SIES

College of Arts, Science & Commerce

RISE WITH EDUCATION

Sion (West), Mumbai – 400022

(Autonomous)

Faculty: Science

Program: M.Sc.-II

Subject: BIOANALYTICAL SCIENCES

Academic Year: 2020 – 2021

Credit Based Semester and Grading System approved by Board of Studies in Bioanalytical Sciences to be brought into effect from August 2020

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)
<u>Semester III and Semester IV</u>
(Credit Based Semester and Grading System, with effect from academic year 2020-21)

Preamble

"All things are poison and nothing is without poison; only the dose makes a thing not a poison." – Paracelsus

Under the aegis of academic autonomy, the Department of Bioanalytical Sciences has the advantage of academic freedom to refine and revise its course and curriculum, however, it is also aware of the fact that 'freedom comes with responsibility'. The revised syllabus will encourage critical thinking, instilling analytical skills, besides inculcating research aptitude and interdisciplinary approach amongst student's to make learning more meaningful, thereby pursuing academic excellence.
Some of the key features of this revised syllabus are as follows:
✓ *Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology – to understand the basics of microbiology and recognize its application in pharmaceuticals; to familiarize students with genomics; to introduce students to principles of toxicology involving relevance of toxicity studies and regulatory guidelines, ethics in animal studies, alternatives to animal models; to give insights to students about regulatory microbiology and its applications in food and pharmaceuticals.*
✓ *MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques – to make students understand MS basics in terms of principle and instrumentation; to introduce students to various hyphenated techniques and its applications and recent developments; to give students insights of principle, instrumentation and applications Thermal analysis in ASU formulations such as Bhasmas; to train students in various bioanalytical methods and techniques with emphasis on sample preparation and method development.*
✓ *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 to make them competent in Biostatistics; to introduce students to concepts, requirements, applications and compliance of GMP with reference to ASU drugs.*
✓ *BA/BE Studies, GCP and Method Validation – to give an introduction to students to the various ethical issues in clinical trials, its guidelines and compliances; give insights to students about Good Clinical Practices; to train students about the concepts of Bioavailability and Bioequivalence; to make students well verse in Analytical method development and validation techniques.*

Considering the aspiration levels of students that are changing under the overarching influences of technological revolution and globalization, educationists need to understand that students have to be provided with opportunities to share, discover and participate actively in the learning process. Therefore, satisfying these aspirations of students and inculcating an interdisciplinary approach in conceptualising the syllabus has been a challenging task. It is indeed reflected in the contents and topics introduced in this revised syllabus, thanks to the collective and constructive efforts of the members of the board of studies comprising distinguished faculty, eminent experts from industry and research institutions. The valubale comments, suggestions and recommendations of the contributors and reviewers have been carefully considered and implemented wherever feasible. The syllabus was approved by the Board of Studies in the subject of Bioanalytical Sciences, SIES College of Arts, Science and Commerce (Autonomous), Sion, Mumbai.

For effective teaching learning, teachers are advised not to follow the syllabus too rigidly but to exercise their professional discretion and judgement in implementing it. After all teaching is about creating a conducive environment for learners to sustain enthusiasm about the subject and help them develop an open, inquiring mind that is willing to explore new territories and learn new things. In conclusion, we have made a modest attempt towards maximizing learning by designing an effective syllabus. We sincerely hope that all stakeholders from faculty to learners exploring this course will appreciate the importance of a well-designed curricular framework in shaping educational outcomes.

Dr. Satish Sarfare
Chairman,
Board of Studies in the subject of Bioanalytical Sciences

Paper	Code	Lectures	Credits	Code	Practical	Credits
Basic Microbiology, Genomics, CE and Toxicology-I	SIPSBN31	60	4	SIPSBNP31	60	2
MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-I	SIPSBN32	60	4	SIPSBNP32	60	**2**
Standardization of ASU drugs, Statistics & GMP-I	SIPSBN33	60	4	SIPSBNP33	60	2
BA/ BE Studies, GCP and Method Validation-I	SIPSBN34	60	4	SIPSBNP34	60	2
TOTAL		**240**	**16**		**240**	**8**
TOTAL CREDITS			**24**			

Paper	Code	Lectures	Credits	Code	Practical	Credits
Basic Microbiology, Genomics, CE and Toxicology-II	SIPSBN41	60	4	SIPSBNP41	60	2
MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-II	SIPSBN42	60	4	SIPSBNP42	60	2
Standardization of ASU drugs, Statistics & GMP-II	SIPSBN43	60	4	SIPSBNP43	60	2
BA/ BE Studies, GCP and Method Validation-II	SIPSBN44	60	4	SIPSBNP44	60	2
TOTAL		**240**	**16**		**240**	**8**
TOTAL CREDITS			**24**			

Paper Code	Unit No.	Unit Name	Credits	Lectures/week
SIPSBN31	1	Basic Microbiology and its application in Pharmaceuticals	4	1
	2	Genomics		1
	3	Basic and Regulatory Toxicology		1
	4	Regulatory Microbiology and its application in pharmaceutical and food industry		1
SIPSBN32	1	MS Basics	4	1
	2	Hyphenation		1
	3	Thermal Analysis		1
	4	Bioanalytical Methods		1
SIPSBN33	1	Standardization of ASU drugs	4	1
	2	General Statistical Methods		1
	3	Concepts of Biostatistics		1
	4	Good Manufacturing Practice		1
SIPSBN34	1	Ethical Issues in Clinical Trials	4	1
	2	Good Clinical Practice (GCP) – 1		1
	3			1

		Bioavailability (BA) & Bioequivalence (BE) studies – 1		
	4	Analytical Method Validation		**1**
SIPSBNP 31	Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology – I		**2**	**4**
SIPSBNP 32	MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques - I		**2**	**4**
SIPSBNP 33	Standardization of ASU Drugs, Statistics and GMP - I		**2**	**4**
SIPSBNP 34	BA/BE Studies, GCP and Method Validation - I		**2**	**4**
	Total		**24**	**32**

Paper Code	Unit No.	Unit Name	Credits	Lectures/week
SIPSBN41	1	Bio assays in Pharmaceutical evaluation	4	1
	2	Polymerase Chain Reaction (PCR) & DNA Fingerprinting		1
	3	Automation and analysis		1
	4	Capillary Electrophoresis		1
SIPSBN42	1	Applications of Quantitative Analysis	4	1
	2	Applications of Qualitative Analysis		1
	3	LC/MS/MS		1
	4	Tracer techniques in Bioanalytical assays		1
SIPSBN43	1	Regulatory Aspects of ASU drugs	4	1
	2	Environmental Safety in Bioanalytical laboratory		1
	3	Electronic Data Management		1
	4	Regulatory Issues		1
SIPSBN44	1	Therapeutic drug monitoring and Pharmacovigilance	4	1
	2	Good Clinical Practice (GCP) – 2		1
	3	Bioavailability (BA) &		1

		Bioequivalence (BE) studies – 2		
	4	QC and QA of ASU drugs		**1**
SIPSBNP 41	Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology – II		**2**	**4**
SIPSBNP 42	MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques - II		**2**	**4**
SIPSBNP 43	Standardization of ASU Drugs, Statistics and GMP - II		**2**	**4**
SIPSBNP 44	BA/BE Studies, GCP and Method Validation - II		**2**	**4**
		Total	**24**	**32**

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES
SEMESTER III- Theory
SIPSBN31- Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology-I
(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To understand the basics of microbiology and to recognize its application in pharmaceuticals*
- *To familiarize students with genomics*
- *To introduce students to various concepts and guidelines of toxicology*
- *To give insights to students about regulatory microbiology and its applications in food and pharmaceuticals*

301.1 Basic Microbiology and its application in Pharmaceuticals (15)

1. Microbes & Their environment, Significance and scope of Microbiology, Biodiversity and types of Microorganisms, Visualization of Microorganisms: staining and Simple and compound microscopy, Electron Microscopy
2. Growth of Microorganisms, methods to study growth of microorganisms, preservation of microorganisms, maintenance media etc.
3. Control of microbial contamination, sources of contamination of pharmaceutical products
4. Sources of antimicrobial agents: plants and microorganisms, therapeutic Antimicrobial Agents e.g. Erythromycin, Amphotericin B, Cephalosporins and their commercial production, Antimicrobial Drug Resistance and Drug Discovery
5. Study of microbial load of raw materials used for drug preparation.

301.2 Genomics (15)

1. Nucleic Acid chemistry
2. Principles of DNA sequencing
3. DNA & RNA probes
4. Concepts of Gene manipulation (introduction only)
5. Restriction enzymes & their uses
6. Vectors & their uses
7. Producing Transgenic organisms
8. Hybridoma technology

9. cDNA production & applications
10. Gene Libraries & applications

301.3 Basic and Regulatory Toxicology (15)

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 irritations, Subacute (Repeat-Dose Study), Subchronic, 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 tetra chloride and acetaminophen).

Dose translation from animals to human – 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 animal testing centre, ethical issues in animal studies

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

301.4 Regulatory Microbiology and its application in pharmaceutical and food industry (15)

Asepsis, Sterilization and Disinfection, concept of Death curve of microbial population, Aseptic filling in pharmaceutical industry, Classification Clean rooms / Clean areas, QA and QC in Microbiology Laboratory

1. Important Microbes for Food & Drug Industry, Pathogenic Organisms in Food & Pharma Industry

2. Sources of contamination, Microbial Contamination in ASU preparations
3. Regulatory Microbiological testing in pharmaceuticals
4. Microbiological Assays for pharmaceutical products
5. Biosafety levels in pharmaceutical and food Industry (Introduction)

SIPSBN 32- MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques - I (Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To make students understand MS basics in terms of principle and instrumentation involved*
- *To introduce students to various hyphenation techniques involved in bioanalytical sciences, its applications and recent developments*
- *To give students insights of Thermal analysis, its principle, instrumentation and application in ASU formulations such as Bhasmas*
- *To train students in various Bioanalytical methods and techniques with emphasis on sample preparation, method development, hyphenated techniques and quality.*

302.1 MS basics (15)

1. MS Basics and MS hybrid
2. MS/MS, TQ/Ion Trap
3. Components: Inlets, Ion sources, Analyzers, Detectors, Vacuum System etc. (Introduction)

302.2 Hyphenated techniques (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. ICP/MS and its applications in pharmaceuticals and food
5. Recent advances in the field of mass spectrometry
6. Introduction to Head space technology.

302.3 Thermal analysis (15)

1. Principles of Thermal Analysis
2. Instrumentation Requirements

3. Applications of Thermal Analysis

4. Thermal analysis of Bhasma preparations

5. Thermal Analysis Techniques

302.4 Bioanalytical Methods (15)

1. Method development and applications
2. Sample preparation
3. Headspace GC and GC-MS
4. Quality by design (QBD) and Process development, Total quality management (TQM)

SIPSBN 33- Standardization of ASU Drugs, Statistics and GMP -I

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To familiarize students with various steps involved in standardization of ASU drugs*
- *To introduce students to basic concepts and applications of general statistics methods*
- *To make students competent in Biostatistics*
- *To introduce students to concepts, requirements, applications and compliance of GMP with example of ASU drug.*

303.1 Standardization of ASU drugs (15)

1. Approaches to standardization;
2. Raw materials
3. In-process materials
4. Need of standardization of Ayurvedic drugs
5. What does standardization involve?
6. Bioanalytical tools for standardization
7. Clinical studies in Standardization
8. Finished products
9. Developing standardized QC methods
10. Shelf life studies on finished products

303.2 General Statistical Methods (15)

1. Basic concepts of sample statistics

2. Concept of sample size and power
3. Concept of randomization and sampling techniques
4. Concept of significance and confidence limits
5. Introduction to Various statistical tests - parametric and non-parametric
6. Use of Statistical Packages for Data evaluation
7. Concept of random sampling and sampling techniques
8. Concept of level of significance, power of test and confidence limits
9. Concept of sample size
10. Application of normal distribution

303.3 Concepts of Biostatistics (15)

1. Statistical approach to biological samples
2. Variations in biological samples & their statistical treatment
3. Introduction to Data collection techniques
4. Design of experiments with e.g. Block designs, Latin square
5. COV and ANOVA
6. Student's t test and F test
7. Regression analysis with application to Standard Graph
8. Non parametric tests with examples
9. Statistical Guidance from regulatory agencies
10. Student's T test, chi square test, Z test and F test
11. Single sample and two sample Non parametric tests with examples
12. Use of statistical packages for data analysis (SPSS software introduction)
13. Introduction to SAS

303.4 Good Manufacturing Practices (15)

1. What is 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

SIPSBN 34- BA/BE Studies, GCP and Method Validation-I

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives:

- *To give an introduction to students to the various ethical issues in clinical trials, its powers, dealings and compliances*
- *Give insights to students about Good Clinical Practices*
- *To train students about the concepts of Bioavailability and Bioequivalence*
- *To well verse students in Analytical method validation techniques.*

304.1 Ethical Issues in Clinical Trials (15)

Subtopics:

1. Origin of Ethical Issues
2. Dealing with Ethical issues
3. Ensuring compliance to ethical issues
4. Ethical Committees & their set up
5. Regulatory powers of ethical committees
6. Ethical issues in animal studies
7. Compliance to ethical guidelines
8. Dealing with Ethical issues (subject compensation and subject rights)
9. Compliance to current ethical guidelines

304.2 Good Clinical Practices (GCP) – 1 (15)

1. What is GCP?
2. Origin of GCP
3. Earlier Guidelines for GCP
4. Requirements of GCP compliance

304.3 Bioavailability (BA) & Bioequivalence (BE) studies – 1 (15)

1. What is BA?
2. Parameters to evaluate BA of a drug
3. Factors that influence BA of a drug
4. Evaluating BA of a drug
5. Estimating BA parameters of a drug

6. What is BE?
7. Parameters to evaluate BE of a drug
8. Factors that influence BE of a drug
9. Evaluating BE of a drug
10. Estimating BE parameters of a drug

304.4 Analytical Method Validation (15)

1. Strategies for Method development
2. What and Why of method validation
3. Regulatory requirements of validation
4. IQ, OQ and PQ of analytical instruments
5. Use of Reference standards
6. Issues of Method transfer
7. Intra and inter lab – Validation
8. Sampling
9. Calibration of glassware and instruments, concepts of Good weighing Practice
10. Use of Reference standards and working standards
11. Format of Certificate of Analysis

DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES
SEMESTER IV- Theory
SIPSBN 41 - Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology -II

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To introduce students to various Bio assays in pharmaceutical evaluation*
- *To familiarize students with concept of Polymerase Chain Reaction and DNA Fingerprinting and its applications and use as diagnostic tools*
- *To provide students with basic insights of automation and analysis*
- *To make students understand basic concepts, working and uses of Capillary Electrophoresis*

401.1 Title: Bio assays in Pharmaceutical evaluation (15)

1. General idea about bio assay systems used in pharmaceutical evaluations (introduction with respect to pharmacokinetics and pharmacodynamics)

2. In vitro assays and in vivo assays
3. Ethical issues of using animal assay systems (In Silico model approach)
4. Alternatives to animal assays – one or two examples (in silico model introduction)

401.2 Polymerase Chain Reaction (PCR) & DNA Fingerprinting (RT- PCR in detail) (15)

1. Types of PCR & its applications (Inclusion of more chemistry-based approach such as more chemistry of dyes and buffers, its significance)
2. DNA amplification w.r.t its applications
3. DNA fingerprinting and applications
4. Use of genomic techniques in diagnostics

401.3 Automation and analysis (15)

1. Automation and its advantages in sample preparation
2. Automation in bioanalysis
3. Advanced automated liquid handling systems
4. Robotic Workstations
5. High throughput Screening

401.4 Capillary Electrophoresis (15)

1. Introduction (Inclusion of more chemistry-based approach)
2. How capillary electrophoresis works
3. Why capillary electrophoresis works
4. CE hardware
5. Use in bioanalysis

SIPSBN 42- MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques-II

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To familiarize students with applications of Quantitative analysis in Bioanalytical Sciences*
- *To familiarize students with applications to Qualitative analysis with example of drug*

metabolite studies

- *To make students understand LC/MS/MS with emphasis on profile of drug, proteomics and pesticide residues in food*
- *To introduce students to Tracer techniques in Bioanalytical assays*

402.1 Applications of Quantitative Analysis (15)

1. SM quantitation for e.g.
2. Macromolecule quantitation for e.g.

402.2 Applications of Qualitative Analysis (15)

1. Technique of generating drug metabolites
2. Metabolite Identification
3. Impurity profiling

402.3 LC/MS/MS (15)

1. Impurity profile in drugs and drug products
2. Proteomics
3. Pesticides, pesticide residues in food

402.4 Tracer techniques in Bioanalytical assays (15)

1. Concept of Radioactivity & Half life
2. α, β, γ emitters and their biological applications
3. Using tracers in assays
4. Detectors and counters
5. Concept of autoradiography
6. Radio labeled probes and their uses

SIPSBN 43- Standardization of ASU Drugs, Statistics and GMP-II

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To familiarize students with regulatory aspects of ASU drugs*
- *To understand environmental safety issues and various guidelines related to Bioanalytical Laboratory*

- *To introduce students to electronic data management*
- *To give introduction to Regulatory issues with respect to Bioanalytical Science*

403.1 Regulatory Aspects of ASU drugs (15)

1. National initiatives for regulation of ASU drugs
2. Schedule T and Schedule Y of Drugs and Cosmetics Act
3. 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

4. Provisions of Drugs and Cosmetics Act applied to ASU (e.g. Schedule T and Y)

403.2 Environmental Safety in Bioanalytical laboratory (15)

1. Strategies to reduce environmental impact of Bioanalytical laboratory
2. Standards of Laboratory Safety (Including Biosafety Levels)
3. Overview of guidelines for laboratories handing Radioactive substances
4. Introduction to ISO 14001 and OSHAS 18001. (Just introduction)
5. Introduction to Environment Impact Assessment & Reporting
6. Biodiversity: Red Data Book, Endemic and endangered Medicinal Plant Species, Conservation and sustainable use of medicinal raw materials, Introduction to Wildlife Act of India &CITES
7. Carbon footprints and Carbon credits.

403.3 Electronic Data Management (15)

1. Electronic Acquisition of data
2. Management of data in Computers
3. Electronic Data Validation and regulatory requirements
4. Electronic signatures & its regulation (Specific regulation)
5. Generating reports using computers
6. Regulatory requirements of Data evaluation (Include post marketing surveillance)

403.4 Regulatory Issues (15)

1. OTC drugs
2. Cosmetics

3. Food supplements
4. Nutraceuticals w.r.t. FSSAI regulations

SIPSBN 44- BA/BE Studies, GCP and Method Validation -II

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

- *To acquaint students with concepts related to Therapeutic Drug Monitoring and Pharmacovigilance*
- *To familiarize students with current guidelines associated with Good Clinical Practice*
- *To train students in various aspects related to Bioavailability and Bioequivalence studies*
- *To introduce students to the concept of QA and QC in ASU drugs*

404.1 Therapeutic drug monitoring and Pharmacovigilance (15)

1. Purpose of therapeutic Drug Monitoring
2. Bioanalytical techniques in TDM
3. Analytical and practical issues of TDM
4. Pharmacoeconomics of TDM
5. Significance and need for Pharmacovigilance (Introduction to various case studies of pharmacovigilance)
6. Indian scenario and the role of regulatory in Pharmacovigilance
7. Pharmacovigilance and safe use of medicines (with case studies, Case studies of drugs which are out due to regulatory rules eg Erythromycin which is supposed to cause skin problems in Asian population)

404.2 Good Clinical Practices (GCP) – 2 (15)

1. GCP guidelines of ICH
2. GCP guidelines of ICMR (with respect to current guidelines of ICMR)
3. Ensuring GCP
4. Documentation of GCP practice
5. Audit of GCP compliance

404.3 Bioavailability (BA) & Bioequivalence (BE) studies (15)

1. What is BA?
2. Parameters to evaluate BA of a drug and Factors that influence BA of a drug
3. Evaluating BA of a drug and Estimating BA parameters of a drug
4. Design and Conduct of a BA study
5. Data collection and evaluation
6. Reporting a BA study and Regulatory requirements of BA
7. What is BE?
8. Parameters to evaluate BE of a drug and Factors that influence BE of a drug
9. Evaluating BE of a drug and Estimating BE parameters of a drug
10. Design of a BE study and Conduct of a BE study
11. Data record and evaluation
12. Regulatory requirements of BA and BE
13. Assessment of Bioequivalence
14. Parameters to evaluate BE of a drug
15. Factors that influence BE of a drug

404.4 QC and QA of ASU drugs (15)

1. Herbal pharmacopoeia and Ayurvedic Formulary of India
2. Approaches to Quality control of ASU formulations
3. Government initiatives
4. Some Initiatives from manufacturers
5. QC of RM and In-process materials (some examples)
6. QC / QA for finished products (some examples)
7. Applications of Herbal pharmacopoeia and Ayurvedic Formulary of India
8. Recent advances in Quality control of ASU formulations
9. QC / QA for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon etc.)

M.Sc. Semester III PRACTICAL SIPSBNP 31

- Plant DNA extraction and separation using agarose Gel.
- DNA fingerprint (Genomic DNA isolation kit may be used) of two bacterial strains e.g. Resistant and wild strains of E. coli)
- Gram staining of bacteria and mounting of filamentous and non-filamentous fungi

(Staphylococcus aureus, E. coli, Candida albicans, Penicillium sps, lactobacillus sps etc.)

- Sterility testing (Microbial load) of drug formulations (According to IP 2013)
- CCl4 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)
- LD 50 evaluation using a suitable model (e.g. *Daphnia* / rice weevil)
- Isolation & screening of industrially important microorganisms
- Sterility testing of laminar airflow bench top.
- Strain improvement by mutation (by UV radiation & Chemical mutagens)
- Central streak with Bacillus species isolated from soil

M.Sc. Semester III PRACTICAL SIPSBNP 32

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

- LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.)
- GC/MS separation of plant essential oil (Demonstration)
- LC/MS/MS quantitation of a modern drug from plasma (e.g. Diclofenac Sodium)
- LC/MS/MS quantitation of metabolite of a modern drug from plasma (e.g. Mycopenolic acid, metabolite of Mycophenolatemofitil)
- Mass Fingerprinting of peptides using a suitable sample.

M.Sc. Semester III PRACTICAL SIPSBNP 33

- The involve application of biostatistics
- Problem project should involve industrial training of 8 to 12 weeks period. Data evaluation must be based on Biostatistics

M.Sc. Semester III PRACTICAL SIPSBNP 34

- Determination of iron from a given sample / sample solution by

i) Redox titration ii) Colorimetry

iii) Atomic Absorption Spectroscopy

- Study of matrix effect on IR spectra using solution IR technique and quantitate the solute from a given sample. Identify solute from a given solution using IR library and carry out a quantitative assay.

(There can be removal of the IR practical and only the AAS practical would be retained)

M.Sc. Semester IV PRACTICAL SIPSBNP 41

- CE separation of a modern drug from plasma and its formulation (e.g. DFS)
- CE separation of peptides (e.g. erythropoietin as per E.P.) (just this practical for CE would be considered)
- CE separation of N. Acids
- PCR (PCR Kit may be used) for Plant DNA and RFLP (RFLP kit may be used) (e.g. *Phyllanthus*sps.)
- DNA sequencing using sample from a suitable organism OR
- Identification of Genetically Modified Organism (GMO identification kit may be used)
- Blue white screening of mutated organism
- Serum levels of drug attained by agar cup method
- Zone of inhibition assay for penicillin (using spiked plasma and formulation)
- Zone of exhibition assay for Vitamin B12

M.Sc. Semester IV PRACTICAL SIPSBNP 42

The project should involve preparation of herbal formulations and standardization.
Students can work on one of the following formulation

1. Any oil based preparation or Ayurvedic Taila preparation
2. Any vati (Ayurvedic) or Guliga (Siddha)
3. Awaleha (semi-solid, jaggery/sugar syrup based formulation)
4. Any preparation from unani e.g. Sufoof, Jawarish, Majoon.

Students should involve any modern chromatographic techniques, microscopic evaluation, chemical and physical tests for QC of formulation prepared.

M.Sc. Semester IV PRACTICAL SIPSBNP 43

- IR patterns of an Ayurvedic Bhasma preparation (e.g. calcium containing shankha bhasma – comparison with pure $CaCO_3$ and formulations like Calcium supplement tablets)
- AAS of a suitable Ayurvedic metal bhasma preparation (e.g. Tamra bhasma) / Paracetamol
- Environment audit report
- Problem based on calculation of carbon credit and carbon footprint

M.Sc. Semester IV PRACTICAL SIPSBNP 44

- BA & BE of a modern drug (Demonstration – witnessing an actual trial)
- Calculation of AUC and bioequivalence from the given data (2 expts.)
- Total viable count of herbal formulations/raw material
- Screening of pathogens from herbal formulation/raw material (*E.coli, S. aureus, Candida albicans*)