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

Program: M.Sc. in Bioanalytical Sciences

(Post-graduate syllabus)

Program Code: RPSBAS

(Choice Based Credit System forthe academic year 2022-23)

GRADUATE ATTRIBUTES

GA	GA Description **A student completing Bachelor's/Master's Degree in Science program will be able to:**
GA1	Demonstrate in depth understanding in the relevant science discipline. Recall, explain, extrapolate and organize conceptual scientific knowledge for execution and application and also to evaluate its relevance.
GA 2	Critically evaluate, analyze and comprehend a scientific problem. Think creatively, experiment and generate a solution independently, check and validate it and modify if necessary.
GA 3	Access, evaluate, understand and compare digital information from various sources and apply it for scientific knowledge acquisition as well as scientific data analysis and presentation.
GA4	Articulate scientific ideas, put forth a hypothesis, design and execute testing tools and draw relevant inferences. Communicate the research work in appropriate scientific language.
GA5	Demonstrate initiative, competence and tenacity at the workplace. Successfully plan and execute tasks independently as well as with team members. Effectively communicate and present complex information accurately and appropriately to different groups.
GA 6	Use an objective, unbiased and non-manipulative approach in collection and interpretation of scientific data and avoid plagiarism and violation of Intellectual Property Rights. Appreciate and be sensitive to environmental and sustainability issues and understand its scientific significance and global relevance.
GA 7	Translate academic research into innovation and creatively design scientific solutions to problems. Exemplify project plans, use management skills and lead a team for planning and execution of a task.
GA8	Understand cross disciplinary relevance of scientific developments and relearn and reskill so as to adapt to technological advancements.

PROGRAM OUTCOMES

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

PROGRAM OUTLINE

YEAR	SEM	COURSE CODE	COURSE TITLE	Course Type	CREDITS
M.Sc. I	I	RPSBAS101 (Core Course)	Modern Pharmaceutical Industry	CC	4
		RPSBAS102 (Core Course)	Pharmacology, Toxicology & Bioassays	CC	4
		RPSBAS103 (Core Course)	Spectroscopy & Chromatography	CC	4
		RPSBAS104 (Skill Enhancement Course)	Techniques in biological analysis	SEC	4
		RPSBAS105 (Ability Enhancement Compulsory Course)	Resume building & Soft Skills	AEC	2
		RPSBASP101	Practical I	-	2
		RPSBASP102	Practical II	-	2
		RPSBASP103	Practical III	-	2
		RPSBASP104	Practical IV	-	2
M.Sc. I	II	RPSBAS201 (Core Course)	Practices in Pharmaceutical Industry	CC	4
		RPSBAS202 (Core Course)	Process of Drug Discovery & Development	CC	4
		RPSBAS203 (Core Course)	Medicinal Systems & Standardization of Herbal Drugs	CC	4
		RPSBAS204 (Skill Enhancement Course)	Bioinformatics & Biostatistics	SEC	4
		RPSBAS205 (Ability Enhancement Compulsory Course)	Research Methodology & Scientific Communication	AEC	2
		RPSBASP201	Practical I	-	2
		RPSBASP202	Practical II	-	2
		RPSBASP203	Practical III	-	2
		RPSBASP204	Practical IV	-	2
M.Sc. II	III	RPSBAS301	Microbiology, Toxicology and Standardization of Ayurveda, Siddha &	-	4

			Unani (ASU) Medicine		
		RPSBAS302	Bioanalytical Techniques and Clinical Data Management (CDM)	-	4
		RPSBAS303	Research Methodology & Biostatistics	-	4
		RPSBAS304	Internship/research Project	-	4
		RPSBASP301	Practical I	-	2
		RPSBASP302	Practical II	-	2
		RPSBASP303	Practical III	-	2
		RPSBASP304	Practical IV	-	2
M.Sc. II	IV	RPSBAS401	Pharmaceutical Biotechnology & Modern Analytical Techniques	-	4
		RPSBAS402	Advances in Bioanalysis	-	4
		RPSBAS403	Fundamentals in Clinical Research	-	4
		RPSBAS404	Research Project /Internship	-	4
		RPSBASP401	Practical I	-	2
		RPSBASP402	Practical II	-	2
		RPSBASP403	Practical III	-	2
		RPSBASP404	Practical IV	-	2

Core Course: RPSBAS101
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.
CO 3	Students will appreciate the therapeutic properties of proteins
CO 4	Students will learn phytochemistry and significance of different phytoconstituents along with its chemistry

DETAILED SYLLABUS

Paper Code	Semester I- Paper I	Lectures
RPSBAS101	**Modern Pharmaceutical Industry**	**60**
101.1 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, Bioavailability, Drug toxicity, Drug addiction, 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**
101.2 Overview of Pharmaceutical Industry		
1. Pharmaceutical Manufacturing 2. Pharmaceutical Microbiology- Clean areas, clean rooms, aseptic filling in pharmaceutical industry, Sterility testing 3. Packaging in pharmaceutical industry 4. Marketing in Pharmaceutical industry		**15**
101.3 Herbal Drug Industry		
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.		**15**

4. Evaluation of Crude drugs 5. Concepts of GAP and GHP for medicinal plants (only introduction) 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	
101.4 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**
RPSBASP101 PRACTICAL I	
1. Study of Hardness and Friability of a tablet 2. Study of Disintegration and Dissolution of a tablet as per IP/USP 3. Total Viable Count of microorganisms from herbal Raw materials and formulations 4. Sterility testing of pharmaceuticals 5. Study of MIC of a pharmaceutical product 6. Microscopic evaluation of sections and powders with adulteration and formulation comparison of the medicinal plants (Any 5) 7. Herbaria preparation & Evaluation of any one annual plant available locally 8. Proximate evaluation of crude drugs	

References:

1. Pharmaceutical Analysis: David Lee
2. Excipients and Delivery Systems of Pharmaceutical formulations: Karsa,Stephenson
3. Remington: Essential of pharmaceutics: Linda Felton
4. Essentials of Pharmacotherapeutics: F S K Barar.
5. Essentials of Medical Pharmacology: K.D.Tripathi, Jaypee Publications
6. Herbal Drug Technology: Agrawal,Paridhavi
7. Pharmacognosy: Tyler,Brody,Robbers

8. High Performance Liquid Chromatography in Phytochemical Analysis (Chromatographic Science Series) : by Monika Waksmundzka-Hajnos , Joseph Sherma
9. Fundamentals of Pharmacognosy and Phytochemistry: Heinrich, Barnes, Gibbons and Williamson

Core Course: RPSBAS102
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 I- Paper II**	**Lectures**
RPSBAS102	**Pharmacology, Toxicology & Bioassays**	**60**
102.1 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**
102.2 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**
102.3 Bioassays		
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		**15**

4. Alternatives to animal assays – one or two examples	
102.4 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**
RPSBASP102 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 B12	

References:

1. Kuby Immunology: Kindt, Goldsby&Osborna
2. Immunology Essentials and Fundamentals: Palan and Pathak
3. Biopharmaceutics and Pharmacokinetics: A Treatise: Brahmankar, Jaiswal: Pharma Dost
4. George M. Brenner, Craig Stevens: Pharmacology
5. Casarett&Doull's Toxicology, The basic Sciences of Poisons: Dr. Curtis Klaassen
6. Fundamentals of toxicology: Pandey, Shukla, Trivedi
7. Bioassay Techniques for Drug Development: Atta-ur-Rahman, M. Iqbal Choudhary, and William J. Thomsen
8. Statistical Techniques in Bioassay: Z. Govindarajulu
9. Pharmaceutical Bioassays: Methods and Applications: Ming Zhao and Shiqi Peng
10. Bioassay Methods in Natural Product Research and Drug Development: Bohlin and Bruhn

Core Course: RPSBAS103

Course Title: 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	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 III**	**Lectures**
RPSBAS103	**Spectroscopy & Chromatography**	**60**
103.1 Atomic Spectroscopy		
1. The electromagnetic spectrum and general properties of electromagnetic radiation 2. Components of optical instruments 3. Instrumentation, Sample preparation and applications of: Atomic Absorption Spectroscopy, Atomic Emission Spectroscopy and Inductively Coupled Plasma (ICP-AES & ICP-OES)		**15**
103.2 Molecular Spectroscopy Techniques		
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		**15**

3. Difference between Raman and IR spectroscopy	
103.3 Chromatography basics	
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 Optimization of Column Performance	**15**
103.4 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**
RPSBASP103 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. Standardization of mobile phase for Separation of plant pigments using paper chromatography 7. Qualitative (TLC) tests for modern drugs, secondary metabolites 8. HPTLC analysis of modern drug from plasma 9. HPTLC analysis of modern drug from formulations	

References:

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

Skill Enhancement Course: RPSBAS104
Course Title: Techniques in Biological Analysis

Academic year 2022-23

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.
CO 7	Students will be able to safely handle different biomatrices.
CO 8	Student should be able to choose and perform appropriate method for extraction and isolation of analytes.

DETAILED SYLLABUS

Paper Code	**Semester I- Paper IV**	**Lectures**
RPSBAS104	**Techniques in Biological Analysis**	60
104.1 Extraction, isolation and Purification of analyte		
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		15

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	
104.2 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
104.3 High Performance Liquid Chromatography	
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
104.4 Gas Chromatography	
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)	

6. Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD) 7. Derivatization for GC 8. GC strategy for analysis involving biological matrices 9. Troubleshooting 10. Applications	
RPSBASP104 PRACTICAL IV	
1. Preparation of analytical standard solutions 2. Liquid – liquid extraction of a modern drug from plasma and formulations 3. Solid Phase extraction of a drug from plasma 4. HPLC analysis of modern drug from plasma 5. Standardization of solvent and Phytochemical extraction by classical & modern methods 6. Qualitative and Quantitative (gravimetric) detection of secondary metabolites 7. Gas Chromatographic separation of solvent mixtures or analysis of herbal formulations by GC 8. HPLC separation of herbal raw material from its formulation (any one example)	

References:

1. High performance liquid chromatography in biotechnology: William S. Hancook
2. Principle and practice of Bioanalysis: Richard F. Venn
3. Basic Gas Chromatography: Mc Nair & Miller
4. Fundamentals of Pharmacognosy and Phytochemistry: Heinrich, Barnes, Gibbons and Williamson
5. Text book of Pharmacognosy:G.E. Trease,W.C. Evans
6. Phytochemicals Extraction, Separation & Analysis : Dr. Deep Panhekar, Ms. Trupti P. Sawant & Dr. D. P. Gogle
7. High Performance Liquid Chromatography in Phytochemical Analysis (Chromatographic Science Series) : by Monika Waksmundzka-Hajnos , Joseph Sherma
8. Principle and practice of Bioanalysis: Richard F. Venn
9. High Throughput Bioanalytical Sample Preparation, Volume 5, 1st Edition, Methods and Automation Strategies:David Wells: Elsevier Science
10. Bioanalysis of Pharmaceuticals, Sample preparation, Separation technique and Mass Spectrometry: Steen Honore Hansen &Stig Pedersen- Bjergaard

Ability Enhancement Compulsory Course: RPSBAS105

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
RPSBAS105	**Emotional well-being through Logic-based thinking**	**30**
105.1 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**
105.2 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		

a. Damnation- Respect b. Awfulizing- Courage c. Can’tstipation- Temperance.	**15**

References:

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

Modality of Assessment

Semester I

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

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: RPSBAS201
Course Title: Modern 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 II- Paper I	Lectures
RPSBAS201	**Practices in Pharmaceutical Industry**	**60**
201.1 Drug Act & Regulations in Pharma		
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**
201.2 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 4. Regulatory certification of GMP 5. GMP in production of ASU drugs 6. Harmonization of SOP of manufacture 7. Audit for GMP compliances		**15**
201.3 Quality Assurance & Stability studies		
Quality Assurance (07 Lectures)		**15**

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	
201.4 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 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**
RPSBASP201 PRACTICAL I	
1. Patent claim drafting and patent evaluation 2. Preparation of Standard Operating Procedure, for any one analytical Instrument 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. Study of certificate of analysis	

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: RPSBAS202
Course Title: Processes of drug discovery and 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 II- Paper II	Lectures
RPSBAS202	**Processes of drug discovery and development**	**60**
202.1 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**
202.2 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**
202.3 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**
202.4 Ethical guidelines in Clinical Trials and GCP		
Ethics (08 Lectures) 1. Origin of Ethical issues 2. Dealing with Ethical issues		**15**

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	
RPSBASP202 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) Study of an Informed consent form	

References:

1. Principles of Good Clinical Practice: McGraw, George, Shearn, Hall and Thomas
2. Good Clinical Practice Standard Operating Procedures for Clinical Researchers: Graeme Scott, Josef Kolman, Paul Meng.
3. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections: Vera Mihajlovic-Madzarevic.
4.

Course Code: RPSBAS203 (Core Course)

Course Title: Medicinal Systems & Standardization of Herbal Drugs
Academic year 2022-23

COURSE OUTCOMES

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

DETAILED SYLLABUS

Paper Code	Semester II- Paper III	Lectures
RPSBAS203	**Medicinal Systems & Standardization of Herbal Drugs**	**60**
203.1 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**
203.2 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**
203.3 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		**15**

203.4 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**
RPSBASP203 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: RPSBAS204
Course Title: Bioinformatics & Biostatistics
Academic year 2022-23

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	This course will introduce students with field bioinformatics.
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 2- Paper 4**	**Lectures**
RPSBAS204	**Bioinformatics & Biostatistics**	**60**
204.1 Basic Bioinformatics		
1. Introduction to Bioinformatics & Databases 2. Application of Bioinformatics 3. INSDC 4. Major Bioinformatics resources: NCBI, EBI, ExPASy 5. Nucleic acid: GENBANK, EMBL, DDBJ 6. Protein structure: domains, motifs (Pfam/Prosite) 7. Protein sequence databases: Uniports, PIR, SWISSPROT, TrEMBL 8. Literature database: PUBMED 9. Genome database: GSS, Genome 10. Specialized database: OMIM 11. Protein structure databases: PDB 12. Metabolic Pathway database: KEGG		**15**
204.2 Bioinformatics in Drug designing		
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**

204.3 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: Measures of central tendency (mean, median, mode) Measures of dispersion (range, sample deviation, variance, CoV) Introduction to correlation & regression analysis	**15**
204.4 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**
RPSBASP204 PRACTICAL IV	
1. INSDC- NCBI,EMBL,DDBJ 2. Sequence databases- EMBL-EBI, Gen Bank, Uniprot 3. Structure databases- PDB 4. Domain Databases- Prosite, PRINT,Pfam 5. Specialized databases- KEGG, PUBMED, OMIM, Use of Rasmol *6.* Tertiary structure and function prediction using homology modeling and *ab initio* method 7. Validation of Predicted structure 8. Visualization of 3D Protein structure using Rasmol, VMD 9. Docking: Using a docking software to study protein-ligand interaction 10. 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 Compulsory Course: RPSBAS205

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 2- Paper V	Lectures
RPSBAS205	**Research Methodology & Scientific Communication**	**30**
205.1 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 Ethics in research – APA Ethics code.		**15**
205.2 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 Informal experimental design: Before & after without control, After- only without control, Before & after with control		**15**

Semester II

Modality of Assessment

Theory Examination Pattern:

C) Internal Assessment- 40%- 40 Marks

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

D) 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:

B) 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

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

M.Sc. in Bioanalytical Sciences

(Post-graduate syllabus)

(Only for A.Y. 2022-23-**Not Based on Choice Based Credit System**)

Course Code: RPSBAS301

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

Academic year 2022-23

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**	
	13. Introduction, History, Scope and types of toxicological studies 14. Toxicants and their classification 15. Mode of action of Toxicants (Toxicokinetics and Toxicdynamics) 16. Dose Toxicity Relationship 17. Adverse drug reaction & treatment of Poisoning 18. Concept of LC 50, LD50, ED50 19. Applications of Toxicology 20. Introduction to Regulatory Toxicology 21. Types of toxicity tests 22. OECD Guidelines on Toxicological studies- Design considerations, Evaluation of results, Extrapolation to man 23. Risk analysis of Food & Drug related substances 24. 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	**15**

	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.	
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 2022-23

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)**	**15**
	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)	
302.2	**Hyphenated Techniques in Bioanalysis**	**15**
	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 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**	
	5. General idea about bioassay systems used in pharmaceutical evaluations 6. In vitro assays and in vivo assays 7. Ethical issues involved in animal assay systems 8. Alternatives to animal assays – one or two examples	**15**
302.4	**Clinical Data Management**	
	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	**15**
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 2022-23

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 2022-23

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:

1. Duration - These examinations shall be of **2.5 Hrs** duration.
2. 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

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: RPSBAS401
Course Title: Pharmaceutical Biotechnology & Modern Analytical Techniques

Academic year 2022-23

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 2. Theory and Applications of: a. Circular Dichroism 1. Optical Rotary Dispersion	**15**
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 2022-23

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		**15**
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		
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 2022-23

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 of Clinical 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 **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**

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 2022-23

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:

1. Duration - These examinations shall be of **2.5 Hrs** duration.
2. 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

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.
