RPSBASP304):

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

Practical Examination Pattern:

A) External Examination: 50 Marks

Semester End Practical Examination:

Particulars	Paper
Required Experiments Performed with appropriate principle, approach, Observations, Result, Demonstration of skills, Conclusion and Viva.	50
Total	**50**

Overall Examination & Marks Distribution Pattern

Course	301			302			303			304			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	—	50	50	—	50	50	—	50	50	—	50	50	200

Course Code: RPSBAS401

Course Title: Pharmaceutical Biotechnology & Modern Analytical Techniques

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This will train students to use appropriate Bioanalytical technique to assess the stability of pharmaceuticals.
CO 2	Students will understand the norms required for manufacturing in pharmaceutical industry
CO 3	Students will also learn the different Cell and Gene therapy products and its manufacture, storage, shipping & labelling.
CO 4	Students will get an insight into Biosimilars and Biopharmaceuticals and the different norms associated with it.
CO 5	Students will learn PCR technique and its applications in detecting genetically modified organisms.
CO 6	Students will get a hands-onDNA extraction and Purity studies &DNA Fingerprinting techniques.
CO 7	Students will get an in-depth knowledge of different analytical techniques like XRD, XRF
CO 8	It will also enlighten students about chiral chromatography and CD-ORD principle and applications in the analytical field.

DETAILED SYLLABUS

Paper Code	Semester IV-Paper I	Lectures
RPSBAS401	**Pharmaceutical Biotechnology & Modern Analytical Techniques**	**60**
401.1: Polymerase Chain Reaction & its applications		
1. Introduction to Polymerase Chain Reaction 2. Types of PCR: Conventional Qualitative PCR, Hot start PCR, Colony PCR, Nested PCR, Realtime PCR, Reverse transcriptase PCR, Touchdown PCR, Multiplex PCR, Assembly PCR, Methylation specific PCR, LAMP assay 3. PCR instrumentation: Principle of thermal cycler 4. PCR standardization 5. Primer designing: Primers for Qualitative PCR, Primers for Epitope tag, Mutagenesis primers 6. Applications of PCR: Gene expression analysis, Cloning, RFLP-PCR, AFLP, RAPD, SNP genotyping, Diagnostics, DNA sequencing.		**15**
401.2: Cell & Gene Therapy Products, Biosimilars & Biopharmaceuticals		
1. Meaning of gene therapy, Viral & non-viral methods for gene delivery 2. Gene editing techniques: Conventional homologous recombination, RNAi, ShRNA, Cre-LoxP,Mega nucleases,Zinc Finger Nucleases, TALENS, CRISPR/Cas9 3. Stem cell therapy 4. General overview of assays to determine identity, dose, purity, potency and safety of Cell and gene therapy products as per USP <1046>, USP <1047> 5. Introduction to Biosimilars &Biopharmaeuticals i. Sources of Biopharmaceuticals (*E.coli*, Animal cells, Additional systems) ii. Biosimilars Development, Review & Approval iii. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product		**15**
401.3: Thermal Analysis & X-ray Diffraction-X-ray Fluorescence		
1. Principles of Thermal Analysis 2. Instrumentation Requirements 3. Applications of Thermal Analysis 4. Thermal analysis of Bhasma preparations 5. Thermal Analysis Techniques 6. Theory of XRD and XRF 7. Crystal structure of solids and concept of crystallography 8. Bragg's law of diffraction 9. Instrumentation of powdered XRD 10. Application in the determination of polymorphs in pharmaceutical compounds 11. Percent crystalanity, Single crystal XRD 12. Determination of the 3D structure 13. Wavelength dispersive (WD) and energy dispersive (ED) XRF 14. Instrumentation of WD and (ED)XRF 15. Applications of XRF for elemental analysis		**15**
401.4: Chiral Chromatography & Circular Dichroism and Optical Rotatory Dispersion		
1. Chiral Chromatography: a. Concept of Chirality b. Chiral HPLC, column chemistry and column conditions in Chiral HPLC c. Applications of chiral HPLC		**15**

2. Theory and Applications of: a. Circular Dichroism 1. Optical Rotary Dispersion	
RPSBASP401 **PRACTICALS**	
1. Plant and bacterial DNA extraction and purity analysis of the same. 2. DNA fingerprinting using RFLP analysis of suitable samples 3. Analysis of Biosimilars for container compatibility/ stability 4. Detection of genetically modified organism using Polymerase chain reaction (PCR) 5. DNA sequencing using sample from a suitable organism(demo)	

References:

1. Pharmaceutical Manufacturing Handbook, Production and Processes, Edited by: Shayne Cox Gad
2. iGenetics A molecular Approach: Russell
3. Regulatory Aspects of Gene Therapy and Cell Therapy Products: A Global Perspective: Galli and Serabian
4. Lehninger's Principle of Biochemistry : David Nelson, Michael Cox : Springer
5. Biopharmaceuticals, Biochemistry and Biotechnology: Gary Walsh
6. Introduction to Spectroscopy: Donald L. Pavia
7. Principles of instrumental analysis: Douglas a. Skoog
8. Ord and Cd in Chemistry and Biochemistry: Pierre Crabbe
9. Chiral Chromatography: Beesley& Scott

Course Code: RPSBAS402

Course Title: Advances in Bioanalysis

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	This will enable the students to use mass spectrometry for qualitative and quantitative analysis of data
CO 2	Students will be able to interpret the Mass Spectra.
CO 3	Students will be able to conduct method development and validation using analytical instruments.
CO 4	Students will get an idea about the additional issues of endogenous substances and biomarkers in Bioanalytical Method Development.
CO 5	Students will get hands on method validation using sophisticated analytical instruments like HPLC or GC.
CO 6	Students will also gain practical idea about Infra-Red Spectroscopy technique and its applications for different samples.
CO 7	Students will also get introduced to the Tracer techniques & use of radioactive tracers in assays.
CO 8	This will train students to interpret spectral data of IR, NMR and LC-MS for structural elucidation of analytes.

DETAILED SYLLABUS

Paper Code	Semester IV-Paper II	Lectures
RPSBAS402	**Advances in Bioanalysis**	**60**
402.1: Qualitative Applications of Mass Spectrometry		
	1. Structural elucidation by MS 2. Technique of generating drug metabolites 3. Metabolite Identification 4. Impurity profiling 5. Analysis of essential oils, pesticides 6. Peptide mapping	**15**

402.2: Quantitative Applications of Mass Spectrometry	
1. Rules of fragmentation 2. Interpretation of MS spectra 3. Structural elucidation 4. Macromolecule quantitation 5. Small Molecule(SM) quantitation 6. Metabolite quantitation	**15**
402.3: Analytical & Bioanalytical Method Validation	
1. Strategies for Method development 2. What and Why of method validation 3. Regulatory requirements of validation 4. Intra and inter lab – Validation 5. Issues of Method transfer 6. Use of Reference standards and working standards 7. Pre- study Validation. 8. Selectivity, Accuracy, Precision, Recovery, Calibration Curve, Sensitivity, Reproducibility, Stability Incurred sample re-analysis (ISR). 9. Documentation and Additional issues like Endogenous substances & Biomarkers etc. 10. In-Study Validation.	**15**
402.4: Tracer techniques	**15**
1. Concept of Radioactivity & Half life 2. ∝, β, γ emitters and their biological applications 3. Using tracers in assays 4. Detectors and counters 5. Concept of autoradiography 6. Radio labelled probes and their uses	
RPSBASP402 PRACTICALS	
1. Impurity profiling of Modern Drug using a suitable analytical technique 2. Content Uniformity analysis of drugs using a suitable analytical technique 3. Analytical Method Validation for any one analysis 4. GC-MS analysis of Essential oil 5. LC-MS-MS analysis of Metabolites of drugs 6. IR patterns of an Ayurvedic Bhasma preparation (e.g. comparison of calcium from ShankhaBhasma – with pure $CaCO_3$ and other modern Calcium supplement	

References:

1. Principles of Instrumental Analysis, Author: Skoog, Holler, Crouch
2. Method Validation in Pharmaceutical Analysis, Edited by: Ermer&Nethercote
3. Analytical Method Development and Validation: Swartz and Krull
4. Validation of Analytical Methods, Methodology and Statistics: Shrivastava and Saxena
5. Bioanalytical Method Validation: Waghulkar, Deshpande & Rathod
6. Radioactive Tracer Techniques: George Keene Schweitzer

Course Code: RPSBAS403
Course Title: Fundamentals of Clinical Research

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	Students will be enlightened about the various aspects of clinical research.
CO 2	Students will get a brief idea regarding the case report format involved in BA/BE study.
CO 3	Students will get an idea about Therapeutic Drug Monitoring and its Pharmacoeconomics.
CO 4	Students will learn the role and significance of Pharmacovigilance along with its process.
CO 5	In the Practical Paper, the students will be able to calculate different Pharmacokinetic parameters and solve Bioavailability & Bioequivalence problems.
CO 6	Students will also be able to apply HPLC in therapeutic drug monitoring.

DETAILED SYLLABUS

Paper Code	**Semester IV-Paper III**	**Lectures**
RPSBAS403	**Fundamentals ofClinical Research**	**60**
403.1: Ethics and Good Clinical Practices in Clinical trial		
Ethics: 1. Origin of Ethical issues 2. Dealing with Ethical issues 3. Ensuring compliance of ethical issues 4. Ethical committees & their setup 5. Regulatory powers of ethical committees 6. Compliance to ethical guidelines 7. Dealing with Ethical issues (subject compensation and subject rights) 8. Compliance to current ethical guidelines		**15**

Good Clinical Practices: 1. Origin of GCP & Earlier Guidelines for GCP 2. GCP Guidelines of ICH 3. Ensuring GCP Compliance 4. Documentation of GCP 5. Audit of GCP compliance	
403.2: Bioavailability (BA)-Bioequivalence(BE) Studies	
1. Concept of BA and BE 2. Parameters to evaluate BA and BE of a drug 3. Factors that influence BA and BE of a drug 4. Evaluating BA and BE of a drug 5. Estimating BA and BE parameters of a drug 6. Design of a BAand BE study 7. Conduct of a BA and BE study 8. Data record and evaluation in BA and BE study 9. Reporting a BA study 10. Regulatory requirements of BA and BE	**15**
403.3: Therapeutic Drug Monitoring	
1. Purpose of therapeutic Drug Monitoring 2. Drugs suitable for therapeutic drug monitoring 3. Measuring and monitoring drug in TDM 4. Bioanalytical techniques in TDM, Analytical and practical issues of TDM 5. Pharmacoeconomics of TDM	**15**
403.4: Pharmacovigilance	
1. Basic concepts in PV 2. Types and sources of data,The process of Pharmacovigilance 3. Significance and need for Pharmacovigilance 4. Indian scenario and the role of regulatory in Pharmacovigilance	**15**
RPSBASP403 **PRACTICALS**	
1. Calculation of AUC and bioequivalence from the given data (2 expts.) 2. Evaluation of a BA/BE Report 3. Calculation of different Pharmacokinetic parameters like Ka, Ke, t½, C max, T_{max} and AUC from the given blood data. 4. Interpretation of IR, NMR and Mass Spectra of a given compound 5. Practicals based on Therapeutic drug monitoring using HPLC	

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: RPSBAS404
Course Title: Research Project

Academic year 2021-22

COURSE OUTCOMES:

COURSE OUTCOME	DESCRIPTION
CO 1	In the Practical paper, students will be able to undertake a research project based on a relevant research problem in the current era.
CO 2	Students will also be able to apply statistical analysis in research.

Paper Code	Semester IV- Paper IV	Lectures
RPSBAS404	**Research project**	**120**

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

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

Research Project

1. Students are expected to identify a research problem relevant to the subject
2. The topic of research should be interdisciplinary, and should involve statistical analysis.
3. Thorough literature review should be carried out by the students.
4. A project Proposal should be submitted by student and should get approval from mentor allotted by the department.
5. Students should report and update the allotted mentor regarding the project work.
6. Students are expected to support detailed report of the project work such as Laboratory notebooks
7. Final hardbound report as well as the soft copy report of the project work should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination
8. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on the project work.

Research Review:

1. Students should identify a topic for literature review
2. They should review at least 15 research articles for the review topic

3. Review article should be a detailed, comprehensive summary of the research articles in student's own words.
4. Final hardbound report as well as the soft copy report of the review article should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination
5. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on review article.

Research based on Survey/Case study

1. Students should identify a topic for survey/case study
2. They should prepare an outline for data collection that can include questionnaire/interviews/referencing and present the same. Data collection can be done online, if required.
3. They should gather data for survey/case study in a stipulated time and keep record of the same.
4. After data, collection, students should analyze the data using appropriate statistical tests and write final conclusion of the study.
5. Final hardbound report as well as the soft copy of the survey/case study report should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination

1. 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.

Semester IV
Modality of Assessment

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:

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

Paper Pattern: (except RPSBAS404)

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) External Examination: 50 Marks

Semester End Practical Examination:

Particulars	Paper
Required Experiments Performed with appropriate principle, approach, Observations, Result, Demonstration of skills, Conclusion and Viva.	50
Total	**50**

Overall Examination & Marks Distribution Pattern

Course	401			402			403			404			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	—	50	50	—	50	50	—	50	50	—	50	50	200
