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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

Choice Based Credit System approved by Board of Studies in Bioanalytical Sciences
Effective from Academic Year:
2020-21

M.Sc. Bioanalytical Sciences Syllabus (Autonomous)
<u>Semester III and Semester IV</u>
(Choice Based Credit 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 valuable 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

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 ProductionSection, Radiation Medicine Centre, BARC (Vice Chancellor's Nominee)*

- ✓ *Professor (Dr.) Sunita Shailajan – Former Head, Department of Botany, Research Project Coordinator, HerbalResearch 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. Kamalakar Sonawne- Consultant, Pharmaceutical industry (Subject expert and industry representative)*

- ✓ *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. Bioanalytical Sciences Syllabus (Autonomous) – Semester III and Semester IV
Choice Based Credit System (With effect from academic year 2020-21)

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	Bioavailability (BA) & Bioequivalence (BE) studies – 1		1
	4	Analytical Method Validation		1
SIPSBNP31	Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology- I		2	4

SIPSBNP32	MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques- I	**2**	**4**
SIPSBNP33	Standardization of ASU Drugs, Statistics and GMP- I	**2**	**4**
SIPSBNP34	BA/BE Studies, GCP and Method Validation- I	**2**	**4**
Total		**24**	**32**

Paper Code	Unit No.	Unit Name	Credits	Lectures/week
SIPSBN41	**1**	Bioassays 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) & Bioequivalence (BE) studies – 2		**1**
	4	QC and QA of ASU Drugs		**1**
SIPSBNP41	Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology- II		**2**	**4**
SIPSBNP42	MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques- II		**2**	**4**
SIPSBNP43	Standardization of ASU Drugs, Statistics and GMP- II		**2**	**4**
SIPSBNP44	BA/BE Studies, GCP and Method Validation- II		**2**	**4**
Total			**24**	**32**

SIES College of Arts, Science and Commerce
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Programme: Master of Science, M.Sc. Part 2 – Bioanalytical Sciences

"All human knowledge is provisional and subject to revision."-Robert Koch

The characteristic graduate attributes comprising of Programme Outcomes, Programme Specific Outcomes and Course Outcomes for a Science Post Graduate in the subject of Bioanalytical Sciences are as follows:

Note the list of abbreviations:

PO: Programme Outcome, PSO: Programme Specific Outcome, CO: Course Outcome
Cognitive Levels: - R: Remember, U: Understand, Ap: Apply, An: Analyze, E: Evaluate, C: Create

Serial Number	**Details of Programme Outcomes (POs)**
PO1 *(Skill Level)*	Problem Solving Ability *(U, Ap)* • Apply the knowledge of various courses learned under a program to break down complex problems into simple components. • Adopt and assimilate problem-based learning models and apply one's learning to solve real life problem situations.
PO2 *(Skill Level)*	Critical Thinking *(U, An, E)* • Develop critical thinking based on a rationale to identify assumptions, verifying the accuracy and validity of assumptions, and making informed decisions. • Inculcate the ability of logical reasoning to question the rationale behind concepts, ideas, and perspectives.
PO3 *(Skill Level)*	Effective Communication Skills *(Ap, C)* • Improve written and oral communication skills so as to express thoughts and ideas effectively. • Demonstrate the ability to listen carefully and imbibe soft skills to convey and receive instructions clearly. • Develop presentation skills to present complex information in a clear, lucid and concise manner.
PO4 *(Skill Level)*	Proficiency with Information and Communication Technology *(U, An, E)* • Demonstrate ability to access, evaluate and use a variety of relevant information resources inclusive of internet and electronic media for the purpose of collating and analyzing data. • Understand the scope and limitations of tools or software used in Information and Communication Technology.
PO5 *(Skill Level)*	Leadership Skills and Team Work *(U, Ap, An, C)* • Demonstrate leadership skills formulating an inspiring vision, thereby building a team, motivating and inspiring team members to engage and achieve that vision. • Develop management skills to guide people in takings tasks to their logical conclusion. • Inculcate the ability to facilitate coordinated effort as a group or team in the interests of common cause and recognize the contribution of team members.

PO6 *(Attitude Level)*	Self-directed and Lifelong Learning *(U, Ap, An)* • Demonstrate the ability to work independently and take responsibility for one's actions. • Acquire the ability to explore and evolve by becoming self-sufficient and self-reliant. • Adapt lifelong learning approaches to broaden one's horizons for personal growth and development.
PO7 *(Attitude Level)*	Ethical Values and Environmental Concerns *(U, Ap, E)* • Embrace moral or ethical values in conducting one's life and implement ethical practices in all aspects of life. • Create awareness and concern for environmental and sustainability issues. • Understand and realize the significance and relevance of co-habitation and co-evolution in attaining the needs of sustainable development.
PO8 *(Attitude Level)*	Gender Sensitization and Community Service *(U, Ap, An)* • Respect gender sensitivity, gender equity and gender justice. • Encourage mutual understanding and express empathetic social concern towards different value systems and different strata of society. • Engage in community service through Institutional Social Responsibility.

Serial Number	**Details of Programme Specific Outcomes (PSOs)**
PSO1	Conceptual Understanding and Emerging Applications *(R, U, Ap, An)* • Understand the nature and basic concepts of quality, drug regulations, environmental safety, omics among other topics, so as to establish the basic foundations of an academia-industry connect. • Demonstrate interest in different disciplines in Bioanalytical Sciences so as to analyze the scope of emerging applications in genetics, food industry, pharmaceutical industry, etc. and apply appropriate methodologies with cutting edge tools/techniques in biological and chemical sciences to seek solutions to emerging problems faced by mankind. • Demonstrate the relevance of the procedural subject knowledge that creates different types of professionals related to the disciplinary/subject areas of Bioanalytical Sciences, including professionals engaged in research and development, teaching, entrepreneurship and in the industry.
PSO2	Analytical reasoning and Scientific Inquiry *(U, An, E)* • Inculcate a sense of inquiry and capability for asking relevant or appropriate questions, articulating problems or concepts or questions. • Encourage the ability to analyze, interpret and draw conclusions from qualitative/quantitative data and critically evaluate ideas, experiences, theories and concepts by following the scientific approach to knowledge development from an open minded and reasoned perspective. • Develop analytical skills involving paying attention to detail and imbibe the ability to construct logical arguments using correct technical language related to the relevant subject.

	• Analyze and interpret data/information collected or related to experiments or investigations, using appropriate methods involving Biostatistics, Bioinformatics among others and report accurately the findings of the experiment/investigations while relating the conclusions/ findings to relevant theories of Bioanalytical Sciences.
PSO3	Laboratory Skills and Fieldwork *(R, U, E, C)* • Understand and apply standard operating procedures as per Good Laboratory Practices so as to develop laboratory skills and qualities required for successful career in teaching, research, industry, etc. • Demonstrate awareness regarding animal ethics, human ethics (in the context of Good Clinical Practices), conservation of flora and fauna, so as to promote safe environment and ecosystem, in the pursuit of disciplinary knowledge. • Develop instrumentation handling skills and laboratory techniques relevant to academia and industry; integrate knowledge, skills with technical competency, so as to create solutions for issues and problems related to biological sciences. • Demonstrate leadership qualities, command trust and respect, thereby, motivating and inspiring team members to work effectively in diverse teams during group projects. Realize the relevance of participation in industrial visits in the context of understanding the theoretical concepts as well as life in the real world.
PSO4	Research Aptitude and Interdisciplinary Approach *(Ap, An, E, C)* • Inculcate and adapt to research aptitude and culture, integrate research-based knowledge in an interdisciplinary framework, and realize the relevance of choosing research as an alternative career option. • Demonstrate the awareness regarding compliance with research ethics, awareness about conflicts of interests and Intellectual Property Rights, and avoiding unethical behavior such as fabricating, falsifying or misrepresenting data or to committing plagiarism. • Inculcate the ability to recognize cause and effect relationships, formulate hypothesis, reporting the results of an experiment or investigation, and application of research tools for analysis and interpretation of data. • Inculcate an interdisciplinary approach, to understand and consolidate fundamental concepts through an inquiry-based curriculum, develop critical thinking and problem-solving ability required to solve different types of biology related problems with well-defined solutions, and tackle open-ended problems that may cross disciplinary-area boundaries.

Course Outcomes for M.Sc. Part 2

At the root of all (science) education (Core Learning Outcome):

"*Knowing is not enough; we must apply. Being willing is not enough; we must do.*"- *Leonardo da Vinci*

Semester III – Theory

Course Code: SIPSBN31
Course Name: Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology-I

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: To understand the basics of microbiology and to recognize its application in pharmaceuticals.	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*
CO2: To familiarize students with genomics	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*
CO3: To introduce students to various concepts and guidelines of toxicology	*R, U, An, Ap, E*	*PO1, PO3* *PSO1, PSO2, PSO3, PSO4*
CO4: To give insights to students about regulatory microbiology and its applications in food and pharmaceuticals	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*

Course Code: SIPSBN32
Course Name: MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques- I

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: To make students understand MS basics in terms of principle and instrumentation involved	*R, U, An*	*PO1, PO3* *PSO1, PSO4*
CO2: To introduce students to various hyphenation techniques involved in bioanalytical sciences, its applications and recent developments	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*
CO3: To give students insights of Thermal analysis, its principle, instrumentation and application in ASU formulations such as Bhasmas	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*
CO4: To train students in various Bioanalytical methods and techniques with emphasis on sample preparation, method development, hyphenated techniques and quality.	*R, U, An, Ap*	*PO1, PO3, PO4* *PSO1, PSO2 PSO3*

Course Code: SIPSBN33
Course Name: Standardization of ASU Drugs, Statistics and GMP -I

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: To familiarize students with various steps involved in standardization of ASU drugs	*R, U, An, Ap*	*PO1, PO3, PO4* *PSO1, PSO4*
CO2: To introduce students to basic concepts and applications of general statistics methods	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO2, PSO4*
CO3: To make students competent in Biostatistics	*R, U, An, Ap, E*	*PO1, PO3* *PSO1, PSO2, PSO4*
CO4: To introduce students to concepts, requirements, applications and compliance of GMP with example of ASU drug	*R, U, An*	*PO1, PO3, PO6* *PSO1, PSO3*

Course Code: SIPSBN34
Course Name: BA/BE Studies, GCP and Method Validation-I

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: To give an introduction to students to the various ethical issues in clinical trials, its powers, dealings and compliances	*R, U, An, Ap*	*PO2, PO3, PO7* *PSO1*
CO2: Give insights to students about Good Clinical Practices	*R, U, An, Ap*	*PO2, PO3, PO7, PO8* *PSO1, PSO2 PSO3*
CO3: To train students about the concepts of Bioavailability and Bioequivalence	*R, U, An, Ap*	*PO1, PO2, PO3* *PSO1, PSO2 PSO4*
CO4: To well verse students in Analytical method validation techniques	*R, U, An, Ap, E*	*PO1, PO3, PO4* *PSO1, PSO3*

PRACTICAL

"*Science is based on experiment, on a willingness to challenge old dogma, on an openness to see the universe as it really is. Accordingly, science sometimes requires courage - at the very least the courage to question the conventional wisdom." – Carl Sagan*

The practical course in Bioanalytical Sciences is designed for giving students first hand exposure to the analytical instruments used in the industry, as well as to perform experiments to strengthen the theoretical base.

It is an effort to invigorate a thought process that can analyze and reason for the sake of awareness and allow for the students to enable them to use their critical thinking ability and accordingly interpret the results.

Semester III – Practical

Course Code: SIPSBNP31
Course Name: Practical I based on SIPSBN31

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP31	• To carry out plant DNA extraction and separation using agarose Gel. • To carry out DNA fingerprinting (Genomic DNA isolation kit may be used) of two bacterial strains e.g. Resistant and wild strains of E. coli) • To perform Gram staining of bacteria and mounting of filamentous and non-filamentous fungi (*Staphylococcus aureus*, *E. coli*, *Candida albicans, Penicillium* sps, *Lactobacillus* sps etc.) • To perform sterility testing (Microbial load) of drug formulations (According to IP 2013) • To induce the liver dysfunction in rats using CCl_4 and to evaluate the liver function using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out)	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3, PSO4*

	• To evaluate LD_{50} of a chemical using a suitable model (e.g. Daphnia / rice weevil) • To isolate & screen industrially important microorganisms • To perform sterility testing of laminar airflow bench top. • To carry out strain improvement by mutation (by UV radiation & Chemical mutagens) • To perform central streaking with *Bacillus* species isolated from soil		

Course Code: SIPSBNP32
Course Name: Practical II based on SIPSBN32

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP32	• To quantify a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.) using LC/MS • To demonstrate separation of essential oils in plants using GC/MS. • To quantify a modern drug (e.g. Diclofenac Sodium) from plasma using LC/MS/MS. • To quantify a metabolite of a modern drug (e.g. Mycophenolic acid, metabolite of Mycophenolate mofetil) from plasma using LC/MS/MS. • To perform mass fingerprinting of peptides using a suitable sample.	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3, PSO4*

Course Code: SIPSBNP33
Course Name: Practical III based on SIPSBN33

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP33	• Solve the word problems related to application of biostatistics • Go for an internship/industrial training for a period of 8-12 weeks and prepare a report and presentation based on the same.	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3, PSO4*

Course Code: SIPSBNP34
Course Name: Practical IV based on SIPSBN34

Course Outcome(CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP34	• To quantitatively determine iron from a given sample / sample solution by i) Redox titration ii) Colorimetry iii) Atomic Absorption Spectroscopy • To study matrix effect on IR spectra using liquid IR technique and quantitate the solute from a given sample, to identify the solute from a given solution using IR library and carry out a quantitative assay.	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3, PSO4*

Semester IV – Theory

Course Code: SIPSBN41

Course Name: Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology -II

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To introduce students to various bioassays in pharmaceutical evaluation	*R, U, An, Ap*	*PO3, PO4* *PSO1, PSO2, PSO4*
• **CO2:** To familiarize students with concept of Polymerase Chain Reaction and DNA Fingerprinting and its applications and use as diagnostic tools	*R, U, An, Ap*	*PO1, PO2, PO3, PO4* *PSO1, PSO2, PSO4*
• **CO3:** To provide students with basic insights of automation and analysis	*R, U, An, Ap*	*PO1, PO2, PO3, PO4* *PSO1, PSO2, PSO4*
• **CO4:** To make students understand basic concepts, working and uses of Capillary Electrophoresis	*R, U, An, Ap*	*PO1, PO2, PO3, PO4* *PSO1, PSO2, PSO4*

Course Code: SIPSBN42

Course Name: MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques-II

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To familiarize students with applications of Quantitative analysis in Bioanalytical Sciences	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*
• **CO2:** To familiarize students with applications of Qualitative analysis with an example of drug metabolite studies	*R, U, An, Ap*	*PO1, PO2, PO3* *PSO1, PSO2, PSO4*
• **CO3:** To make students understand LC/MS/MS with emphasis on profile of drug, proteomics and pesticide residues in food	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO4*
• **CO4:** To introduce students to Tracer techniques in Bioanalytical assays	*R, U, An, Ap*	*PO1, PO2, PO3* *PSO1, PSO2, PSO4*

Course Code: SIPSBN43

Course Name: Standardization of ASU Drugs, Statistics and GMP-II

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
• **CO1:** To familiarize students with regulatory aspects of ASU drugs	*R, U, An*	*PO1, PO3* *PSO1, PSO4*
• **CO2:** To understand environmental safety issues and various guidelines related to Bioanalytical Laboratory	*R, U, An*	*PO1, PO3, PO7* *PSO1, PSO3, PSO4*
• **CO3:** To introduce students to electronic data management	*R, U, An, Ap*	*PO1, PO3, PO4* *PSO1, PSO3, PSO4*
• **CO4:** To give an introduction to Regulatory issues with respect to Bioanalytical Sciences	*R, U, An, Ap*	*PO1, PO3* *PSO1, PSO2*

Course Code: SIPSBN44
Course Name: BA/BE Studies, GCP and Method Validation-II

The study of this course will accomplish the following outcomes:

Course Outcome (CO)	**Cognitive Level**	**Affinity with PO/ PSO**
CO1: To acquaint students with concepts related to Therapeutic Drug Monitoring and Pharmacovigilance	*R, U, An, Ap*	*PO1, PO2, PO3* *PSO1, PSO2, PSO4*
CO2: To familiarize students with current guidelines associated with Good Clinical Practice	*R, U, An, Ap*	*PO2, PO3, PO7, PO8* *PSO1, PSO2, PSO3*
CO3: To train students in various aspects related to Bioavailability and Bioequivalence studies	*R, U, An, Ap, E*	*PO1, PO2, PO3* *PSO1, PSO2, PSO4*
CO4: To introduce students to the concept of QA and QC in ASU drugs	*R, U, An, Ap, E*	*PO1, PO2, PO3* *PSO1, PSO2, PSO4*

Semester IV – Practical

Course Code: SIPSBNP41

Course Name: Practical I based on SIPSBN41

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP41	• To separate a modern drug from plasma and its formulation (e.g. DFS) by using CE • To separate peptides (e.g. erythropoietin as per E.P.) using CE • To separate Nucleic Acids using CE • To carry out PCR (PCR Kit may be used) and RFLP of plant DNA (RFLP kit may be used) (e.g. *Phyllanthus* sps.) • To carry out DNA sequencing using a sample from a suitable organism OR • To identify a Genetically Modified Organism (GMO identification kit may be used) • To carry out blue white screening of a mutated organism • To measure serum levels attained by a drug by using agar cup method • To perform a zone of inhibition assay for penicillin (using spiked plasma and formulation) • To perform a zone of exhibition assay for Vitamin B_{12}	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3, PSO4*

Course Code: SIPSBNP42
Course Name: Practical II based on SIPSBN42

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP42	• Prepare any one of the following Ayurvedic/Siddha/Unani formulation: - Any oil-based preparation or Ayurvedic Taila preparation Any vati (Ayurvedic) or Guliga (Siddha) Awaleha (semi-solid, jaggery/sugar syrup-based formulation) Any preparation from unani e.g. Sufoof, Jawarish, Majoon Carry out its QC by using physical and chemical tests, any modern chromatographic techniques, microscopic evaluation and prepare a report and presentation on the same.	*R, U, An, Ap, E, C*	*PO1, PO2, PO3, PO4, PO5, PO6* *PSO1, PSO2, PSO3, PSO4*

Course Code: SIPSBNP43
Course Name: Practical III based on SIPSBN43

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP43	• To compare IR patterns of an Ayurvedic Bhasma preparation (e.g. calcium containing Shankha Bhasma) with pure $CaCO_3$ and formulations like Calcium supplement tablets • To determine the metal content of a suitable Ayurvedic metal bhasma preparation (e.g. Tamra bhasma) /Paracetamol by using AAS • To read an environment audit report and to provide recommendations based on it. • To solve problems based on calculation of carbon credit and carbon footprint	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO7* *PSO1, PSO3, PSO4*

Course Code: SIPSBNP44
Course Name: Practical IV based on SIPSBN44

Course Outcome (CO)	Details	Cognitive Level	Affinity with PO/ PSO
SIPSBNP44	• Demonstration of calculation of BA & BE of a modern drug by witnessing an actual trial • To calculate AUC and bioequivalence from the given data • To carry out a total viable count of herbal formulations/raw material • To screen pathogens (*E. coli*, *S. aureus*, *Candida albicans*) from an herbal formulation/from herbal raw material	*R, U, An, Ap, E*	*PO1, PO2, PO3, PO6* *PSO1, PSO2, PSO3, PSO4*

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), 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 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 center, 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)

1. 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

2. Important Microbes for Food & Drug Industry, Pathogenic Organisms in Food & Pharma Industry
3. Sources of contamination, Microbial Contamination in ASU preparations
4. Regulatory Microbiological testing in pharmaceuticals
5. Microbiological Assays for pharmaceutical products
6. Biosafety levels in pharmaceutical and food Industry (Introduction)

SIPSBN32- 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)

SIPSBN33- 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

SIPSBN34- 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
SIPSBN41 - 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 Bioassays 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 a more chemistry-based approach)
2. How does capillary electrophoresis work?
3. Why does capillary electrophoresis work?
4. CE hardware
5. Use in bioanalysis

SIPSBN42- 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

SIPSBN43- 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

SIPSBN44- 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 e.g. 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)
- 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)
- 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 SIPSBNP32

(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. Mycophenolic acid, metabolite of Mycophenolate mofetil)
- Mass Fingerprinting of peptides using a suitable sample.

M.Sc. Semester III PRACTICAL SIPSBNP33

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

M.Sc. Semester III PRACTICAL SIPSBNP34

- 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 SIPSBNP42

The project should involve preparation of herbal formulations and standardization.

Students can work on one of the following formulations: -

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*)