Resolution number: AC/I(21-22).2(II). RPS1

S. P. Mandali's

Ramnarain Ruia Autonomous College

(Affiliated to University of Mumbai)

RUIA COLLEGE
Explore • Experience • Excel

Syllabus for

Integrated M.Sc. in Bioanalytical Sciences

(Post-graduate syllabus)

Program Code: RPSBAS

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

PROGRAM OUTCOMES

PO	PO Description **A student completing Bachelor's/Master's Degree in Science program will be able to:**
PO 1	Demonstrate in depth understanding in the relevant science discipline. Recall, explain, extrapolate and organize conceptual scientific knowledge for execution and application and also to evaluate its relevance.
PO 2	Critically evaluate, analyze and comprehend a scientific problem. Think creatively, experiment and generate a solution independently, check and validate it and modify if necessary.
PO 3	Access, evaluate, understand and compare digital information from various sources and apply it for scientific knowledge acquisition as well as scientific data analysis and presentation.
PO 4	Articulate scientific ideas, put forth a hypothesis, design and execute testing tools and draw relevant inferences. Communicate the research work in appropriate scientific language.
PO 5	Demonstrate initiative, competence and tenacity at the workplace. Successfully plan and execute tasks independently as well as with team members. Effectively communicate and present complex information accurately and appropriately to different groups.
PO 6	Use an objective, unbiased and non-manipulative approach in collection and interpretation of scientific data and avoid plagiarism and violation of Intellectual Property Rights. Appreciate and be sensitive to environmental and sustainability issues and understand its scientific significance and global relevance.
PO 7	Translate academic research into innovation and creatively design scientific solutions to problems. Exemplify project plans, use management skills and lead a team for planning and execution of a task.
PO 8	Understand cross disciplinary relevance of scientific developments and relearn and reskill so as to adapt to technological advancements.

PROGRAM SPECIFIC OUTCOMES

PSO	Description **A student completing Integrated Master's Degree in Science program in the subject of Bioanalytical Sciences will be able to:**
PSO 1	Gain high quality science education in a vibrant academic ambience with the faculty of distinguished teachers and scientists.
PSO 2	Take up the challenge of doing quality research and teaching and also contribute to industrial production and R & D in the fields of Bioanalysis, Bioinformatics and Nutraceutical Sciences.
PSO 3	Amalgamate classical analytical chemical techniques with modern genomic and proteomic technologies of manufacturing and analysis to better characterize the products useful as medicines as well as nutraceuticals.

PROGRAM OUTLINE

YEAR	SEM	COURSE CODE	COURSE TITLE	Course Type	CREDITS
I.M.Sc. I	VII	RPSBAS701 (Core Course)	Modern Pharmaceutical Industry	CC	4
		RPSBAS702 (Core Course)	Pharmacology, Toxicology & Bioassays	CC	4
		RPSBAS703 (Core Course)	Advances in Spectroscopy & Chromatography	CC	4
		RPSBAS704 (Skill Enhancement Course)	Extraction methodologies in Biological Analysis	SEC	4
		RPSBAS705 (Ability Enhancement Compulsory Course)	Resume Building & Soft Skills	AEC	2
		RPSBASP701	Practical I	-	2
		RPSBASP702	Practical II	-	2
		RPSBASP703	Practical III	-	2
		RPSBASP704	Practical IV	-	2
I.M.Sc. I	VIII	RPSBAS801 (Core Course)	Practices in Pharmaceutical Industry	CC	4
		RPSBAS802 (Core Course)	Process of Drug Discovery & Development	CC	4
		RPSBAS803 (Core Course)	Medicinal Systems & Standardization of Herbal Drugs	CC	4

		RPSBAS804 (Skill Enhancement Course)	Bioinformatics & Biostatistics	SEC	4
		RPSBAS805 (Ability Enhancement Compulsory Course)	Research Methodology & Scientific Communication	AEC	2
		RPSBAS801	Practical I	-	2
		RPSBASP802	Practical II	-	2
		RPSBASP803	Practical III	-	2
		RPSBASP804	Practical IV	-	2

I.M.Sc. II	IX	RPSBAS901	Automation and Data management	-	4
		RPSBAS902	Bioanalytical Techniques	-	4
		RPSBAS903	Research methodology and Biostatistics	-	4
		RPSBAS904	Internship/Research Project	-	6
		RPSBASP901	Practical I	-	2
		RPSBASP902	Practical II	-	2
		RPSBASP903	Practical III	-	2
I.M.Sc. II	X	RPSBAS1001	Analytical Techniques and their validation	-	4
		RPSBAS1002	Advances in Bioanalysis	-	4
		RPSBAS1003	Clinical research and ethics	-	4
		RPSBAS1004	Project work	-	6
		RPSBASP1001	Practical I	-	2
		RPSBASP1002	Practical II	-	2
		RPSBASP1003	Practical III	-	2

Core Course: RPSBAS701
Course Title: Modern Pharmaceutical Industry

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VII- Paper I	Lectures
RPSBAS701	**Modern Pharmaceutical Industry**	**60**
701.1: Pharmaceutical Manufacturing & Pharmaceutical Microbiology		
Pharmaceutical Manufacturing (07 lectures) 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 2. Important microbes for Food and drug industry, Pathogenic organisms in Food and Pharmaceutical Industry. 3. Sources of Contamination, Microbial Contamination in Ayurveda, Siddha & Unani (ASU) preparations. 4. Regulatory microbiological testing in pharmaceuticals 5. Microbiological assays for pharmaceutical products **Pharmaceutical Microbiology (08 Lectures)** 1. Overview of Pharmaceutical manufacturing 2. Importance of Schedule M (D& C) in Pharmaceutical manufacturing process 3. Regulatory requirements in pharmaceutical manufacturing process Unit operations and advances in: Manufacturing of oral solid dosage forms, oral liquid dosage forms, sterile injectables and topical dosage forms		**15**

701.2: Packaging of Pharmaceutical Products	
1. Introduction to Packaging 2. Fundamentals of Distribution 3. Packaging Forms & their Significance 4. Packaging Materials 5. Paper, Paper Board and CFB Glass, metals, Basic Polymer based materials, Polymer based composite materials 6. Ancillary Mats 7. Package Material Testing 8. Compatibility & Migration Studies 9. Packaging Validation 10. Packaging Laws and regulatory compliance	**15**
701.3: Marketing of Pharmaceuticals	
1. Stages leading to marketing Authorization 2. Marketing authorization in EU and India 3. Unlicensed indication 4. Advertising of Pharmaceuticals a. FDA b. Direct to Consumer Advertising i. Disclaimer ii. Perception of Risk 5. Medical representatives & Promotional activities 6. Ethics	**15**
701.4: Nutraceuticals	
1. Organizational elements 2. Classification of nutraceuticals, dietary supplements, fortified foods, functional foods and phytonutracuticals. 3. Scope involved in the industry, Indian and global scenario.	
4. Nutraceuticals of plant and animal origin: a. Plant secondary metabolites- classification and sub-classification - Alkaloids, phenols, Terpenoids. Extraction and purification, applications with specific examples with reference to skin, hair, eye, bone, muscle, heart, brain, liver, kidney, general health and stimulants. Concept of cosmoceuticals and aquaceuticals. b. Animal metabolites - Sources and extraction of nutraceuticals of animal origin. Examples: chitin, chitosan, glucosamine, chondroitin sulphate and other polysaccharides of animal origin, uses and applications in preventive medicine and treatment. c. Microbial and algal nutraceuticals Concept of prebiotics and probiotics - principle, mechanism, production and technology involved, applications - examples of bacteria used as probiotics, use of prebiotics in maintaining the useful microflora - extraction from plant sources. Synbiotics for maintaining good health. Algae as source of omega - 3 fatty acids, antioxidants and minerals - extraction and enrichment. 5. Basis of claims for a compound as nutraceuticals. 6. Regulatory issues for nutraceuticals including CODEX role of nutraceuticals/functional foods 7. Clinical testing of nutraceuticals and health foods	**15**
RPSBASP701: PRACTICAL I	

1. Total Viable Count of microorganisms from herbal Raw materials and formulations 2. Study of MIC of a pharmaceutical product 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 compatibility of container (primary/secondary packaging) with the drug 6. Evaluation of a nutraceutical production as per corresponding standard protocols	

References:

1. Pharmaceutical Manufacturing Handbook, Production and Processes, Edited by: Shayne Cox Gad
2. Hugo and Russell's Pharmaceutical Microbiology
3. Prescott, Harley and Klein's Microbiology: Willey, Sherwood and Woolverton
4. Remington The Science and Practice of Pharmacy- Lippincott Wiliams & Wilkins
5. Pharmaceutical Packaging Handbook: Edward Bauer
6. Remington, Essentials of Pharmaceutics: Linda Felton

Core Course: RPSBAS702

Course Title: Pharmacology, Toxicology & Bioassays

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VII- Paper II	Lectures
RPSBAS702	**Pharmacology, Toxicology & Bioassays**	**60**
702.1: Pharmacology		
1. Scope of Pharmacology 2. Routes of Drug Administration 3. Dose- Response Relationship 4. Factors influencing drug dosage and drug action. 5. Drug disposition & Pharmacokinetics 6. Drug Metabolism: Introduction, Absorption, Distribution, Bio-transformation, Excretion 7. Mechanisms of Drug Action- Pharmacodynamics 8. Different Pharmacokinetic & Pharmacodynamics parameters and their meanings and basic techniques to evaluate the parameters 9. Basic types of models in Pharmacokinetics & Pharmacodynamics		**15**
702.2: 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**

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

References:

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

Core Course: RPSBAS703

Course Title: Advances in Spectroscopy & Chromatography

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VII- Paper III	Lectures
RPSBAS703	**Advances in Spectroscopy & Chromatography**	**60**
703.1: Atomic Spectroscopy		
1. Components of optical instruments 2. Instrumentation, Sample preparation and Applications of Atomic Absorption		

3. Components of optical instruments 4. Instrumentation, Sample preparation and Applications of Atomic Absorption Spectroscopy, Atomic Emission Spectroscopy and Inductively Coupled Plasma (ICP-AES & ICP-OES).	**15**
703.2: Molecular Spectroscopy	
Principle, Instrumentation, precautions for sample preparation and applications of : 1. UV-Visible and fluorescence spectroscopy: Derivative spectroscopy (Zero order, First order and Second order) 2. IR spectroscopy: Principles of Diffuse Reflectance Spectroscopy and Attenuated Total Reflectance 3. Difference between Raman and IR spectroscopy	**15**
703.3: Advances in Chromatography	
1. Specialized columns & detectors in HPLC and GC 2. Ultra Performance Liquid Chromatography (UPLC) 3. Preparative HPTLC & HPLC 4. 2D-HPLC	**15**
703.4: Other Techniques of analysis	
Principles, Instrumentation, Sample preparations and Applications of: 1. Nephelometry & Turbidimetry 2. Particle Size Analyzer 3. Size exclusion chromatography & Affinity chromatography for protein separation 4. Ion exchange chromatography 5. Electrophoresis(Agarose, SDS-PAGE, IEF & Capillary Electrophoresis)	**15**
RPSBASP703: PRACTICAL III	
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. Qualitative analysis of organic solids using IR spectroscopy 5. IR analysis of modern drug (any one example) 6. HPTLC analysis of modern drug from plasma 7. HPTLC analysis of modern drug from formulations	

References:

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

Skill Enhancement Course: RPSBAS704

Course Title: Extraction methodologies in Biological Analysis

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VII- Paper IV	Lectures
RPSBAS704	**Extraction methodologies in Biological Analysis**	**60**
704.1: Sample handling and Biomatrices		
1. Introduction to Bio-matrices-Microbial, Plant & Animal 2. Collection and storage of Biological samples 3. Microbes-Bacteria, Algae, Fungi, Protozoans 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)		**15**
704.2: Phytochemical Extraction and Analysis		
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 4. Supercritical Fluid extraction 5. Classical methods of analysis (Gravimetric & Titrimetric) 6. Chromatographic & Spectroscopic analysis of phytoconstituents 7. Chromatographic fingerprints 8. Phytochemical variations in plants 9. Analysis of herbal formulations 10. Effect of drying on phytoconstituents		**15**

704.3: Extraction, Isolation & Purification of analytes from Biological Matrices	
1. Physico-chemical properties of drugs and solvents 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**
704.4: Super Critical Fluid Extraction (SCFE) & Super Critical Fluid Chromatography (SCFC)	
1. The concept of SCFE & SCFC 2. Instrumentation of SCFE & SCFC 3. Factors affecting SCFE & SCFC 4. Benefits of SCFE & SCFC 5. Application of SCFE for natural products and Application of SCFC	**15**
RPSBASP704: PRACTICAL IV	
1. Bioanalysis of Urine 2. Liquid-Liquid Extraction of a modern drug 3. Solid Phase Extraction (SPE) of a drug from Plasma 4. Protein precipitation techniques 5. TLC for essential oils 6. Analysis of betalains by UV visible spectroscopy 7. Extraction of phytoconstituents by classical and modern methods 8. Microscopic evaluation of sections and powders with adulteration and formulation comparison of the medicinal plants (any5)	

References:

1. Fundamentals of pharmacognosy and Phytochemistry: Heinrich, Barnes, Gibbons and Williamson
2. Phytochemical methods: A guide to modern techniques of plant analysis: Harborne
3. Phytochemical extraction, separation and analysis: Dr. Deep Panhekar, Ms.Trupti P. Sawant and Dr.D.P. Gogle
4. Fundamentals of Phytochemical analysis: Mr.Vishnu Balamurugan
5. Herbal Drg Technology: Agrawal, Paridhavi
6. Pharmacognosy: Tyler, Brody, Robbers
7. Textbook of Pharmacognosy: G.E. Trease and W.C. Evans
8. Pharmacognosy: Chandrakant Kokate
9. High Performance Liquid Chromatoraphy in Phytochemical analysis(Chromatographic Science Series): Monika Waksmundzka-Hajnos, Joseph Sherma
10. Solvent extraction: Classical and Modern Approaches- Vladimir K. Kislik
11. Analytical Supercritical Fluid Extraction Techniques - E.D. Ramsey

Ability Enhancement Compulsory Course: RPSBAS705

Course Title: Emotional well-being through Logic-based thinking

Academic year 2022-23

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Understand the connection between thinking patterns, emotions, and behavior.
CO 2	Identify one's faulty thinking patterns (fallacies) and methods for refuting them.
CO 3	Replace faulty thinking patterns with positive and rational thinking patterns.
CO 4	Using philosophical antidotes to promote a healthy state of mind.

DETAILED SYLLABUS

Paper Code	Semester VII- Paper IV	Lectures
RPSBAS705	**Emotional well-being through Logic-based thinking**	**30**
705.1 Relation between Emotions and Thinking		
1. Fundamentals of emotional well-being. 2. Tracing the thoughts behind an emotional problem. 3. Some prominent faulty thinking patterns/fallacies causing harm to oneself and others: a. Demanding perfection b. World Revolves Around Me c. Damnation d. Awfulizing e. Can't stipation.		**15**
705.2 Strengthening rational thinking patterns		
1. How to refute the fallacies a. Fallacy-Antidotes-Virtues framework 2. Some uplifting Antidotal reasoning to overcome the fallacies 3. Corresponding Guiding virtues for the fallacies: a. Demanding perfection- Metaphysical security b. World Revolves Around Me- Empathy c. Damnation- Respect d. Awfulizing- Courage e. Can't stipation- Temperance.		**15**

References:

1. Elliot D Cohen, *What Would Aristotle Do: Self-Control through the Power of Reason*, Prometheus Books, 2003.

Modality of Assessment

Sem VII

Theory Examination Pattern:

A) Internal Assessment- 40%- 40 Marks

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

B) External Examination- 60%- 60 Marks

Semester End Theory Examination:

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

Paper Pattern:

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

Practical Examination Pattern:

A) Internal Examination: 40%- 40 Marks

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

B) External Examination: 60%- 60 Marks

Semester End Practical Examination:

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

Overall Examination & Marks Distribution Pattern

Semester VII

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

External Examination- 60%- 60 Marks

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

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

Core Course: RPSBAS801

Course Title: Practices in Pharmaceutical Industry

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VIII - Paper I	Lectures
RPSBAS801	**Practices in Pharmaceutical Industry**	**60**
801.1: Drug Act & Regulations in Pharma		
1. Indian Drugs and Cosmetics Act with respect to Schedule 1,2 and Schedule A, H, M, S, T, X, & Y 2. Introduction to foreign guidelines (for import of drugs) with respect to US, EU, Australia & Japan 3. Introduction to 21 CFR Part 11		**15**
801.2: Good Laboratory Practices & Good Manufacturing Practices		
Good Laboratory Practices (07 Lectures) 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 **Good Manufacturing Practices (08 Lectures)** 1. Introduction to GMP 2. Requirements of GMP implementation 3. Documentation of GMP practices		**15**

4. Regulatory certification of GMP 5. GMP in production of ASU drugs 6. Harmonization of SOP of manufacture 7. Audit for GMP compliances	
801.3: Quality Assurance & Stability studies	
Quality Assurance (07 Lectures) 1. Introduction to QC & QA 2. Requirements for implementing QA 3. QA concepts in ASU drugs 4. Standardizing an Analytical method 5. Factors affecting standardization 6. Support work & documentation, Validation 7. Audit requirements, audits and audit reports 8. Personnel Responsibility in QA **Stability Studies (08 Lectures)** 1. Types of Stability studies 2. Stability Chambers 3. Regulatory requirements for stability studies 4. Factors affecting stability of Products 5. Predicting shelf life of a finished product 6. Guidelines for Stability studies	**15**
801.4: IPR in Pharma	
1. Concept of IPR 2. Types of IPR 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. 5. Indian Patent Act - a. Criteria to be fulfilled for Patentability, introduction to WIPO b. Non-patentable subject matter c. Concept of Mailbox and EMR 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. f. Patent infringement 6. IPR as a strategic tool - a. Concepts of piracy, reverse engineering and knowledge worker. 7. IP clearance – Precautions before launching of product anywhere in the world 8. Putting IPR related disclaimers while advertising product list or selling products.	**15**
RPSBASP801 PRACTICAL I	
1. Patent Claim Drafting, Patent Evaluation 2. Preparation of Standard Operating Procedure (SOP) for any one analytical instrument 3. Study of Certificate of Analysis (COA) 4. Study of Shelf life of herbal drugs 5. Stability studies of drugs (API & Formulation) with respect to the effect of pH, Temperature, Moisture and Light (any 4 experiments)	

References:

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

Core Course: RPSBAS802

Course Title: Process of Drug Discovery & Development

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VIII - Paper II	Lectures
RPSBAS802	**Process of Drug Discovery & Development**	**60**
802.1: Drug discovery and development process		
1. Introduction to Drug Discovery, Design and Development 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. Current Status		**15**
802.2: Preclinical Research		
1. Importance of preclinical studies 2. Types of preclinical studies 3. Design of animal trial in compliance with CPCSEA guidelines 4. Ethical considerations in animal testing 5. Model organisms used in drug testing studies 6. Extrapolation of data to humans		**15**
802.3: Basics of Clinical Trials		
1. Importance of clinical trials 2. Phases involved in clinical trials 3. Types of clinical trials 4. Regulatory requirements for clinical trials 5. Schedule Y compliance		**15**

802.4: Ethical guidelines in Clinical Trials and GCP	
Ethics (08 Lectures) 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 **Good Clinical Practices (07 Lectures)** 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	**15**
RPSBASP802 PRACTICAL II	
1. LC_{50} evaluation using a suitable model (Daphnia/Rice weevils/*Chyronomous larvae*) 2. Study of Hepatoprotective action of a herbal drug against CCl_4 liver dysfunction in rats (an experimental comparison using suitable groups of controls, natural recovery & treatment with known hepatoprotectants to be carried out) 3. Study of Disintegration and Dissolution of a tablet as per IP/USP (enteric coated) 4. Study of an Informed consent form	

References:

1. Principles of Good Clinical Practice: McGraw, George, Shearn, Hall and Thomas
2. Good Clinical Practice Standard Operating Procedures for Clinical Researchers: Graeme Scott, Josef Kolman, Paul Meng.
3. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections: Vera Mihajlovic-Madzarevic.

Core Course: RPSBAS803

Course Title: Medicinal Systems & Standardization of Herbal Drugs

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester VIII - Paper III	Lectures
RPSBAS803	**Medicinal Systems & Standardization of Herbal Drugs**	**60**
803.1: Modern Medicine		
1. History of Modern Medicine 2. Concept of disease, types of diseases 3. Treatment of Infections (With special emphasis on Covid) 4. Management of endocrine disorders- Polycystic ovarian syndrome, Diabetes 5. Management of vascular disorders- Cardiovascular disorders		**15**
803.2: Indian Medicinal Systems		
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		**15**
803.3: Standardization of ASU drugs		
1. Need of standardization of Ayurvedic, Siddha & Unani drugs 2. Sources of Raw materials & Finished products as per ASU drugs 3. Methods of manufacture-raw materials to finished products 4. Quality control of ASU drugs in India 5. Shelf-life studies on finished products 6. Analytical tools for standardization 7. Clinical studies in Standardization		

803.4: 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 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.	**15**
RPSBASP803 PRACTICAL III	
1. Standardization of any one formulation using classical and modern analytical techniques 2. HPLC analysis of modern drugs from plasma, formulations and combination formulations 3. High Performance Liquid Chromatography (HPLC) separation of herbal raw material from its formulation (any one example) 4. Comparative estimation of caffeine by using UV-Visible spectrophotometer, HPTLC & HPLC.	

References:

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

Skill Enhancement Course: RPSBAS804

Course Title: Bioinformatics & Biostatistics

Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

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

804.3: Descriptive Statistics & Regression Analysis	
1. Concepts: Population, Sample, sample size, Normal distribution, Level of significance, Confident limits, Power of test 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) 5. Introduction to correlation & regression analysis	**15**
804.4: Test of Significance	
1. Introduction to hypothesis testing & Errors in Testing 2. Introduction to parametric tests- Z-test, t-test, Chi-Square test, F-test, ANOVA (One way and Two way). 3. Introduction to non-parametric test- Mann–Whitney U test, Kruskal-Wallis test 4. Design of experiments: Block designs (CRD, RBD), Latin square design 5. Introduction to statistical packages for data analysis	**15**
RPSBASP804 PRACTICAL IV	
1. Tertiary structure and function prediction using homology modeling and *ab initio* method 2. Validation of Predicted structure 3. Visualization of 3D Protein structure using Rasmol, VMD 4. Docking: Using a docking software to study protein-ligand interaction 5. Problems based on Biostatistics	

References:

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

Ability Enhancement Course: RPSBAS805

Course Title: Research Methodology & Scientific Communication

Academic year 2022-23

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Student will understand the importance of research methodology and research designs in all fields of research.
CO2	Students will also be able to use descriptive statistics and test of significance for accurate statistical calculations in research.

DETAILED SYLLABUS

Paper Code	Semester VIII - Paper IV	Lectures
RPSBAS805	**Research Methodology & Scientific Communication**	**30**
805.1 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 Emperical 3. Overview & flowchart of research process. 4. Literature review: Surveying, synthesizing, critical analysis, reading materials, reviewing, rethinking, critical evaluation, interpretation Research Purposes 5. Ethics in research – APA Ethics code.		**15**
805.2 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**

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

Modality of Assessment

Sem VIII

Theory Examination Pattern:

A) Internal Assessment- 40%- 40 Marks

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

B) External Examination- 60%- 60 Marks

Semester End Theory Examination:

1. Duration - These examinations shall be of **2.5 Hrs** duration.

2. Theory question paper pattern:

Paper Pattern:

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

Practical Examination Pattern:

A) Internal Examination: 40%- 40 Marks

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

B) External Examination: 60%- 60 Marks

Semester End Practical Examination:

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

Overall Examination & Marks Distribution Pattern

Semester VIII

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

External Examination- 60%- 60 Marks

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

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

Syllabus for

Integrated M.Sc. in Bioanalytical Sciences

(Post-graduate syllabus)

(Credit Based Semester and Grading System for academic year 2022–2023)

Course Code: RPSBAS901

Course Title: Automation & Data Management
Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester IX- Paper I	Lectures
RPSBAS901	**Automation & Data Management**	**60**
901.1: Automation of sample preparation		**15**
1. Introduction to Automation 2. Need for Automation in chemical, clinical analysis 3. Approaches to Automation: Solid phase extraction, Protein precipitation methods, Multi-well plate technology, Liquid handling procedures avoiding evaporation 4. Importance of automation in Bioanalysis		
901.2: Electronic Data Management		**15**
1. Electronic Acquisition of data 2. Management of data in Computers 3. Electronic Data Validation and regulatory requirements 4. Electronic signatures & its regulation 5. Generating reports using computers 6. Regulatory requirements of Data evaluation		
901.3: Bioinformatics in Disease Management		**15**
1. Basic concepts on identification of genes responsible for diseases 2. Role of bioinformatics in human disease analysis 3. OMIM database 4. Reference genome sequence & integrated genomic maps 5. Gene expression profiling		
901.4: Introduction to 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	
RPSBASP901 PRACTICALS	**Practical**
1. Tertiary structure and function prediction using homology modeling and *ab initio* method 2. Validation of Predicted structure 3. Visualization of 3D Protein structure using Rasmol, VMD 4. Docking: Using a docking software to study protein-ligand interaction	

References:

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

Course Code: RPSBAS902

Course Title: Bioanalytical techniques
Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

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

902.4: Application of Tracer techniques	
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. Radiolabeled probes and their uses	**15**
RPSBASP902 PRACTICALS	
1. HPLC analysis of modern drug from plasma 2. LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.) 3. GC/MS separation of plant essential oil (Demonstration) 4. LC/MS/MS quantitation of a modern drug from plasma (e.g. Diclofenac Sodium) 5. LC/MS/MS quantitation of metabolite of a modern drug from plasma (e.g. Mycopenolic acid, metabolite of Mycophenolatemofitil). 6. Mass Fingerprinting of peptides using a suitable sample	

References:

1. Principles of Instrumental Analysis - Skoog, Holler, Crouch
2. Modern Practices in Gas-Chromatography- Robert L. Grob, Eugene F. Barry
3. Radioactive Tracer Techniques by George Keene Schweitzer
4. Handbook of Analytical Techniques, Vol I & II- Wiley Publications

Course Code: RPSBAS903

Course Title: Research Methodology & Biostatistics

Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester IX- Paper III	Lectures
RPSBAS903	**Research Methodology & Biostatistics**	**60**
903.1:Introduction to Research Methodology		
6. Meaning, objectives and motivation of Research 7. Various Types of Research: a) Descriptive v/s Analytical b) Applied v/s Fundamental c) Quantitative v/s Qualitative d) Conceptual v/s Emperical 8. Overview & flowchart of research process. 9. Literature review: Surveying, synthesizing, critical analysis, reading materials, reviewing, rethinking, critical evaluation, interpretation Research Purposes 10. Ethics in research – APA Ethics code.		**15**
903.2:Research design		
4. Definition of research design & its importance 5. Features of Good Research Design 6. Important Concepts regarding Research Design: e) Dependent, Independent, Extraneous variables f) Importance of control g) Research hypothesis, experimental & non-experimental hypothesis testing h) Treatment, experimental & experimental units 6. Research designs: Exploratory research, Descriptive & diagnostic research, Hypothesis testing research 7. Informal experimental design: Before & after without control, After- only without control, Before & after with control		**15**
903.3: Descriptive Statistics & Regression Analysis		
1. Concepts: Population, Sample, sample size, Normal distribution, Level of significance, Confident limits, Power of test 2. Sampling Design:		**15**

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 correlation & regression analysis	
903.4: Test of Significance	**15**
1. Introduction to hypothesis testing & Errors in Testing 2. Introduction to parametric tests- Z-test, t-test, Chi-Square test, F-test, ANOVA (One way and Two way). 3. Introduction to non-parametric test- Mann–Whitney U test, Kruskal-Wallis test 4. Design of experiments: Block designs (CRD, RBD), Latin square design 5. Introduction to statistical packages for data analysis	
RPSBASP903 PRACTICALS	
1. Report writing 2. Case studies on Covid-19 3. Abstract writing 4. Research paper review 5. Questionnaire designing 6. Graphical Representation of a data 7. Problems based on Biostatistics	

References:

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

Course Code: RPSBASP904

Course Title: Internship

Academic year 2021-22

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO1	Student will be trained to face the challenges of industry and will acquire requisite skills in the field of Bioanalysis and research.

DETAILED SYLLABUS

Paper Code	Semester IX- Paper IV	Lectures
RPSBASP904	**Internship**	**120**
Industrial Training, and/or research project/ Online training (Swayam/Coursera/NPTEL/MOOC, etc.)/Online internship 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.		

Modality of Assessment

Sem IX

Theory Examination Pattern:

A) Internal Assessment- 40%- 40 Marks

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

B) External Examination- 60%- 60 Marks

Semester End Theory Examination:

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

Paper Pattern (except RPSBASP904):

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

Practical Examination Pattern:

A) Internal Examination: 40%- 40 Marks

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

B) External Examination: 60%- 60 Marks

Semester End Practical Examination:

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

Overall Examination & Marks Distribution Pattern

Semester IX

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

External Examination- 60%- 60 Marks

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

Course Code: RPSBAS1001

Course Title: Analytical Techniques and their Validation

Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester X- Paper I	Lectures
RPSBAS1001	**Analytical Techniques and their Validation**	**60**
1001.1: Thermal Analysis & XRD		**15**
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 crystallinity, 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		
1001.2: Chiral chromatography, Circular Dichroism-Optical Rotatory Dispersion		**15**
1. Chiral Chromatography: 2. Concept of chirality, Chiral HPLC, Column chemistry and column conditions in chiral HPLC, Applications of chiral HPLC 3. Theory and Applications of Circular Dichroism & Optical Rotary Dispersion		
1001.3: Analytical Method Validation		**15**
1. Concept of method validation 2. Regulatory requirements of validation 3. System suitability, Parameters for Method Validation 4. Use of Reference standards		

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

References:

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

Course Code: RPSBAS1002

Course Title: Advances in Bioanalysis

Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

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

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

References

1. Principles of Instrumental Analysis, Author: Skoog, Holler, Crouch
2. Method Validation in Pharmaceutical Analysis, Edited by: Ermer&Nethercote
3. Analytical chemistry by open learning- Mass spectrometry
4. Analytical Method Development And Validation: Swartz and Krull
5. Validation of Analytical Methods, Methodology and Statistics : Shrivastava and Saxena
6. Bioanalytical Method Validation: Waghulkar, Deshpande & Rathod

Course Code: RPSBAS1003

Course Title: Clinical Research & Ethics

Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester X- Paper III	Lectures
RPSBAS1003	**Clinical Research & Ethics**	**60**
1003.1: Ethics & Good Clinical Practices		
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 **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		**15**
1003.2: Pharmacovigilance		
1. Introduction to Pharmacovigilance 2. Significance and need for Pharmacovigilance 3. Indian scenario and the role of regulatory in Pharmacovigilance 4. Pharmacovigilance and safe use of medicines (with case studies)		**15**

1003.3: Bioavailability (BA) & Bioequivalence (BE) Studies	
1. Concept of BA and BE 2. Parameters to evaluate BAand BE of a drug 3. Factors that influence BAand BE of a drug 4. Evaluating BAand 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**
1003.4 Therapeutic Drug Monitoring (TDM)	
1. Purpose of therapeutic drug monitoring 2. Bioanalytical techniques in TDM 3. Analytical and practical issues of TDM 4. Pharmaco-economics of TDM	**15**
RPSBASP1003: 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. Study of matrix effect by IR 5. Use of IR spectroscopy as a quantitative tool	

References:

1. Principles of Good Clinical Practice: McGraw, George, Shearn, Hall and Thomas
2. Good Clinical Practice Standard Operating Procedures for Clinical Researchers: Graeme Scott, Josef Kolman, Paul Meng
3. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections: Vera Mihajlovic-Madzarevic
4. Design & Analysis of Bioavailability & Bioequivalence studies:Shein-Chung Chow & Jen-Pei Liu
5. Biopharmaceutics Applications in Drug Development: Rajesh Krishna & Lawrence Yu
6. Bioavailability and Bioequivalance in Pharmaceutical technology: T. K. Pal, P. K. Ganesan
7. Therapeutic Drug Monitoring: Newer Drugs and Biomarkers: Amitava Dasgupta
8. Therapeutic Drug Monitoring and Toxicology by Liquid Chromatography: Wong

Course Code: RPSBASP1004

Course Title: Project Work

Academic year 2021-22

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester X- Paper IV	Lectures
RPSBASP1004	**Project work**	**120**

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

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

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

Research Project

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

8. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on the project work. **Research Review:** 1. Students should identify a topic for literature review 2. They should review at least 15 research articles for the review topic 3. Review article should be a detailed, comprehensive summary of the research articles in student's own words. 4. Final hardbound report as well as the soft copy report of the review article should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination 5. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on review article. **Research based on Survey/Case study** 1. Students should identify a topic for survey/case study 2. They should prepare an outline for data collection that can include questionnaire/interviews/referencing and present the same. Data collection can be done online, if required. 3. They should gather data for survey/case study in a stipulated time and keep record of the same. 4. After data, collection, students should analyze the data using appropriate statistical tests and write final conclusion of the study. 5. Final hardbound report as well as the soft copy of the survey/case study report should be prepared by the student as per the guidelines/ format provided by the institution & should submit the same to the department before the examination 6. Student is expected to prepare a PowerPoint presentation and present the same at the time of Practical examination and should face Viva voce based on survey/case study article.	

Modality of Assessment

Sem X

Theory Examination Pattern:

A) Internal Assessment- 40%- 40 Marks

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

B) External Examination- 60%- 60 Marks

Semester End Theory Examination:

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

Paper Pattern (Except RPSBASP1004):

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

Practical Examination Pattern:

A) Internal Examination: 40%- 40 Marks

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

B) External Examination: 60%- 60 Marks

Semester End Practical Examination:

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

Overall Examination & Marks Distribution Pattern

Semester X

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

External Examination- 60%- 60 Marks

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