AC/2024/RS 2

SIES College of Arts, Science & Commerce

RISE WITH EDUCATION

Sion (West), Mumbai – 400022

(Autonomous)

(*Affiliated to University of Mumbai*)

Faculty: Science

Program: M.Sc.-II

Subject: BIOANALYTICAL SCIENCES

Academic Year: 2024 – 2025

Revised Syllabus under Choice Based Credit System (CBCS) approved by the Board of Studies in Bioanalytical Sciences
Effective from Academic Year: 2024-25
Under the aegis of National Education Policy (NEP)

Preamble

"Where the mind is without fear and the head is held high ...." — A poem written by Nobel Laureate Rabindranath Tagore (Nobel Prize in Literature in 1913), the poem represents Tagore's vision of a new and awakened India (it is quoted in this preamble in the context of National Education Policy).

Our institution was one of the lead colleges, affiliated to University of Mumbai in implementing India's National Education Policy 2020 (NEP 2020) in academic year 2023-24. Moreover, we were also conferred with 'Empowered Autonomous Status' in 2023-24, which becomes all the more relevant, in terms of our contribution as an educational institution to fulfill the visionary and transformative objectives of National Education Policy. Under the aegis of academic autonomy, the Department of Bioanalytical Sciences has the privilege of 'academic freedom' to revise its course and curriculum, however, it is also aware of the fact that 'freedom' comes with 'responsibility' and it needs to be justified with 'excellence'. One of the ways to achieve this is through fine-tuning the curriculum. Thus, in addition to enable students to acquire an in depth knowledge of the Core/Mandatory subject, the current syllabus also attempts to integrate a few courses under Department Specific Electives, which will help students to be equipped with the necessary skills to enhance their core competencies in understanding synergism of pure and applied sciences, in order to make them self-sufficient and build a future.

Some of the key features of this revised syllabus are as follows:

- ✓ *Research project/Dissertation – to inculcate research aptitude and to develop an open, inquiring mind that is willing to explore new territories and learn new things; to encourage the spirit of curiosity of students, who are not just learners but also potential problem solvers and scientific investigators.*
- ✓ *Environmental Safety and Impact, Anthropology and Sustainable Development: to help students understand environmental safety issues, to create awareness in them about the real world impact of climate change and to introduce them to concepts like environmental anthropology, sustainable development, etc.*
- ✓ *Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology – to understand basics of microbiology besides giving information about regulatory microbiology and its applications in food and pharmaceuticals; to familiarize students with genomics and its relevance in toxicology and pharmacology; to introduce students to principles of toxicology, relevance of toxicity studies, regulatory guidelines, ethics in animal studies, alternatives to animal models.*
- ✓ *MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques – to make students understand Mass Spectrometry (MS) in terms of principle and instrumentation; to introduce students to hyphenated techniques, its applications and recent developments; to give students insights into the principle, instrumentation and applications of Thermal analysis in Ayurveda Siddha Unani (ASU) formulations such as Bhasmas.*
- ✓ *Standardization of ASU Drugs, Statistics and GMP – to familiarize students with steps involved in standardization of ASU drugs; to introduce students to basic concepts, applications of statistical methods and tomake them competent in Biostatistics; to introduce students to concepts, requirements, applications and compliance of Good Manufacturing Practices (GMP) with reference to ASU drugs.*
- ✓ *BA/BE Studies, GCP and Method Validation – to introduce the students to ethical issues in clinical trials, its guidelines and compliances; give insights to students about Good Clinical Practices (GCP); to train students about the concepts of Bioavailability and Bioequivalence (BA/BE); to train students in various Bioanalytical methods and techniques with emphasis on sample preparation, method development, and method validation techniques.*
- ✓ *Department Specific Elective in the form of Applied Microbiology and Biotechnology - A course which has been restructured, whereby, it will give insights to students about regulatory microbiology, bioassays and its applications in food, pharmaceuticals, and biotechnology; to make students aware of the recent advances and developments in Applied Microbiology and Biotechnology.*

This revised syllabus is a collective and constructive effort of the faculty, experts from research institutions, alumni and the board members whose valuable suggestions and expertise were instrumental in materializing this syllabus. The comments and recommendations of the contributors and reviewers have been carefully considered and incorporated wherever feasible.

For effective teaching-learning, teachers are advised not to follow the syllabus too rigidly, but to exercise their professional discretion and judgment in implementing it. After all teaching is also about creating a conducive environment for learners to sustain enthusiasm about the subject. We sincerely hope that this revised syllabus will encourage critical thinking, instill analytical skills, besides inculcating interdisciplinary approach amongst student's to make learning more meaningful, thereby pursuing academic excellence.

Dr. Satish Sarfare
Chairman
Board of Studies in the subject of Bioanalytical Sciences
SIES College of Arts, Science and Commerce (Empowered Autonomous)
Sion (West), Mumbai
Email: satishs@sies.edu.in

Members of the Board of Studies in the subject of Bioanalytical Sciences and Syllabus Committee

- ✓ *Professor (Dr.) Savita Kulkarni – Scientific Officer (H), Homi Bhabha National Institute, Head, Tuberculosis Immunology & Immunoassay Development Section and Medical Cyclotron & Radiopharmaceutical Production Section, Radiation Medicine Centre, BARC (Vice Chancellor's Nominee)*

- ✓ *Professor (Dr.) Sunita Shailajan – Former Head, Department of Botany, Research Project Coordinator, Herbal Research Lab, Ruia College, Mumbai (Subject Expert from outside college for special course of study)*

- ✓ *Dr. Sasikumar Menon – Director, Institute for Advanced Training & Research in Interdisciplinary Sciences (IATRIS), (Therapeutic Drug Monitoring Lab), Sion, Mumbai; Faculty, Pharma Analytical Sciences, Ruia College, Mumbai (Subject Expert from outside college for specific course/special course of study)*

- ✓ *Dr. Naomita Dhume – Head, Department of Bioanalytical Sciences, Khalsa College, Mumbai (Subject Expert from other college)*

- ✓ *Dr. Ajit Datar – Currently Advisor, Borosil Ltd; Former Advisor, Shimadzu Analytical Pvt Ltd (Subject Expert and Industry representative)*

- ✓ *Mr. Hemant Deshpande – CEO, Pollux Life Sciences Solutions, Mumbai (Representative from Corporate sector / Allied area)*

- ✓ *Dr. Mandar Mhatre – Manager, Ajanta Pharma, Mumbai (Subject Expert and Industry representative)*

- ✓ *Dr. Supriya Shidhaye – Principal; Vivekanand Education Society's College of Pharmacy, Mumbai (Subject Expertfrom outside college for specific course/special course of study)*

- ✓ *Dr. Juliet Victoria – Post doctoral fellow, Chemical Engineering Department, Copenhagen, Denmark (Postgraduate Meritorious Alumnus)*

- ✓ *Dr. Tara Menon – Head, Department of Biotechnology, SIES College, Mumbai*

- ✓ *Dr. Pallavi Roy – Faculty, Department of Chemistry, SIES College, Mumbai*

- ✓ *Ms. Pracheta Salunkhe – Faculty, Department of Bioanalytical Sciences, SIES College, Mumbai*

- ✓ *Mr. Tejas Karandikar – Faculty, Department of Bioanalytical Sciences, SIES College, Mumbai*

- ✓ *Dr. Satish Sarfare – Coordinator and Faculty, Department of Bioanalytical Sciences, SIES College, Mumbai*

M.Sc. Part II- Bioanalytical Sciences- Semester III (Syllabus Grid)

THEORY			
Course name and code	**Unit**	**Topic Headings**	**Credits**
SEMESTER III			
A) Major			
a) Mandatory/Core Papers			
Paper I: Toxicology, GCP, BA & BE Studies and Pharmacovigilance			
SIPBACC611	1	Basic and Regulatory Toxicology	**4**
	2	Ethical Issues in Clinical Trials and Good Clinical Practices	
	3	Bioavailability (BA) & Bioequivalence (BE) Studies	
	4	Therapeutic Drug Monitoring and Pharmacovigilance	
Paper II: MS and Hyphenated Techniques, Thermal Analysis and Tracer Techniques			
SIPBACC612	1	Basics of MS	**4**
	2	Thermal analysis and tracer techniques	
	3	Hyphenated Techniques and their applications	
	4	Bioanalytical methods and automation in analysis	
b) Electives			
Paper III: Applied Microbiology and Biotechnology-I			
SIPBAEL611	1	Genomics	**3**
	2	Regulatory microbiology and it's applications in the pharmaceutical and food industry	
	3	Gene manipulation techniques	
Paper IV: Research Project			
	1	**No Theory Paper**	**-**
PRACTICAL			
SIPBACCP611	1	Based on Core Course 1 (SIPBACC611)	**2**
SIPBACCP612	2	Based on Core Course 2 (SIPBACC612)	**2**
SIPBAELP611	3	Based on Department Specific Elective (SIPBAEL611)	**1**
SIPBARP611	4	Research Project	**6**
		Total	**22**

M.Sc. Part II- Bioanalytical Sciences- Semester IV (Syllabus Grid)

THEORY			
Course name and code	**Unit**	**Topic Headings**	**Credits**
SEMESTER IV			
A) Major			
a) Mandatory/Core Papers			
Paper I: Environment Safety and Impact, Analytical Method Validation and Electronic Data Management			
SIPBACC621	1	Environmental Safety in a Bioanalytical Laboratory	**4**
	2	Environmental Anthropology and Sustainable Development	
	3	Electronic Data Management	
	4	Analytical Method Validation	
Paper II: Standardization of ASU Drugs, Drug Regulation and GMP			
SIPBACC622	1	Standardization of ASU Drugs	**4**
	2	QC and QA of ASU Drugs	
	3	Regulatory aspects of ASU Drugs	
	4	Good Manufacturing Practices	
c) Electives			
Paper III: Applied Microbiology and Biotechnology-II			
SIPBAEL621	1	Polymerase Chain Reaction (PCR)	**3**
	2	Modes of Capillary Electrophoresis (CE) & factors affecting it	
	3	Bioassays in Pharmaceutical Evaluation	
Paper IV: Research Project			
	1	**No Theory Paper**	**-**
PRACTICAL			
SIPBACCP621	**1**	Based on Core Course 1 (SIPBACC621)	**2**
SIPBACCP622	**2**	Based on Core Course 2 (SIPBACC622)	**2**
SIPBAELP621	**3**	Based on Department Specific Elective (SIPBAEL621)	**1**
SIPBARP621	**4**	Research Project	**6**
		Total	**22**

MSc – Part II - Bioanalytical Sciences Syllabus - Semester III

CORE / MANDATORY PAPER 1: SIPBACC611

Toxicology, GCP, BA & BE Studies and Pharmacovigilance

Theory Credits	Practical Credits
4	2

Course Outcomes	• To gain an insight into the various aspects of toxicology. • To understand the ethical issues that can arise before a clinical trial. • To gain a historical perspective on Good Clinical Practices and get familiarized with its guidelines. • To learn about the various concepts in Bioavailability and Bioequivalence studies • To create awareness about the safe use of medicines and to learn about the various aspects of Therapeutic Drug Monitoring
Learning Objectives	✓ *To introduce students to various concepts and guidelines of toxicology* ✓ *To introduce students to the various ethical issues in clinical trials, the powers of the ethical Committees, ways of dealing with ethical issues, compliance to the current ethical guidelines and to give insights to the students about Good Clinical Practices* ✓ *To teach students about the concepts of Bioavailability and Bioequivalence* ✓ *To acquaint students with concepts related to Therapeutic Drug Monitoring and Pharmacovigilance*

Unit 1

Basic and Regulatory Toxicology **15 Lectures**

- Principles of toxicology – Different areas of toxicology – Descriptive, Mechanistic, and Regulatory
- Characteristics of Exposure – Duration of exposure, frequency of exposure, site of exposure and routes of exposure
- Dose-Response relationship – Individual/ Graded dose response relationships, Quantal dose-response relationships, shape of dose response curves, Concept of LD_{50}, LC_{50}, ED_{50}, Therapeutic Index, Margin of safety and exposure
- Descriptive animal toxicity tests – Acute toxicity testing, skin, and eye irritation, sub-acute (Repeat-Dose Study), sub-chronic, chronic, developmental, and reproductive toxicity, absorption, distribution, and excretion of toxicants – absorption of toxicants by gastrointestinal tract, lungs, skin; volume of distribution of toxicants, urinary excretion, fecal excretion.
- Biotransformation of xenobiotics – Xenobiotic biotransformation by Phase I enzymes and Phase II reactions (examples of carbon tetrachloride and acetaminophen).
- Dose translation from animals to humans – Concept of extrapolation of dose, NOAEL (No Observed Adverse Effect Level), Safety factor, ADI (Acceptable Daily Intake)
- OECD guidelines for testing of chemicals
- CPCSEA guidelines for the animal testing center, ethical issues in animal studies and animal models used in regulatory toxicology studies
- Alternative methods to animal testing in toxicology (in vitro / in silico approach), Schedule Y and its interpretation
- Case studies – Sulfanilamide, Thalidomide, Diethylstilbestrol, Saccharin

References: -

Klaassen, Curtis D. Casarett & Doull's Toxicology The Basic Science of Poisons (2008). New York: McGraw Hill

Reinhardt, Christoph A., Alternatives to Animal Testing (2006). Weinheim, New York: VCH Verlagsgesellschaft mBH, VCH Publishers Inc.

Unit 2

Ethical Issues in Clinical Trials and Good Clinical Practices **15 Lectures**

Part A: Ethical Issues in Clinical Trials

- Origin of Ethical Issues
- Dealing with Ethical issues
- Ensuring compliance to ethical issues
- Ethical Committees & their set up
- Regulatory powers of ethical committees
- Ethical issues in animal studies
- Compliance to ethical guidelines
- Dealing with Ethical issues (subject compensation and subject rights)
- Compliance to current ethical guidelines

Part B: Good Clinical Practices

- What is GCP?
- Origin of GCP
- Earlier Guidelines for GCP
- Requirements of GCP compliance
- GCP guidelines of ICH
- GCP guidelines of ICMR (with respect to current guidelines of ICMR)
- Ensuring GCP
- Documentation of GCP practice
- Audit of GCP compliance

References: -

Hawkins, Jennifer S., Emanuel, Ezekiel J. (2008) Exploitation and Developing Countries The Ethics of Clinical Research

Gluck, John P., DiPasquale, Tony, Orlans, F. Barbara (2002) Applied Ethics in Animal Research Philosophy, Regulation and Laboratory Applications. West Lafayette: Purdue University Press

McGraw, Michael J. (2010) Principles of Good Clinical Practice. London: Pharmaceutical Press

Mihajlovic-Madzarevic, Vera (2010) Clinical Trials Audit Preparation A Guide for Good Clinical Practice (GCP) Inspections. Hoboken: John Wiley & Sons Inc.

Unit 3:

Bioavailability (BA) & Bioequivalence (BE) Studies **15 Lectures**

- What is BA?
- Parameters to evaluate BA of a drug and Factors that influence BA of a drug
- Evaluating BA of a drug and Estimating BA parameters of a drug
- Designing and Conducting of a BA study, Data collection, and evaluation of a BA study
- Reporting a BA study and Regulatory requirements of BA
- What is BE?
- Parameters to evaluate BE of a drug and Factors that influence BE of a drug
- Evaluating BE of a drug and Estimating BE parameters of a drug
- Designing and Conducting of a BE study and Data record and evaluation of BE study
- Regulatory requirements of BA and BE and Assessment of Bioequivalence study

References: -

Chow, Shein-Chung, Liu, Jen-pei (2009) Design and Analysis of Bioavailability and Bioequivalence Studies. Boca Raton: CRC Press

Kanfer, Isadore, Shargel, Leon (2010) Generic Drug Product Development International Regulatory Requirements for Bioequivalence. Boca Raton: CRC Press

Hauschke, Dieter, Steinijans, Volker, Pigeot, Iris (2007) Bioequivalence Studies in Drug Development Methods and Applications. West Sussex: John Wiley & Sons Ltd.

Van de Waterbeemd, H., Lennernäs, H., Artursson, P. (2003) Drug Bioavailability Estimation of Solubility, Permeability, Absorption and Bioavailability. Weinheim: Wiley-VCH Verlag GmbH & Co

Unit 4

Therapeutic Drug Monitoring and Pharmacovigilance **15 Lectures**

- Purpose of Therapeutic Drug Monitoring
- Bioanalytical techniques in TDM
- Analytical and practical issues of TDM
- Pharmacoeconomics of TDM
- Significance and need for Pharmacovigilance (Introduction to various case studies of pharmacovigilance)
- Indian scenario and the role of regulatory agencies in pharmacovigilance
- Pharmacovigilance and the safe use of medicines (with case studies of drugs which have been banned due to regulatory issues e.g., Erythromycin which is supposed to cause skin problems in Asian population)

References: -

Xu, Q. Alan, Madden, Timothy L. (2011) Analytical Methods for Therapeutic Drug

Monitoring and Toxicology. Hoboken: John Wiley & Sons, Inc.

Waller, Patrick, Harrison-Woolrych, Mira (2017) An Introduction to Pharmacovigilance

Second Edition. West Sussex: John Wiley & Sons Ltd.

Andrews, Elizabeth B., Moore, Nicholas (2014) Mann's Pharmacovigilance Third Edition. West Sussex: John Wiley & Sons Ltd.

CORE / MANDATORY PAPER 2: SIPBACC612

MS and Hyphenated Techniques, Thermal Analysis and Tracer Techniques

Theory Credits	Practical Credits
4	2

Course Outcomes	• To build a strong foundation of the concepts in Mass Spectrometry • To build on the basics of Mass Spectrometry learnt and extend the knowledge to the various hyphenated techniques in Mass Spectrometry and their applications • To reintroduce the basic concepts of effects of heat on various substances in the form of thermal analysis techniques. • To revise the basic concepts of radiation and half-life and to introduce students to various tracer techniques used in bioanalytical assays
Learning Objectives	✓ *To make students understand basics of MS in terms of principle and the instrumentation involved.* ✓ *To introduce students to various hyphenation techniques in MS and their application in various fields.* ✓ *To give students insights into the various Thermal analysis techniques, their principles, instrumentation and applications in the analysis of ASU formulations such as Bhasmas and in other areas and to introduce students to the Tracer Techniques in Bioanalytical assays.* ✓ *To train students in various Bioanalytical methods and techniques and make them aware of the automated technologies that have been developed for bioanalysis.*

Unit 1

Basics of MS **15 Lectures**

- Introduction to Mass Spectrometry (MS) and the concept of mass to charge ratio (m/z)
- Components of a Mass Spectrometer (MS):
    a. Inlets
    b. Ion sources (Electron Ionization, Chemical Ionization, Electrospray Ionization, Atmospheric Pressure Photoionization, Atmospheric Pressure Chemical Ionization, Matrix Assisted Laser Desorption Ionization)
    c. Mass analyzers (Quadrupole, Ion trap, Time of Flight, Magnetic Sector Analyzer, Ion Cyclotron Resonance)
    d. Detectors
    e. Vacuum systems
- MS/MS in space and MS/MS in time, Triple Quadrupole (TQ)

References: -

De Hoffmann, Edmond, Stroobant, Vincent (2007) Mass Spectrometry Principles and Applications. West Sussex: John Wiley & Sons, Ltd.

Gross, Jürgen H. (2011) Mass Spectrometry A Textbook. Heidelberg: Springer-Verlag Berlin

Cutting Edge by Spinco Biotech, Volume 13, Issue 9, January 2024, Issue 11, March 2024

Cutting Edge by Spinco Biotech, Volume 14, Issue 2, June 2024

Unit 2

Thermal analysis and Tracer Techniques **15 Lectures**

Part A: Thermal Analysis

- Principle of Thermal Analysis
- Requirements of Thermal Analysis and the basic components of a thermal analysis instrument
- Factors affecting the results of a thermal analysis
- Simultaneous and complementary thermal analysis
- Thermal Analysis Techniques (principle, instrumentation and working) and their applications: -

a. Thermogravimetric Analysis (TGA)

b. Differential Thermal Analysis (DTA) and Differential Scanning Calorimetry (DSC)

c. Hyphenated Thermal Analysis Techniques e.g. Thermogravimetry-Mass Spectrometry (TG-MS)

d. Evolved Gas Analysis (EGA)

- Thermal analysis of Bhasma preparations

Part B: Tracer Techniques

- Concept of Radioactivity & Half life
- α, β, γ emitters and their biological applications
- Using tracers in assays:
    a) Neutron Activation Analysis (NAA)
    b) Radioimmunoassay (RIA)
    c) Isotope Dilution Analysis
    d) Carbon dating
    e) Autoradiography
- Detectors and counters
    a) Ionization Chamber
    b) Proportional counter
    c) Geiger Muller (GM) counter
    d) Scintillation counter
    e) Semiconductor detector (with the example of a reverse bias p-n junction detector)
    f) Track detector
    g) Thermoluminescence Dosimeter (TLD)
- Radio labeled probes (an example of 99m-Tc) and their uses (with an example of imaging modalities in diagnostics- PET scan and SPECT scan)

References: -

- Haines, P.J. (2002) Principles of Thermal Analysis and Calorimetry. Cambridge: The Royal Society of Chemistry
- Brown, Michael E. (2004) Introduction to Thermal Analysis Techniques and Applications. Dordrecht: Kluwer Academic Publishers
- L'Annunziata, Michael F. (2016) Radioactivity Introduction and History, From the Quantum to Quarks. Cambridge: Elsevier Publishing
- Malley, Marjorie C. (2011) Radioactivity A History of a Mysterious Science. New York: Oxford University Press Inc
- L'Annunziata, Michael F. (2020) Handbook of Radioactivity Analysis: Volume 1: Radiation Physics and Detectors

Unit 3

Hyphenated Techniques and their applications **15 Lectures**

- GC/MS, GC/MS/MS, their applications in qualitative analysis, structural elucidation by rules of fragmentation, quantitative analysis of pesticides, applications of headspace analysis and extractable leachable studies
- LC/MS and LC/MS/MS and their applications in quantitative analysis of small molecules and macromolecules (biopharmaceuticals), pesticide residue analysis in food and qualitative analysis (Metabolite generation and identification, impurity profiling)
- Hyphenated techniques involving Electrospray Ionization (ESI) e.g. ESI-MS and their applications
- Scan events in TQ and other tandem systems and hybrid systems
- ICP/MS and its applications in pharmaceuticals and food
- Recent advances in the field of mass spectrometry

References: -

- De Hoffmann, Edmond, Stroobant Vincent (2007) Mass Spectrometry Principles and Applications. West Sussex: John Wiley & Sons, Ltd.
- Niessen, Wilfried M.A. (2006) Liquid Chromatography-Mass Spectrometry. Boca Raton: CRC Press
- Lavagnini, Irma et al. (2006) Quantitative Applications of Mass Spectrometry. West Sussex: John Wiley & Sons Ltd.
- Cutillas, Pedro R., Timms, John F. (2010) LC-MS/MS in Proteomics Methods and Applications. New York: Humana Press
- Tsipi, Despina, Botitsi, Helen, Economou, Anastasios (2015) Mass Spectrometry for the Analysis of Pesticide Residues and their Metabolites. Hoboken: John Wiley & Sons, Inc.
- Sparkman, David O., Penton, Zelda, Kitson, Fulton (2011) Gas Chromatography and Mass Spectrometry A Practical Guide. Oxford: Elsevier Publishing
- Thomas, Robert (2008) Practical Guide to ICP-MS A Tutorial for Beginners. Boca Raton: CRC Press

- Evans, Gary (2004) A Handbook of Bioanalysis and Drug Metabolism. Boca Raton: CRC Press
- Cole, Richard B. (2010) Electrospray and MALDI Mass Spectrometry Fundamentals, Instrumentation, Practicalities, and Biological Applications. Hoboken: John Wiley & Sons, Inc.
- Cutting Edge by Spinco Biotech, Volume 13, Issue 4, August 2023, Issue 5, September 2023, Issue 6, October 2023, Issue 7, November 2023, Issue 8, December 2023, Issue 12, April 2024
- Cutting Edge by Spinco Biotech, Volume 14, Issue 1, May 2024, Issue 2, June 2024, Issue 3, July 2024

Unit 4

Bioanalytical Methods and Automation in Analysis **15 Lectures**

- Method development and applications
- Sample preparation
- Headspace GC and GC-MS
- Quality by Design (QbD), Process Analysis Technology (PAT) and Total Quality Management (TQM)
- Automation and its advantages in sample preparation
- Automation in bioanalysis
- Advanced automated liquid handling systems
- Robotic Workstations
- High Throughput Screening

References: -

Poole, Colin F. (2021) Gas Chromatography. Cambridge: Elsevier Inc.

Swartz, Michael, Krull, Ira S. (1997) Analytical Method Development and Validation. Boca Raton: CRC Press

Beg, Sarwar et al. (2021) Handbook of Analytical Quality By Design. Cambridge: Elsevier Inc.

Luthra, Sunil et al. (2021) Total Quality Management Principles, Methods, and Applications. Boca Raton, Oxon: CRC Press

Venn, Richard F. (2005) Principles and Practices of Bioanalysis. New York: Taylor & Francis Inc.

Cutting Edge by Spinco Biotech, Volume 13, Issue 5, September 2023, Issue 6, October 2023, Issue 7, November 2023, Issue 8, December 2023, Issue 9, January 2024, Issue 10, February 2024

Cutting Edge by Spinco Biotech, Volume 14, Issue 1, May 2024. Issue 2, June 2024, Issue 3, July 2024

ELECTIVE PAPER: SIPBAEL611

Applied Microbiology and Biotechnology-I

Theory Credits	Practical Credits
3	1

Course Outcomes	• To relearn concepts like the biochemistry of nucleic acids and acquire the knowledge of concepts in biotechnology like hybridoma technology, vectors, etc. • To reinforce the basic concepts of microbiology like asepsis, sterilization, disinfection, to study about the applications of microbes in the food and pharmaceutical industry and to make the students aware about the regulatory aspects of microbiology. • To explore the field of DNA fingerprinting and know about the various tools in DNA fingerprinting and its applications
Learning Objectives	✓ *To familiarize students with genomics* ✓ *To give insights to students about regulatory microbiology and its applications in food and pharmaceuticals and to introduce regulatory issues with respect to Bioanalytical Sciences* ✓ *To familiarize students with the concepts of DNA Fingerprinting and its applications and use as diagnostic tools*

Unit 1:

Genomics **15 Lectures**

- Nucleic acid chemistry
- Principles and techniques in DNA sequencing e.g. Sanger Sequencing, Next Generation Sequencing (NGS), etc.
- DNA & RNA probes
- Concepts of gene manipulation (introduction only)
- Restriction enzymes & their uses
- Vectors & their uses
- Producing transgenic organisms
- cDNA production & applications
- Gene libraries & their applications

References: -

Nelson, L. David, Cox, M. Michael (2004) Lehninger Principles of Biochemistry. New York: W.H. Freeman

Munshi, Anjana (2012) DNA Sequencing- Methods and Applications. Rijeka: InTech

Patil, Nayana, Sivaram, Aruna (2022) A Complete Guide to Gene Cloning: From Basic to Advanced. Cham: Springer Nature Switzerland AG

Ying Shao-Yao (2010) Generation of cDNA Libraries: Methods and Protocols. Totowa, New Jersey: Humana Press

Lu Chaofu, Browse, John, Wallis, James G. (2011) cDNA Libraries: Methods and Applications. Totowa, New Jersey: Humana Press

Cutting Edge by Spinco Biotech, Volume 13, Issue 4, August 2023, Volume 13, Issue 9, January 2024, Issue 11, March 2024

Unit 2

Regulatory Microbiology and its Application in the pharmaceutical and food industry **15 Lectures**

- Asepsis, sterilization and disinfection, the concept of death curve of microbial population, aseptic filling in the pharmaceutical industry, classification of clean rooms/ clean areas, QA, and QC in a microbiology laboratory
- Important microbes for food & drug industry, pathogenic organisms in food & pharmaceutical industry and nutraceuticals w.r.t. FSSAI regulations
- Regulatory microbiological testing in pharmaceuticals
- Microbiological assays for pharmaceutical products
- Biosafety levels in the pharmaceutical and food industry
- OTC drugs
- Cosmeceuticals
- Food supplements

References: -

Willey, Joanne M., Sherwood, Linda M., Woolverton, Christopher J. (2014) Prescott's Microbiology. New York: McGraw Hill

Pelczar Jr., Michael J., Chan, E.C.S, Krieg R. Noel (2012) Microbiology. New Delhi: Tata McGraw Hill

Halls, Nigel (2004) Microbiological Contamination Control in Pharmaceutical Clean Rooms. Boca Raton: CRC Press

Sandle, Tim (2016) Pharmaceutical Microbiology Essentials for Quality Assurance and Quality Control. Cambridge: Woodhead Publishing Limited

Salerno, Reynolds M., Gaudioso, Jennifer (2015) Laboratory Biorisk Management Biosafety and Biosecurity. Boca Raton: CRC Press

Hewitt, William (2003) Microbiological Assay for Pharmaceutical Analysis: A Rational Approach. Boca Raton: CRC Press

Lintner, Karl (2009) Global Regulatory Issues for the Cosmetics Industry. Norwich: William Andrew Inc.

Kapur, Devesh, Khosla, Madhav (2019) Regulation in India: Design, Capacity, Performance. London: Hart Publishing

Bagchi, Debasis (2019) Nutraceutical and Functional Food Regulations in the United States and around the World. London: Academic Press

Cutting Edge by Spinco Biotech, Volume 13, Issue 4, August 2023

Unit 3

Gene manipulation techniques **15 Lectures**

- Concept of DNA Fingerprinting
- Different tools used in DNA Fingerprinting
- Hybridoma technology
- Applications of DNA Fingerprinting
- Use of genomic techniques for the diagnosis of various case studies e.g. CRISPR-Cas9 and gene therapy with a few examples

References: -

McPherson, Michael, Møller, Simon (2006) PCR. New York: Taylor & Francis Group

Lo, Y.M. Dennis, Chiu, Rossa W.K., Chan, Allen K.C. (2006) Clinical Applications of PCR Second Edition. Totowa: Humana Press Inc.

O'Connell, Joe (2002) RT-PCR Protocols. Totowa: Humana Press Inc.

Cutting Edge, Volume 13, Issue 6, October 2023

Cutting Edge, Volume 14, Issue 1, May 2024, Issue 3, July 2024

Dash, Hirak Ranjan et al. (2018) DNA Fingerprinting: Advancements and Future Endeavors. Singapore: Springer Nature Singapore Pte. Ltd.

Primorac, Dragan, Schanfield, Moses S. (2023) Forensic DNA Applications An Interdisciplinary Perspective Second Edition. Boca Raton, Oxon: CRC Press, CRC Press

Springer, Timothy A. (1985) Hybridoma Technology in the Biosciences and Medicine. New York: Plenum Press

RESEARCH PROJECT

Course Outcomes/Learning Objectives:

- To inculcate research aptitude and develop an open, inquiring mind amongst the students
- To encourage students to explore new territories and learn new things
- To encourage the spirit of curiosity of students and to think of research as potential career option
- To motivate and inspire students to come up with solutions for real life problems facing the society and nation

Details of Research project component for Semester III are as follows:

1. The students will prepare an outline/ scheme of the project proposal based on AYUSH/Interdisciplinary topic under Bioanalytical Sciences at the end of Semester III.
2. A teacher from the department will act as a project mentor to the student.
3. It will be the duty of the mentor to assign to the group a topic related to a particular theme covered in the syllabi / interdisciplinary topic.

4. The mentor will prepare, guide and supervise the group by giving orientation / instructions about writing the project proposal.

5. The **outline / scheme** of the project proposal will include literature review / search, introduction, objectives, purpose and rationale, materials and methods, expected outcomes / results, relevance of the project and bibliography (Note that the students have been taught Research Methodology in the revised syllabus of M.Sc. Part I (post-NEP pattern) in the subject of Bioanalytical Sciences)

MSc – Part II - Bioanalytical Sciences Syllabus - Semester IV

CORE / MANDATORY PAPER 1: SIPBACC621

Environment Safety & Impact, Analytical Method Validation and Electronic Data Management

Theory Credits	Practical Credits
4	2

Course Outcomes	• To encourage students to follow the environment safety practices in a bioanalytical laboratory and to increase their awareness of the concepts of biodiversity, conservation, etc. • To attempt to inculcate an environmentally friendly attitude in the minds of the students by introducing them to concepts like sustainability, environmental anthropology, etc. • To introduce students to various aspects of method validation including calibration. • To make students aware of the various concepts in electronic data management including 21 CFR Part 11.
Learning Objectives	✓ *To understand environmental safety issues and various guidelines related to a Bioanalytical Laboratory.* ✓ *To make students realize the real world impact of climate change and to introduce them to concepts like environmental anthropology, sustainable development, etc.* ✓ *To provide a conceptual understanding to the students in analytical method validation.* ✓ *To introduce students to electronic data management.*

Unit 1

Environmental Safety in a Bioanalytical Laboratory **15 Lectures**

- Strategies to reduce the environmental impact of a bioanalytical/clinical laboratory
- Standards of Laboratory Safety (Including Biosafety Levels)
- Overview of guidelines for laboratories handling radioactive substances
- Introduction to ISO 14001 and ISO 45001 (formerly OHSAS 18001)
- Introduction to Environment Impact Assessment & reporting
- Concepts related to biodiversity and conservation: Red Data Book, Endemic and endangered medicinal plant species, conservation and sustainable use of medicinal raw materials, Introduction to Wildlife Act of India & CITES
- Carbon footprints and Carbon credits

References: -

Salerno, Reynolds M., Gaudioso, Jennifer (2015) Laboratory Biorisk Management Biosafety and Biosecurity. Boca Raton: CRC Press

Glasson, John, Therivel Riki, Chadwick, Andrew (2012) Introduction to Environmental Impact Assessment 4th Edition. Oxon: Routledge

Sinha, Samir (2010) Handbook on Wildlife Law Enforcement in India. TRAFFIC India: New Delhi

Franchetti, Matthew John, Apul, Defne (2013) Carbon Footprint Analysis Concepts, Methods, Implementation and Case Studies. Boca Raton: CRC Press

Unit 2

Environmental Anthropology and Sustainable Development **15 Lectures**

- Introduction to environmental anthropology
- Role of environmental anthropology in Environment Impact Assessment (EIA)- the concept of social impact assessment (SIA)
- An introduction to environmental treaties- The Kyoto Protocol, The Montreal Protocol, Rio Earth Summit, etc.
- Introduction to sustainability and sustainable development
- Need/significance of sustainable development in the context of climate change (by giving examples of case studies related to climate change- Nisarga cyclone, bleaching of The Great Barrier Reef, wildfires in Canada- the heat dome effect, etc.)
- Green chemistry and environmental sustainability (with an example of green chemistry in the pharmaceutical industry, etc.)
- United Nations Sustainable Development Goals (SDGs)- an introduction (emphasis on SDG 3: - Good Health and Well Being)

References: -

Kopnina, Helen, Shoreman-Ouimet, Eleanor (2017) Routledge Handbook of Environmental Anthropology. Oxon and New York: Routledge

De Miranda Azeiteiro, Ulisses Manuel, Paulo Davim, J. (2020) Higher Education and Sustainability: Opportunities and Challenges for Achieving Sustainable Development Goals. Boca Raton: CRC Press

Dunn, Peter J., Wells, Andrew S. and Williams, Michael T. (2010) Green Chemistry in the Pharmaceutical Industry. Weinheim: Wiley-VCH Verlag GmbH & Co. KGaA

Cutting Edge by Spinco Biotech, Volume 13, Issue 8, December 2023, Issue 12, April 2024

Cutting Edge by Spinco Biotech, Volume 14, Issue 3, July 2024

Unit 3:

Analytical Method Validation **15 Lectures**

- Strategies for Method development
- What and Why of method validation
- Regulatory requirements of validation
- IQ, OQ and PQ of analytical instruments
- Use of reference standards
- Issues of method transfer
- Intra and inter-lab validation
- Sampling
- Calibration of glassware and instruments, concepts of Good Weighing Practice
- Use of reference standards and working standards
- Format of Certificate of Analysis

References: -

Chan, Chung Chow et al. (2004) Analytical Method Validation and Instrument Performance Verification. Hoboken: John Wiley & Sons, Inc.

Fajgelj, A., Ambrus, A. (2000) Principles and Practices of Method Validation. Cambridge: The Royal Society of Chemistry

Seidman, Lisa A. et al (2023) Laboratory Manual for Biotechnology and Laboratory Science: The Basics, Revised Edition. Boca Raton, CRC Press

Ostrove, Steven (2019) Equipment Qualification in the Pharmaceutical Industry. San Diego: Elsevier Science

Cutting Edge by Spinco Biotech, Volume 13, Issue 5, September 2023, Issue 6, October 2023, Issue 12, April 2024

Unit 4

Electronic Data Management **15 Lectures**

- Electronic Acquisition of data
- Electronic data capture systems, transfer of data and its regulatory requirements
- Management of data in Computers
- Laboratory Information Management System (LIMS) and Data Integrity
- Electronic Data Validation and regulatory requirements
- Electronic signatures & its regulation (Specific regulation)
- Generating reports using computers
- Regulatory requirements of Data evaluation (Include post marketing surveillance)

References: -

Young, Simon S. (2001) Computerized Data Acquisition and Analysis for the Life Sciences A Hands-on Guide. New York: Cambridge University Press

McDowall, R.D. (2017) Validation of Chromatography Data Systems Ensuring Data Integrity, Meeting Business and Regulatory Requirements 2nd Edition. Cambridge: The Royal Society of Chemistry

COMPACT REGS™ Part 11 Code of Federal Regulations 21 Part 11 Electronic Records; Electronic Signatures

Lopez, Orlando (2017) Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Best Practices Guide to Electronic Records Compliance. Boca Raton: CRC Press

Cutting Edge by Spinco Biotech, Volume 14, Issue 3, July 2024

CORE / MANDATORY PAPER 2: SIPBACC622

Standardization of ASU Drugs, Drug Regulation and GMP

Theory Credits	Practical Credits
4	2

Course Outcomes	• To emphasize the significance of standardization of ASU drugs on the students. • To introduce students to various global regulations applicable to ASU drugs. • To familiarize students with the various aspects of QC and QA of ASU drugs. • To reinforce and also to introduce some new concepts to the students which are related to GMP.
Learning Objectives	✓ *To familiarize students with various steps involved in standardization of ASU drugs.* ✓ *To familiarize students with regulatory aspects of ASU drugs.* ✓ *To introduce students to the concept of QA and QC in ASU drugs.* ✓ *To introduce students to concepts, requirements, applications, and compliance of GMP with an example of ASU drugs.*

Unit 1

Standardization of ASU Drugs **15 Lectures**

- Approaches to standardization
- Raw materials
- In-process materials
- Need of standardization of Ayurvedic drugs
- What does standardization involve?
- Bioanalytical tools in standardization
- Clinical studies in Standardization
- Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

References: -

Saroya Singh, Amritpal (2016) Regulatory and Pharmacological Basis of Ayurvedic Formulations. Boca Raton: CRC Press

Mandal, Subhash C., Chakraborty, Raja, Sen, Saikat (2021) Evidence Based Validation of Traditional Medicines. Singapore: Springer Nature Singapore Pte Ltd.

Bagetta, Giacinto et al. (2012) Herbal Medicines Development and Validation of Plant-Derived Medicines for Human Health. Boca Raton: CRC Press

Mukherjee, Pulok K. (2019) Quality Control and Evaluation of Herbal Drugs Evaluating Natural Products and Traditional Medicine. Cambridge: Elsevier Inc.

Unit 2

QC and QA of ASU Drugs **15 Lectures**

- Herbal Pharmacopoeia and the Ayurvedic Formulary of India
- Approaches to Quality control of ASU formulations
- Government initiatives
- Some initiatives from manufacturers
- QC of RM and In-process materials (some examples)
- QC / QA for finished products (some examples)
- Applications of Herbal Pharmacopoeia and the Ayurvedic Formulary of India
- Recent advances in Quality control of ASU formulations
- QC / QA for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon, etc.)

References: -

Mukherjee, Pulok K. (2019) Quality Control and Evaluation of Herbal Drugs Evaluating Natural Products and Traditional Medicine. Cambridge: Elsevier Inc.

Mukherjee, Pulok K. (2015) Evidence-Based Validation of Herbal Medicine. Waltham: Elsevier Inc.

Unit 3

Regulatory Aspects of ASU Drugs **15 Lectures**

- Government initiatives for regulation of ASU drugs
- Schedule T and Schedule Y of Drugs and Cosmetics Act with examples of case studies related to regulatory issues of ASU Drugs e.g. The Patanjali case, etc.
- International initiatives for regulation of ASU drugs with special reference to
  - WHO guidelines on traditional medicine
  - Approaches of US and EU to ASU drug regulation
- Provisions of Drugs and Cosmetics Act applied to ASU (e.g., Schedule T and Y) (specifically with reference to ASU Drugs)

References: -

Schedule T, Drugs & Cosmetics Rules, 1945

Schedule Y, Drugs & Cosmetics Rules, 1945

Saroya Singh, Amritpal (2016) Regulatory and Pharmacological Basis of Ayurvedic Formulations. Boca Raton: CRC Press

Unit 4

Good Manufacturing Practices **15 Lectures**

- What is GMP?
- Requirements of GMP implementation
- Documentation of GMP practices
- Regulatory certification of GMP
- GMP in production of ASU drugs
- Harmonization of SOP of manufacture
- Audit for GMP compliance

References: -

Bunn, Graham P. (2019) Good Manufacturing Practices for Pharmaceuticals Seventh Edition. Boca Raton: CRC Press

Part 1 Schedule M, Drugs & Cosmetics Rules, 1945

Bliesner, David M. (2020) Laboratory Control System Operations in a GMP Environment. Hoboken: John Wiley & Sons Inc.

Steinborn, Leonard (2003) GMP/ISO Quality Audit Manual for Healthcare Manufacturers

and Their Suppliers Volume 1. Boca Raton: CRC Press

Cutting Edge by Spinco Biotech, Volume 14, Issue 1, May 2024

ELECTIVE PAPER: SIPBAEL621

Applied Microbiology and Biotechnology-II

Theory Credits	Practical Credits
3	1

Course Outcomes	• To introduce students to various concepts in PCR and DNA amplification. • To make students aware of the recent advances and developments in CE and its applications. • To familiarize students with the various bioassay techniques in the pharmaceutical industry.
Learning Objectives	✓ *To familiarize students with the concepts in Polymerase Chain Reaction and its applications.* ✓ *To acquaint the students with different modes of Capillary Electrophoresis, factors affecting it and uses of Capillary Electrophoresis* ✓ *To introduce students to various Bioassays in pharmaceutical evaluation.*

Unit 1

Polymerase Chain Reaction (PCR) 15 Lectures

- Introduction to Polymerase Chain Reaction and its components
- Types of PCR (Inclusion of more chemistry-based approach such as more chemistry of dyes and buffers, its significance)
- DNA amplification w.r.t its applications
- Applications of PCR

References: -

McPherson, Michael, Møller, Simon (2006) PCR. New York: Taylor & Francis Group

Lo, Y.M. Dennis, Chiu, Rossa W.K., Chan, Allen K.C. (2006) Clinical Applications of PCR Second Edition. Totowa: Humana Press Inc.

O'Connell, Joe (2002) RT-PCR Protocols. Totowa: Humana Press Inc.

Dash, Hirak Ranjan et al. (2018) DNA Fingerprinting: Advancements and Future Endeavors. Singapore: Springer Nature Singapore Pte. Ltd.

Primorac, Dragan, Schanfield, Moses S. (2023) Forensic DNA Applications An Interdisciplinary Perspective Second Edition. Boca Raton, Oxon: CRC Press, CRC Press

Unit 2

Modes of Capillary Electrophoresis (CE) & factors affecting it 15 Lectures

- Modes of Capillary Electrophoresis (CE): -

A) Microchip Electrophoresis (ME)
B) Chiral Capillary Electrophoresis (Chiral CE)
C) Multidimensional Capillary Electrophoresis
D) Capillary Electrophoresis in Continuous-Flow Systems, etc.

- Capillary Electrophoresis-Mass Spectrometry (CE-MS)
- Factors affecting Capillary Electrophoresis
- Biological applications of Capillary Electrophoresis

References: -

Altria, Kevin D. (1996) Capillary Electrophoresis Guidebook Principles, Operation and Applications. Totowa: Humana Press

Grossman, Paul D., Colburn, Joel C. (1992) Capillary Electrophoresis Theory & Practice. San Diego: Academic Press Inc.

Manz, Andreas et al. (2015) Bioanalytical Chemistry Second Edition. London: Imperial College Press

Unit 3

Bioassays in Pharmaceutical Evaluation **15 Lectures**

- General idea about bioassay systems used in pharmaceutical evaluations (introduction with respect to pharmacokinetics and pharmacodynamics)
- In vitro assays and in vivo assays
- Ethical issues of using animal assay systems (in silico model approach)
- Alternatives to animal assays – one or two examples (in silico model introduction)

References: -

Rahman, Atta-ur, Choudhary, M. Iqbal (2005) Bioassay Techniques for Drug Development. Netherlands: Harwood Academic Publishers

Cronin, Mark T.D., Madden, Judith C. (2010) In silico Toxicology Principles and Applications

Reinhardt, Christoph A., Alternatives to Animal Testing (2006). Weinheim, New York: VCH Verlagsgesellschaft mBH, VCH Publishers Inc.

Cutting Edge by Spinco Biotech, Volume 13, Issue 9, January 2024

RESEARCH PROJECT

Course Outcomes/Learning Objectives:

- To inculcate research aptitude and develop an open, inquiring mind amongst the students
- To encourage students to explore new territories and learn new things
- To encourage the spirit of curiosity of students and to think of research as potential career option
- To motivate and inspire students to come up with solutions for real life problems facing the society and nation

Research Project Component based on AYUSH/Interdisciplinary topic under Bioanalytical Sciences

1. Actual execution / practical work of this project is to be done in Semester IV, inclusive of Diwali vacation/Winter vacation and on weekends/holidays of semester IV.

2. Actual execution may involve laboratory/ table work and or field work and or survey (the approach for the project work can be *in vitro* / *in vivo* / *in silico*, among others) as per the specifications mentioned in their project proposal.

3. The mentor for the respective group will keep a track of the actual execution of the project.

4. After completion of the practical work the student will prepare a '**Dissertation**' which will have copy of the outline/scheme of the proposal, abstract/ synopsis of the research work, introduction, materials and methods, observations, interpretation of results, conclusion and discussion, future plan / extension of work.

5. The student will also give a '**Power point presentation**' for the research project.

Evaluation of Research Project during practical examination for Semester IV will be as follows:

1. The examiner will evaluate the '**Dissertation**' for the research project by taking into account the following evaluation criteria given below:

Title
Abstract/ synopsis
Materials and Methods
Observations
Interpretation of results
Conclusion and Discussion
Relevance of work

2. The examiner will evaluate the '**Power point presentation**' for the research project by taking into account the following evaluation criteria given below:

Title
Content of the presentation
Quality of the presentation
Presentation skills
Viva/ Question- Answer session

Practical Component MSc Bioanalytical Sciences Part 2 - Semester III
Based on Core/ Mandatory Paper 1: SIPBACCP611

- CCl_4 liver dysfunction in rats and evaluation using liver function tests (An experimental comparison using suitable groups of controls, natural recovery, and treatment with known hepatoprotectants to be carried out) (Using SGOT/SGPT/cholesterol kit method)
- LC_{50} evaluation of nicotine/copper sulphate using a suitable model (e.g., *Daphnia* / rice weevil/*Chironomus* larvae)
- BA & BE of a modern drug (Demonstration – witnessing an actual trial)
- Calculation of AUC and bioequivalence from the given data (2 expts.)

Practical Component MSc Bioanalytical Sciences Part 2 - Semester III
Based on Core/ Mandatory Paper 2: SIPBACCP612

(More emphasis on interpretation of practical rather than actual practical)

- LC/MS quantitation of a modern drug, integration, and interpretation of spectra (e.g., Diclofenac Sodium, Ezetimibe etc.)
- LC/MS/MS quantitation of a modern drug from plasma (e.g., Diclofenac Sodium) / metabolite of a modern drug from plasma (e.g., Mycophenolic acid, a metabolite of Mycophenolate mofetil)
- Mass Fingerprinting of peptides using a suitable sample.
- Gravimetric analysis of diclofenac sodium
- Identification of organic compounds from their GC-MS spectra

Practical Component MSc Bioanalytical Sciences Part 2 - Semester III
Based on Elective Paper: SIPBAELP611

- Plant DNA isolation, extraction and separation using agarose Gel (CTAB method or a DNA isolation kit might be used)
- RFLP (RFLP kit may be used)
- Isolation & screening of industrially important microorganisms
- Sterility testing (Microbial load) of drug formulations (According to IP 2013) (sterile water/eye drops)

Practical Component MSc Bioanalytical Sciences Part 2 - Semester III
Based on Research Project: SIPBARP611

Research Project Component based on AYUSH/Interdisciplinary topic under Bioanalytical Sciences

Details of Research project component for Semester III are as follows:

1. The students will prepare an outline/ scheme of the project proposal based on AYUSH/Interdisciplinary topic under Bioanalytical Sciences at the end of Semester III.

2. A teacher from the department will act as a project mentor to the student.

3. It will be the duty of the mentor to assign to the group a topic related to a particular theme covered in the syllabi / interdisciplinary topic.

4. The mentor will prepare, guide and supervise the group by giving orientation / instructions about writing the project proposal.

6. The **outline / scheme** of the project proposal will include literature review / search, introduction, objectives, purpose and rationale, materials and methods, expected outcomes / results, relevance of the project and bibliography (Note that the students have been taught Research Methodology in the revised syllabus of M.Sc. Part I (post-NEP pattern) in the subject of Bioanalytical Sciences)

Practical Component MSc Bioanalytical Sciences Part 2 - Semester IV
Based on Core/ Mandatory Paper 1: SIPBACCP621

- Environment audit report
- Problems based on calculation of carbon credit and carbon footprint

- Study of matrix effect on the IR spectrum of Diclofenac Sodium by using sucrose as a matrix
- Calibration of an instrument (For example: - Calibration of a visible spectrophotometer using $KMnO_4$ and checking various validation parameters)

- Determination of iron from a given sample/sample solution by:
  i) Redox titration
  ii) Colorimetry
  iii) Atomic Absorption Spectroscopy

Practical Component MSc Bioanalytical Sciences Part 2 - Semester IV
Based on Core/ Mandatory Paper 2: SIPBACCP622

- IR patterns of an Ayurvedic Bhasma preparation (e.g., calcium containing Shankha Bhasma – comparison with pure $CaCO_3$)
- AAS of a suitable Ayurvedic metal Bhasma preparation (e.g., Tamra Bhasma/Paracetamol)
- Total viable count of herbal formulations/raw material
- Screening of pathogens from herbal formulation/raw material (by culturing in selective media and Gram staining)

Practical Component MSc Bioanalytical Sciences Part 2 - Semester IV
Based on Elective Paper: SIPBAELP621

- PCR (PCR Kit may be used) for a given DNA sample
- Identification of Genetically Modified Organism (GMO identification kit may be used)
- Blue-white screening of mutated organism
- Zone of inhibition/exhibition assay for penicillin/Vitamin B_{12}

Practical Component MSc Bioanalytical Sciences Part 2 - Semester IV

Based on Research Project: SIPBARP621

Research Project Component based on AYUSH/Interdisciplinary topic under Bioanalytical Sciences

1. Actual execution / practical work of this project is to be done in Semester IV, inclusive of Diwali vacation/Winter vacation and on weekends/holidays of semester IV.
2. Actual execution may involve laboratory/ table work and or field work and or survey (the approach for the project work can be *in vitro* / *in vivo* / *in silico*, among others) as per the specifications mentioned in their project proposal.
3. The mentor for the respective group will keep a track of the actual execution of the project.
4. After completion of the practical work the student will prepare a '**Dissertation**' which will have copy of the outline/scheme of the proposal, abstract/ synopsis of the research work, introduction, materials and methods, observations, interpretation of results, conclusion and discussion, future plan / extension of work.
5. The student will also give a '**Power point presentation**' for the research project.

Evaluation of Research Project during practical examination for Semester IV will be as follows:

1. The examiner will evaluate the '**Dissertation**' for the research project by taking into account the following evaluation criteria given below:

Title
Abstract/ synopsis
Materials and Methods
Observations
Interpretation of results
Conclusion and Discussion
Relevance of work

2. The examiner will evaluate the '**Power point presentation**' for the research project by taking into account the following evaluation criteria given below:

Title
Content of the presentation
Quality of the presentation
Presentation skills
Viva/ Question- Answer session