Resolution number: AC/II(22-23).3.RPS1

S. P. Mandali's

Ramnarain Ruia Autonomous College

(Affiliated to University of Mumbai)

RUIA COLLEGE
Explore • Experience • Excel

Syllabus for

Program: Integrated M.Sc. in Bioanalytical Sciences

Program Code: RPSINBAS

(Post-graduate Syllabus)

(As per the guidelines of National Education Policy 2020-Academic year 2023-24)

(Choice based Credit System)

Graduate Attributes

S. P. Mandali's Ramnarain Ruia Autonomous College has adopted the Outcome Based Education model to make its science graduates globally competent and capable of advancing in their careers. The Bachelors Program in Science also encourages students to reflect on the broader purpose of their education.

GA	GA Description **A student completing Bachelor's/Master's Degree in Science program will be able to:**
GA 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.
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.
GA 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.
GA 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.
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.
GA 8	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 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

Syllabus for Integrated M.Sc I				
Semester	**Paper Type**	**Paper Code**	**Paper Title**	**Credits**
VII	Core Paper I	RPSINBAS.O501	Modern Pharmaceutical Industry	3
	Core Paper-II	RPSINBAS.O502	Pharmacology, Toxicology & Bioassays	3
	Core Paper-III	RPSINBAS.O503	Advances in Spectroscopy & Chromatography	3
	Core Paper-IV	RPSINBAS.O504	Techniques in Biological Analysis	2
	RM	RPSRMINBAS.O505	Research Methodology	4
	Discipline Specific Electives (DSE) I	RPSINBAS.O506	Nutraceuticals and Functional foods I	3
	Discipline Specific Electives (DSE) II	RPSINBAS.O507	Nanotechnology	
		RPSINBASP.O501	Practical based on RPSINBAS.O501	1

		RPSINBASP.O502	Practical based on RPSINBAS.O502	1
		RPSINBASP.O503	Practical based on RPSINBAS.O503	1
		RPSINBASP.O506	Practical based on RPSINBASP.O506	1
		RPSINBASP.O507	Practical based on RPSINBASP.O507	
	Total Credits			**22**

Core Course: RPSINBAS.O501
Course Title: Modern Pharmaceutical Industry
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Summarize the applications of microbiology for testing quality of pharmaceutical products.
CO 2	Discuss and learn the norms required for manufacturing in pharmaceutical industry.

DETAILED SYLLABUS

Paper Code	Semester VII- Paper I	Credits/ Hours
RPSINBAS.O501	**Modern Pharmaceutical Industry**	**3/45**
501.1: Pharmaceutical Manufacturing & Pharmaceutical Microbiology		
Pharmaceutical Microbiology (08 L) 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 Manufacturing (07 L)** 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**
501.2: 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		**15**

9. Packaging Validation 10. Packaging Laws and regulatory compliance	
501.3: 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**
RPSINBASP.O501: PRACTICAL	
1. Total Viable Count of microorganisms from raw materials and finished product 2. Sterility Testing of a Pharmaceutical Preparation 3. Study of MIC of a pharmaceutical product 4. Study of Hardness and Friability of a tablet 5. Study of Disintegration and Dissolution of a tablet as per IP/USP (uncoated) 6. Study of packaging material of a pharmaceutical preparation 7. Turbidometric & Nephalometric analysis of Pharmaceutical Products	**1/30**

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: RPSINBAS.O502
Course Title: Pharmacology, Toxicology & Bioassays
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Design and perform bioassays.
CO 2	State the significance of toxicological studies for ensuring safe administration of pharmaceuticals.
CO 3	Acquire training in toxicological assays.

DETAILED SYLLABUS

Paper Code	Semester VII- Paper II	Credits/ Hours
RPSINBAS.O502	**Pharmacology, Toxicology & Bioassays**	**3/45**
502.1: 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. 6. Drug Metabolism: Introduction, Absorption, Distribution, Bio-transformation, Excretion 7. Mechanisms of Drug Action- Pharmacodynamics 8. 8. Different Pharmacokinetic & Pharmacodynamics parameters and their meanings and basic techniques to evaluate the parameters 9. Basic types of models in Pharmacokinetics & Pharmacodynamics		**15**
502.2: Toxicology		
Introduction, History, Scope and types of toxicological studies 1. Toxicants and their classification 2. Mode of action of Toxicants (Toxicokinetics and Toxicodynamics) 3. Dose Toxicity Relationship 4. Adverse drug reaction & treatment of Poisoning 5. Concept of LC 50, LD50, ED50 6. Applications of Toxicology 7. Introduction to Regulatory Toxicology 8. Types of toxicity tests 9. 1010. OECD Guidelines on Toxicological studies- Design considerations, Evaluation of results, Extrapolation to man 10. Risk analysis of Food & Drug related substances 11. Environmental impact assessment		**15**
502.3: Bioassays & Immunoassays		

Bioassays (08 L) 1. General idea about bioassay systems used in pharmaceutical evaluations 2. *Invitro* assays and *invivo* assays 3. Alternatives to animal assays – one or two examples **Immunoassays (07 L)** 1. Requirements for immunoassay 2. Principles and instrumentation in immunoassay 3. Types of Detection systems in immunoassay 4. Applications of immunoassay 5. Advantages & Disadvantages of immunoassay	**15**
RPSINBASP.O502: PRACTICAL	
1. Immunoassays for detection of Hepatitis B/Dengue 2. LC50 study on a suitable organism (Any two) 3. Study of hepatotoxicity using suitable animal model 4. Bioassay of Penicillin 5. Bioassay of Vitamin B_{12} 6. Electrophoresis of Proteins (SDS-PAGE)	**1/30**

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: RPSINBAS.O503
Course Title: Advances in Spectroscopy & Chromatography
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Highlight the importance of Electromagnetic spectrum and introduce the students to components of optical instruments.
CO 2	Compare atomic absorption and atomic emission spectroscopy.
CO 3	Understand the Principles and applications of different molecular spectroscopy techniques.
CO 4	Describe the principle, and applications of spectroscopic techniques based on light scattering.
CO 5	Compare and Evaluate modern analytical techniques such as HPTLC, HPLC, UV-Vis spectroscopy for standardization of pharmaceutical products.
CO 6	Operate Nephelometer, Turbidimeter, IR spectrophotometer.
CO 7	Analyze samples using Flame Photometry and Atomic Absorption Spectroscopy.

DETAILED SYLLABUS

Paper Code	**Semester VII- Paper III**	**Credits/ Hours**
RPSINBAS.O503	**Advances in Spectroscopy & Chromatography**	**3/45**
503.1 Atomic Spectroscopy		
1. Components of optical instruments 2. Instrumentation, Sample preparation and Applications of Atomic Absorption 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**
503.2: 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**
503.3: Advances in Chromatography and Other techniques in analysis		
1. Specialized columns & detectors in HPLC and GC 2. Ultra Performance Liquid Chromatography (UPLC) 3. Preparative HPLC & HPLC 4. Preparative HPLC and 2D-HPLC		**15**

5. Size exclusion chromatography, Ion exchange chromatography, Affinity chromatography for protein separation 6. High Performance Thin Layer Chromatography (HPTLC) In Situ Densitometric scanning, Troubleshooting, HPTLC Fingerprinting, Preparative HPTLC 7. Nephelometry & Turbidimetry, Particle Size Analyzer 8. Electrophoresis (Agarose, SDS-PAGE, IEF & Capillary Electrophoresis)	
RPSINBAS.O503: PRACTICAL	
1. Flame Photometric estimation of metals with special emphasis on interference 2. Sample Preparation for AAS & analysis of pharmaceutical products/Crude drugs for their metal content using AAS 3. Qualitative analysis of organic solids using IR spectroscopy 4. IR analysis of modern drug (any one example) 5. Liquid-liquid extraction of a modern drug from plasma 6. HPTLC analysis of modern drug from plasma and formulations	**1/30**

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

Core Course: RPSINBAS.O504
Course Title: Extraction methodologies in Biological Analysis
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Comment on the different safety protocols while handling the biofluids.
CO 2	Justify the appropriate techniques for extraction and isolation from biological matrices.
CO 3	Classify and identify the applications of biological matrix.

DETAILED SYLLABUS

Paper Code	**Semester I- Paper IV**	**Credits/ Hours**
RPSINBAS.O504	**Extraction methodologies in Biological Analysis**	**2/30**
504.1: 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**
504.2: 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**

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

Core Course: RPSRMINBAS.O505
Course Title: Research Methodology
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Compare data types and its collection methods in biostatistics.
CO 2	Analyse biological samples in a regulated manner and transfer suitable statistical tests to extrapolate the observations to relevant results.
CO 3	Summarize the importance of research methodology and research designs in all fields of research.
CO 4	Apply descriptive statistics and test of significance for accurate statistical calculations in research.

DETAILED SYLLABUS

Paper Code	**Semester I- Paper V**	**Credits/ Hours**
RPSRMINBAS.O505	**Research Methodology**	**4/60**
505.1: 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**
505.2: 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 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**
505.3: 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) 5. Introduction to correlation & regression analysis	
505.4: 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**

References:

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

Core Course: RPSINBAS.E511
Course Title: Practices in Pharmaceutical Industry
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Infer the importance of Drug act and the need for regulations in Bioanalysis.
CO 2	Recognize the good practices followed in industrial operations.
CO 3	Correlate the importance of documentation and strict adherence to protocol in bioanalytical industries.

DETAILED SYLLABUS

Paper Code	Semester II- Paper I	Credits/ Hours
RPSINBAS.E511	**Practices in Pharmaceutical Industry**	**3/45**
511.1: 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**
511.2: Good Laboratory Practices & Good Manufacturing Practices		
Good Laboratory Practices (07 Lectures) 1. Guidelines to GLP 2. Documentation of Laboratory work 3. Preparation of SOPs 4. Calibration records 5. Significance of validation in GLP 6. Transfer of methods 7. Documentation of results **Good Manufacturing Practices (08 Lectures)** 1. Requirements of GMP implementation 2. Documentation of GMP practices 3. Regulatory certification of GMP 4. GMP in production of ASU drugs 5. Harmonization of SOP of manufacture 6. Audit for GMP compliances		**15**
511.3: Quality Assurance& Stability studies		
Quality Assurance (07 Lectures) 1. Introduction to QC & QA 2. Requirements for implementing QA		**15**

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	
RPSINBASP.E511: PRACTICAL	
1. Preparation of Standard Operating Procedure (SOP) for any one analytical instrument 2. Study of Certificate of Analysis (COA) 3. Study of Shelf life of herbal drugs 4. Stability studies of drugs (API & Formulation) with respect to the effect of pH, Temperature, Moisture and Light (any 4 experiments)	**1/30**

References:

1. Drugs and Cosmetics Act 1940 and Rules 1945
2. Remington, Essentials of Pharmaceutics: Linda Felton
3. GLP Essentials: A Concise guide to Good Laboratory Practice, 2nd Edition: Milton A. Anderson 4. The Certified Pharmaceutical GMP Professional Handbook, Second Edition: Mark Allen Durivage
5. Good Laboratory Practice Regulations: Sandy Weinberg
6. Handbook of Stability tasting in pharmaceutical development: regulations, methodologies and best practices: Springe

Core Course: RPSINBAS.E512

Course Title: Process of Drug Discovery & Development
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Justify the importance of preclinical research.
CO 2	Compare the different stages of clinical trials and understand the regulatory norms for conduct of clinical trials.
CO 3	Recognize a new chemical entity and describe the process of new drug development
CO 4	Quote the ethical issues to be addressed while conducting a clinical trial

DETAILED SYLLABUS

Paper Code	Semester II- Paper II	Credits/ Hours
RPSINBAS.E512	**Process of Drug Discovery & Development**	**3/45**
512.1: 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**
512.2: Preclinical Research and Basics of Clinical Trials **Preclinical Research (07 lectures)** 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 **Basics of Clinical Trials (08 lectures)** 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**
512.3: Ethical guidelines in Clinical Trials and GCP		
Ethics (08 Lectures)		**15**

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	
RPSINBASP.E512: PRACTICAL	
1. LC50 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	**1/30**

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: RPSINBAS.E513

Course Title: Spectroscopy & Chromatography II
Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Describe the instrumentation and applications of Gas Chromatography and effectively use chromatographs for analysis of samples and interpret the results.
CO 2	Describe the principles and applications of electrophoretic techniques.
CO 3	Devise simultaneous analysis of phytoconstituents using sophisticated analytical techniques like HPTLC and GC.
CO 4	Troubleshoot in operation of High Performance Liquid Chromatography.

DETAILED SYLLABUS

Paper Code	Semester II- Paper III	Credits/ Hours
RPSINBAS.E513	**Spectroscopy & Chromatography II**	**3/45**
513.1 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**
513.2 Gas Chromatography		
1. Principles and Instrumentation 2. Factors that affect the chromatographic separation (Temperature, Type of column etc.) 3. GC techniques		**15**

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	
513.3 Advances in Chromatography	
Advances in Chromatography (07 Lectures): 1. Specialized columns &detectors in HPLC and GC 2. Ultra Performance Liquid Chromatography (UPLC) 3. Preparative HPLC, 2D-HPLC **Principles, Instrumentation, Sample preparations and Applications of (08 Lectures):** 1. Size exclusion chromatography & Affinity chromatography for protein separation 2. Ion exchange chromatography 3. Electrophoresis(Agarose, SDS-PAGE, IEF & Capillary Electrophoresis)	**15**
RPSINBASP.E513: PRACTICAL ON RPSBASP.E513	
1. Qualitative analysis of organic solids using IR spectroscopy 2. IR analysis of modern drug (any one example) 3. Purification of caffeine by Prep HPLC 4. Purification of gallic acid by Prep HPLC 5. Separation of Proteins by SDS-PAGE 6. Seperation of Eugenol by GC/HPLC	**1/30**

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
6. Principles and practices in Biochemistry: Wilson and Walker

Course: RPSINBAS.E514

Course Title: Medicinal Systems and Standardization of ASU drugs Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Describe Indian Systems of Medicine and regulatory aspects of ASU drugs.
CO 2	Justify the importance of Bioanalytical techniques for standardization of traditional medicines.
CO 3	Correlate microscopic evaluation of Ayurveda, Siddha and Unani Drugs in compliance to evaluation of Ayurveda, Siddha and Unani Drugs in compliance to Pharmacopoeia.

DETAILED SYLLABUS

Paper Code	Semester II- Paper IV	Credits/ Hours

RPSINBAS.E514	Medicinal Systems and Standardization of ASU drugs	2/30
514.1: 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**
514.2: 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 8. Regulatory Aspects of ASU Drugs		**15**

References:

Database on medicinal plant used in Ayurveda: Sharma, Yelne and Dennis 2. Globalisation of Ayurvedic& Herbal products, challenges and strategies

RP Course: RPSINBAS.E515

Course Title: Field project

Academic year 2023-24

COURSE OUTCOMES

COURSE OUTCOME	DESCRIPTION
CO 1	Explain the hypothesis and conduct literature survey based on the relevant survey.
CO 2	Analyze field data using statistical tools and softwares to interpret the scientific data for the field project.

DETAILED SYLLABUS

Paper Code	Semester II- Paper V	Lectures
RPSINBAS.E515	**Field project**	**4/60**

Field project

A. Survey based projects on the theme given by the department B. Compliance studies w.r.t GMP, GLP,GCP or any other relevant criteria in Industries visited during the Industry visit

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.
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.
5. Thorough literature review should be carried out by the students.
6. Students should report and update the allotted mentor regarding the field project.
7. Students are expected to support detailed report of the field project such as Laboratory notebooks
8. Final hardbound report as well as the soft copy report of the field 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
9. 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 field project.

Modality of Assessment

Sem VII / VIII

Class	Semester	Course	Credits	Marks for the First Internal Class Test	Pattern of the Exam (Class Test/Assignment etc)	Marks for the Second Internal Assessment	Pattern of the Exam (Class Test/Assignment etc)	Marks for Semester End Examination
MSc	VII/VIII	DSC 1	3	20	Class Test	10	Assignment	45
		DSC 2	3	20	Class Test	10	Assignment	45
		DSC 3	3	20	Class Test	10	Assignment	45
		DSC 4	2					50
		DSE 1	3	20	Class Test	10	Assignment	45
		RM	4	20	Class Test	20	Assignment	60

		Practical DSC 1	1	-	-	-	-	50
		Practical DSC 2	1	-	-	-	-	50
		Practical DSC 3	1	-	-	-	-	50
		DSE 1	1	-	-	-	-	50