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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: 2023 – 2024**

**Revised Syllabus under Choice Based Credit System (CBCS) approved by the Board of Studies in Bioanalytical Sciences**
**Effective from Academic Year: 2023-24**

***Preamble***

*"What is there that is not poison? All things are poison and nothing (is) without poison. Solely the dose determines that a thing is not a poison." – Paracelsus (1493-1541; Swiss physician-alchemist)*

*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 'academic freedom' needs to be justified with '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 besides giving 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 involving relevance of toxicity studies and 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 to make 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.*
- ✓ *Industry Internship – to strengthen academia-industry linkage and to increase employability of students, to give students structured training for exposure to working environment so as to combine experiential learning with theoretical concepts.*
- ✓ *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.*

*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.*

*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. The 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. Thus, 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.*

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***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)*

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| Paper Code (Semester 3) | Unit No. | Unit Name (Semester III) | Credits | Lectures/Week |
|---|---|---|---|---|
| SIPSBN31 | 1 | Basic and Regulatory Microbiology and its Applications in Pharmaceuticals | 4 | 1 |
| | 2 | Genomics | | 1 |
| | 3 | Basic and Regulatory Toxicology | | 1 |
| | 4 | Regulatory Microbiology and its Application in the pharmaceutical and food industry | | 1 |
| SIPSBN32 | 1 | MS Basics | 4 | 1 |
| | 2 | Hyphenated Techniques and their applications | | 1 |
| | 3 | Thermal analysis and Tracer Techniques | | 1 |
| | 4 | Bioanalytical Methods and Automation in Analysis | | 1 |
| SIPSBN33 | 1 | Ethical Issues in Clinical Trials | 4 | 1 |
| | 2 | Good Clinical Practices (GCP) | | 1 |
| | 3 | Bioavailability (BA) and Bioequivalence (BE) studies - 1 | | 1 |
| | 4 | Analytical Method Validation | | 1 |
| SIPSBN34 | - | Industrial Training/Internship/Apprenticeship | 4 | 4 |
| SIPSBNP31 | - | Microbiology, Genomics and Toxicology | 2 | 4 |
| SIPSBNP32 | - | Mass Spectroscopy and Hyphenated Techniques, Thermal Analysis, and Tracer Techniques | 2 | 4 |
| SIPSBNP33 | - | Clinical Trials, GCP, BA/BE studies, and Method Validation | 2 | 4 |
| SIPSBNP34 | - | Industrial Training/Internship/Apprenticeship | 2 | 4 |
| Total | | | 24 | 32 |

| Paper Code (Semester 4) | Unit No. | Unit Name (Semester IV) | Credits | Lectures/Week |
|---|---|---|---|---|
| **SIPSBN41** | **1** | Bioassays in Pharmaceutical Evaluation | **4** | **1** |
| | **2** | Polymerase Chain Reaction (PCR) | | **1** |
| | **3** | DNA Fingerprinting (RT-PCR in detail) | | **1** |
| | **4** | Capillary Electrophoresis | | **1** |
| **SIPSBN42** | **1** | Therapeutic Drug Monitoring and Pharmacovigilance | **4** | **1** |
| | **2** | Environmental Safety in a Bioanalytical Laboratory | | **1** |
| | **3** | Electronic Data Management | | **1** |
| | **4** | Concepts of Statistics and Biostatistics | | **1** |
| **SIPSBN43** | **1** | Standardization of ASU Drugs | **4** | **1** |
| | **2** | QC and QA of ASU drugs | | **1** |
| | **3** | Regulatory Aspects of ASU drugs | | **1** |
| | **4** | Good Manufacturing Practices | | **1** |
| **SIPSBN44** | **-** | Research Project | **4** | **4** |
| **SIPSBNP41** | **-** | Bioassay, Polymerase Chain Reaction and Capillary Electrophoresis | **2** | **4** |
| **SIPSBNP42** | **-** | Therapeutic Drug Monitoring and Pharmacovigilance, Electronic Data Management and Biostatistics | **2** | **4** |
| **SIPSBNP43** | **-** | Standardization of ASU Drugs, Drug Regulation and GMP | **2** | **4** |
| **SIPSBNP44** | **-** | Research Project/Dissertation | **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)*<br>• Apply the knowledge of various courses learned under a program to break down complex problems into simple components.<br>• 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)*<br>• Develop critical thinking based on a rationale to identify assumptions, verifying the accuracy and validity of assumptions, and making informed decisions.<br>• Inculcate the ability of logical reasoning to question the rationale behind concepts, ideas, and perspectives. |
| PO3 *(Skill Level)* | Effective Communication Skills *(Ap, C)*<br>• Improve written and oral communication skills so as to express thoughts and ideas effectively.<br>• Demonstrate the ability to listen carefully and imbibe soft skills to convey and receive instructions clearly.<br>• 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)*<br>• 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.<br>• 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)*<br>• Demonstrate leadership skills formulating an inspiring vision, thereby building a team, motivating and inspiring team members to engage and achieve that vision.<br>• Develop management skills to guide people in takings tasks to their logical conclusion.<br>• 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)*<br>• Demonstrate the ability to work independently and take responsibility for one's actions.<br>• Acquire the ability to explore and evolve by becoming self-sufficient and self-reliant.<br>• 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)*<br>• Embrace moral or ethical values in conducting one's life and implement ethical practices in all aspects of life.<br>• Create awareness and concern for environmental and sustainability issues.<br>• 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)*<br>• Respect gender sensitivity, gender equity and gender justice.<br>• Encourage mutual understanding and express empathetic social concern towards different value systems and different strata of society.<br>• 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)*<br>• 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.<br>• 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.<br>• 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)*<br>• Inculcate a sense of inquiry and capability for asking relevant or appropriate questions, articulating problems or concepts or questions.<br>• 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.<br>• 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.<br>• 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)*<br>• 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.<br>• 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.<br>• 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.<br>• 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)*<br>• 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.<br>• 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.<br>• 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.<br>• 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: Microbiology, Genomics and Toxicology**
The study of this course will accomplish the following outcomes:

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

**Course Code: SIPSBN32**
**Course Name: Mass Spectrometry and Hyphenated Techniques, 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:**<br><br>To make students understand MS basics in terms of principle and instrumentation involved | *R, U, An* | *PO1, PO3*<br><br>*PSO1, PSO4* |
| **CO2:**<br><br>To introduce students to various hyphenation techniques involved in bioanalytical sciences, its applications and recent developments | *R, U, An, Ap* | *PO1, PO3*<br><br>*PSO1, PSO4* |
| **CO3:**<br><br>To give students insights of Thermal analysis, its principle, instrumentation and application in ASU formulations such as Bhasmas and to introduce students to Tracer Techniques in Bioanalytical assays. | *R, U, An, Ap* | *PO1, PO2, PO3*<br><br>*PSO1, PSO2, PSO4* |
| **CO4:**<br><br>To train students in various Bioanalytical methods and make them aware of the automated technologies that have been developed for bioanalysis. | *R, U, An, Ap* | *PO1, PO2, PO3, PO4*<br><br>*PSO1, PSO2 PSO3, PSO4* |

**Course Code: SIPSBN33**
**Course Name: Clinical Trials, GCP, BA/BE Studies and Method Validation**

The study of this course will accomplish the following outcomes:

| **Course Outcome (CO)** | **Cognitive Level** | **Affinity with PO/ PSO** |
|---|---|---|
| **CO1:**<br><br>To introduce students to the various ethical issues in clinical trials, the powers of the ethical Committees, ways of dealing with ethical issues, and compliance to the current ethical guidelines | *R, U, An, Ap* | *PO2, PO3, PO7*<br><br>*PSO1* |
| **CO2:**<br><br>To give insights to the students about Good Clinical Practices | *R, U, An, Ap, E* | *PO2, PO3, PO7, PO8*<br><br>*PSO1, PSO2, PSO3* |
| **CO3:**<br><br>To teach students about the concepts of Bioavailability and Bioequivalence | *R, U, An, Ap, E* | *PO1, PO2, PO3*<br><br>*PSO1, PSO2, PSO4* |
| **CO4:**<br><br>To provide a conceptual understanding to the students in analytical method validation. | *R, U, An* | *PO1, PO3, PO4*<br><br>*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 isolation, extraction and separation using agarose Gel.<br>• To perform Gram staining of soil microflora<br>• To perform sterility testing (Microbial load) of drug formulations (According to IP 2013) (sterile water/eye drops)<br>• 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)<br>• To evaluate $LC_{50}$ of a chemical using a suitable model (e.g. *Daphnia*/*Chironomus* larva)<br>• To isolate and screen industrially important microorganisms<br>• To demonstrate the effect of media on the growth curves of a given microorganism, using two different media (minimal and enriched) | *R, U, An, Ap, E* | *PO1, PO2, PO3, PO6*<br>*PSO1, PSO2, PSO3, PSO4* |

**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<br>• To identify organic compounds from their GC/MS spectra.<br>• To quantify a modern drug (e.g. Diclofenac Sodium) from plasma using LC/MS/MS.<br>• To quantify a metabolite of a modern drug (e.g. Mycophenolic acid, metabolite of Mycophenolate mofetil) from plasma using LC/MS/MS.<br>• To perform mass fingerprinting of peptides using a suitable sample.<br>• To quantitatively determine residual solvents (Carbon tetrachloride, etc.) by static headspace GC-MS | *R, U, An, Ap, E* | *PO1, PO2, PO3, PO6*<br>*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** | • To quantitatively determine iron from a given sample / sample solution by<br>i) Redox titration<br>ii) Colorimetry<br>iii) Atomic Absorption Spectroscopy<br>• 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*<br>*PSO1, PSO2, PSO3, PSO4* |

**Course Code: SIPSBN34 and SIPSBNP34**
**Course Name: Industrial Training/Internship/Apprenticeship**

| Course Outcome(CO) | Details | Cognitive Level | Affinity with PO/ PSO |
|---|---|---|---|
| **SIPSBN34 and SIPSBNP34** | • To give students structured training for exposure to real working environment<br>• To combine experiential learning with theoretical concepts<br>• To increase employability of students<br>• To strengthen academia-industry linkage | *R, U, An, Ap, E* | *PO1, PO2, PO3, PO6*<br>*PSO1, PSO2, PSO3, PSO4* |

## Semester IV – Theory

**Course Code: SIPSBN41**
**Course Name: Bioassay, Polymerase Chain Reaction, and Capillary Electrophoresis**

The study of this course will accomplish the following outcomes:

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

**Course Code: SIPSBN42**
**Course Name: Therapeutic Drug Monitoring and Pharmacovigilance, Electronic Data Management, and Biostatistics**
The study of this course will accomplish the following outcomes:

| Course Outcome (CO) | Cognitive Level | Affinity with PO/ PSO |
|---|---|---|
| • **CO1:**<br>To acquaint students with concepts related to Therapeutic Drug Monitoring and Pharmacovigilance | *R, U, An, Ap* | *PO1, PO2, PO3*<br>*PSO1, PSO2, PSO4* |
| • **CO2:**<br>To understand environmental safety issues and various guidelines related to Bioanalytical Laboratory | *R, U, An, Ap* | *PO1, PO3, PO7*<br>*PSO1, PSO3, PSO4* |
| • **CO3:**<br>To introduce students to electronic data management | *R, U, An, Ap* | *PO1, PO3*<br>*PSO1, PSO3, PSO4* |
| • **CO4:**<br>To introduce students to basic concepts and applications of general statistics methods and to make them competent in Biostatistics | *R, U, An, Ap* | *PO1, PO3*<br>*PSO1, PSO2, PSO4* |

**Course Code: SIPSBN43**
**Course Name: Standardization of ASU Drugs, Drug Regulation and GMP-**
The study of this course will accomplish the following outcomes:

| Course Outcome (CO) | Cognitive Level | Affinity with PO/ PSO |
|---|---|---|
| • **CO1:**<br>To familiarize students with various steps involved in standardization of ASU drugs | *R, U, An* | *PO1, PO3, PO4*<br>*PSO1, PSO4* |
| • **CO2:**<br>To familiarize students with regulatory aspects of ASU drugs | *R, U, An* | *PO1, PO3*<br>*PSO1, PSO3, PSO4* |
| • **CO3:**<br>To introduce students to the concept of QA and QC in ASU drugs | *R, U, An, Ap* | *PO1, PO2, PO3*<br>*PSO1, PSO2, PSO4* |
| • **CO4:**<br>To introduce students to concepts, requirements, applications, and compliance of GMP with an example of ASU drugs. | *R, U, An, Ap* | *PO1, PO3, PO6*<br>*PSO1, PSO3* |

**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 carry out PCR (PCR Kit may be used)<br>• To carry out RFLP (RFLP kit may be used)<br>• To identify a Genetically Modified Organism (GMO identification kit may be used)<br>• To carry out blue white screening of a mutated organism<br>• To perform a zone of inhibition assay for penicillin<br>• To perform a zone of exhibition assay for Vitamin $B_{12}$ | *R, U, An, Ap, E* | *PO1, PO2, PO3, PO6*<br>*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** | • To solve word problems based on biostatistics.<br>• To compare the IR patterns of an Ayurvedic Bhasma preparation (e.g. calcium containing Shankha Bhasma-comparison with pure $CaCO_3$).<br>• To perform AAS of a suitable Ayurvedic metal Bhasma preparation/a modern drug (e.g. Tamra Bhasma/Paracetamol).<br>• To read an environment audit report and to provide recommendations based on it.<br>• To solve problems based on calculation of carbon credit and carbon footprint. | *R, U, An, Ap, E, C* | *PO1, PO2, PO3, PO7*<br>*PSO1, PSO3, PSO4* |

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

| Course Outcome (CO) | Details | Cognitive Level | Affinity with PO/ PSO |
|---|---|---|---|
| **SIPSBNP43** | • Demonstration of calculation of BA & BE of a modern drug by witnessing an actual trial<br>• To calculate AUC and bioequivalence from the given data<br>• To carry out the total viable count of an herbal formulation/raw material<br>• To screen pathogens from an herbal formulation/from herbal raw material (by culturing in selective media and Gram staining) | *R, U, An, Ap, E* | *PO1, PO2, PO3, PO6*<br>*PSO1, PSO2, PSO3, PSO4* |

**Course Code: SIPSBN44 and SIPSBNP44**
**Course Name: Research Project based on AYUSH/Interdisciplinary topic under Bioanalytical Sciences**

| Course Outcome(CO) | Details | Cognitive Level | Affinity with PO/ PSO |
|---|---|---|---|
| **SIPSBN44 and SIPSBNP44** | • To inculcate research aptitude and develop an open, inquiring mind amongst the students<br>• To encourage students to explore new territories and learn new things<br>• To encourage the spirit of curiosity of students and to think of research as potential career option<br>• To motivate and inspire students to come up with solutions for real life problems facing the society and nation | *R, U, An, Ap, E, C* | *PO1, PO2, PO3, PO4, PO5, PO6*<br>*PSO1, PSO2, PSO3, PSO4* |

**SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**
**SEMESTER III- Theory**
**SIPSBNP31-Microbiology, Genomics and Toxicology**
**(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 and to introduce regulatory issues with respect to Bioanalytical Sciences*

**3.1.1 Basic and Regulatory 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, simple and compound microscopy, Electron Microscopy
2. Growth of microorganisms, methods to study the growth of microorganisms, preservation of microorganisms, maintenance media, etc.
3. Sources of microbial contamination, various types of microbial contaminations and control of microbial contamination, sources of contamination of pharmaceutical products, and study of microbial load of raw materials used for drug preparation (Herbal/ Botanical/ ASU drug formulations)
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

**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

**3.1.2 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

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

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

### 3.1.3 Basic and Regulatory Toxicology (15)

1. Principles of toxicology – Different areas of toxicology – Descriptive, Mechanistic, and Regulatory
2. Characteristics of Exposure – Duration of exposure, frequency of exposure, site of exposure and routes of exposure
3. 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
4. Descriptive animal toxicity tests – Acute toxicity testing, skin, and eye irritation, Draize test, sub-acute (Repeat-Dose Study), sub-chronic, chronic, absorption, distribution, and excretion of toxicants – by gastrointestinal tract, lungs, skin
5. Biotransformation of xenobiotics – Xenobiotic biotransformation by Phase I enzymes and Phase II reactions (examples of carbon tetrachloride and acetaminophen).
6. Dose translation from animals to humans – Concept of extrapolation of dose, *HED* (Human Equivalent Dose), *NOAEL* (No Observed Adverse Effect Level), Safety factor, *ADI* (Acceptable Daily Intake), R*f*D (Reference dose)
7. OECD guidelines (Organization for Economic Cooperation and Development) for testing of chemicals
8. CCSEA guidelines (Committee for Control and Supervision of Experiments on Animals) for animal testing center, ethical issues in animal studies and animal models used in regulatory toxicology studies
9. Alternative methods to animal testing in toxicology (in vitro / in silico approach), Schedule Y and its interpretation
10. Case studies – Sulfanilamide, Thalidomide, Diethylstilbestrol, Saccharin

**References: -**

Klaassen, Curtis D. Casarett & Doull's Toxicology - The Basic Science of Poisons (2008). McGraw Hill
Toxicity testing handbook – Jacobson Kram and Keller
General toxicology - Jaroslava
Reinhardt, Christoph A., Alternatives to Animal Testing (2006). Weinheim, New York: VCH Verlagsgesellschaft mBH, VCH Publishers Inc.
OECD guidelines for testing of chemicals, Revised and Updated
CCSEA guidelines for animal testing facility

### 3.1.4 Regulatory Microbiology and its Application in the pharmaceutical and food industry (15)

1. 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
2. Important microbes for food & drug industry, pathogenic organisms in food & pharmaceutical industry
3. Regulatory microbiological testing in pharmaceuticals
4. Microbiological assays for pharmaceutical products
5. Biosafety levels in the pharmaceutical and food industry
6. OTC drugs
7. Cosmetics
8. Food supplements
9. Nutraceuticals w.r.t. FSSAI regulations

**References: -**

Willey, Joanne M., Sherwood, Linda M., Woolverton, (2014) Prescott's Microbiology. 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

**SIPSBN32- Mass Spectroscopy and Hyphenated Techniques, Thermal Analysis, and Tracer Techniques**

**(Lecture allotment includes periods for Seminars and Discussions)**

*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 of Thermal analysis, its principle, instrumentation and application in ASU formulations such as Bhasmas and to introduce students to 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.*

**3.2.1 MS basics** **(15)**

1. Basics of MS
2. MS/MS, TQ/Ion Trap
3. Components:

a) Inlets

b) Ion sources (Electron Ionization, Chemical Ionization, Electrospray Ionization, Atmospheric Pressure Photoionization, Atmospheric Pressure Chemical Ionization, Matrix Assisted Laser Desorption Ionization) (Introduction)

c) Mass analyzers (Quadrupole, Ion trap, Time of Flight, Magnetic Sector Analyzer, Ion Cyclotron Resonance), Detectors, Vacuum System etc. (Introduction)

**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

**3.2.2 Hyphenated Techniques and their applications (15)**

1. 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

2. 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)

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

**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

### 3.2.3 Thermal analysis and Tracer Techniques (15)

1. Principle of Thermal Analysis
2. Requirements of Thermal Analysis and the basic components of a thermal analysis instrument
3. Factors affecting the results of a thermal analysis
4. Simultaneous and complementary thermal analysis
5. 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) Thermomechanical analysis (TMA) and Dynamic Mechanical Analysis (DMA)
d) Evolved Gas Analysis (EGA)
6. Thermal analysis of Bhasma preparations
7. Concept of Radioactivity & Half life
8. α, β, γ emitters and their biological applications
9. Using tracers in assays
10. Detectors and counters
11. Concept of autoradiography
12. Radio labeled probes and their uses

**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

### 3.2.4 Bioanalytical Methods and Automation in Analysis (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)
5. Automation and its advantages in sample preparation
6. Automation in bioanalysis
7. Advanced automated liquid handling systems
8. Robotic Workstations
9. 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.

**SIPSBN33- Clinical Trials, GCP, BA/BE Studies and Method Validation**

**(Lecture allotment includes periods for Seminars and Discussions)**

*Learning objectives:*

- *To introduce students to the various ethical issues in clinical trials, the powers of the ethical Committees, ways of dealing with ethical issues, and compliance to the current ethical guidelines*
- *Give insights to the students about Good Clinical Practices*
- *To teach students about the concepts of Bioavailability and Bioequivalence*
- *To provide a conceptual understanding to the students in analytical method validation.*

**3.3.1 Ethical Issues in Clinical Trials (15)**

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

**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

**3.3.2 Good Clinical Practices (GCP) (15)**

1. What is GCP?
2. Origin of GCP
3. Earlier Guidelines for GCP
4. Requirements of GCP compliance
5. GCP guidelines of ICH
6. GCP guidelines of ICMR (with respect to current guidelines of ICMR)
7. Ensuring GCP
8. Documentation of GCP practice
9. Audit of GCP compliance

**References: -**

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.

**3.3.3 Bioavailability (BA) & Bioequivalence (BE) studies – 1 (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. Designing and Conducting of a BA study, Data collection, and evaluation of a BA study
5. Reporting a BA study and Regulatory requirements of BA
6. What is BE?
7. Parameters to evaluate BE of a drug and Factors that influence BE of a drug

8. Evaluating BE of a drug and Estimating BE parameters of a drug
9. Designing and Conducting of a BE study and Data record and evaluation of BE study
10. 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

**3.3.4 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

**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

**SIPSBN34- Industrial Training/Internship/Apprenticeship**

***Learning objectives***

- *to give students structured training for exposure to real working environment*
- *to combine experiential learning with theoretical concepts*
- *to increase employability of students*
- *to strengthen academia-industry linkage*

**SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**
**SEMESTER IV- Theory**
**SIPSBN41 - Bioassay, Polymerase Chain Reaction, and Capillary Electrophoresis**
**(Lecture allotment includes periods for Seminars and Discussions)**

*Learning objectives*

*• To introduce students to various Bioassays in pharmaceutical evaluation*
*• To familiarize students with concept of Polymerase Chain Reaction and DNA Fingerprinting and its applications and use as diagnostic tools*
*• To make students understand the basic concepts, working and uses of Capillary Electrophoresis*

**4.1.1 : Bioassays in Pharmaceutical Evaluation (15)**

1. General idea about bioassay 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)

**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.

**4.1.2 Polymerase Chain Reaction (PCR) (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

**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

**4.1.3 DNA Fingerprinting (RT-PCR in detail) (15)**

1. Concept of DNA Fingerprinting
2. Different tools of DNA Fingerprinting
3. Applications of DNA Fingerprinting
4. Use of genomic techniques for the diagnosis of various case studies

**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

#### 4.1.4 Capillary Electrophoresis (15)

1. Introduction (Inclusion of a chemistry-based approach)
2. How does capillary electrophoresis work?
3. Why does capillary electrophoresis work?
4. CE hardware
5. Use in bioanalysis
6. Introduction to CE-MS and its principle
7. Instrumentation and working of CE-MS
8. Advantages and disadvantages of CE-MS
9. Applications of CE-MS

**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

**SIPSBN42 – Therapeutic Drug Monitoring and Pharmacovigilance, Electronic Data Management, and Biostatistics**

**(Lecture allotment includes periods for Seminars and Discussions)**

*Learning objectives*

- *To acquaint students with concepts related to Therapeutic Drug Monitoring and Pharmacovigilance*
- *To understand environmental safety issues and various guidelines related to*
- *Bioanalytical Laboratory*
- *To introduce students to electronic data management*
- *To introduce students to basic concepts and applications of general statistics methods and to make them competent in Biostatistics*

**4.2.1 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 agencies in pharmacovigilance
7. Pharmacovigilance and the safe use of medicines (with case studies of drugs which have been banned dueto 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.

**4.2.2 Environmental Safety in Bioanalytical laboratory (15)**

1. Strategies to reduce the environmental impact of a bioanalytical/clinical laboratory
2. Standards of Laboratory Safety (Including Biosafety Levels)
3. Overview of guidelines for laboratories handling radioactive substances
4. Introduction to ISO 14001 and ISO 45001 (formerly OHSAS 18001)
5. Introduction to Environment Impact Assessment & reporting
6. 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
7. 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

**4.2.3 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)

**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

**4.2.4 Concepts in Statistics and Biostatistics** **(15)**

**Part A- Concepts in Statistics**

1. Basic concepts of sample statistics (Mean, Median, Mode, Standard Deviation)
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 level of significance, power of test and confidence limits
8. Application of normal distribution

**Part B- Concepts in Biostatistics**

1. Statistical approach to biological samples
2. Introduction to Data collection techniques
3. Design of experiments, for e.g. Block designs, Latin square
4. COV and ANOVA (one way ANOVA and two way ANOVA)
5. Concept of correlation, coefficient of correlation and its calculation by using Pearson's coefficient of correlation
6. Regression analysis with application to Standard Graph
7. Nonparametric tests with examples (Sign Test, Run Test, Kruskal Wallis Test, Spearman's rank coefficient of correlation)
8. Statistical Guidance from regulatory agencies
9. Student's t test, chi square test, z test and f test
10. Use of statistical packages for data analysis and an introduction to SAS and SPSS

**References: -**

Rastogi, Veer Bala (2010) Fundamentals of Biostatistics Ane's Student Edition. New Delhi: Ane Books Pvt. Ltd.

Arora, P.N., Malhan, P.K. (2009) Biostatistics. Pune: Himalaya Publishing House

Rosner, Bernard (2016) Fundamentals of Biostatistics 8th Edition. Boston: Cengage Learning

Norman, Geoffrey R., Streiner, David L. (1998) Biostatistics The Bare Essentials. Hamilton: B.C. Decker Inc.

Le, Chap T. (2003) Introductory Biostatistics. Hoboken: John Wiley & Sons, Inc.

**SIPSBN43 – Standardization of ASU drugs, Drug Regulation and GMP**
**(Lecture allotment includes periods for Seminars and Discussions)**

*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.*

**4.3.1 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

**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.

**4.3.2 QC and QA of ASU drugs** **(15)**

1. Herbal Pharmacopoeia and the 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 the 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.)

**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.

**4.3.3 Regulatory Aspects of ASU drugs** **(15)**

1. Government 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) (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

**4.3.4 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 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

**SIPSBN44- Research Project based on AYUSH / Interdisciplinary topic under Bioanalytical Sciences**

***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*

**Practical's for Semester III and Semester IV in Bioanalytical Sciences**

**M.Sc. Semester III Practicals for SIPSBNP31**

- Plant DNA isolation, extraction and separation using agarose Gel (CTAB method or a DNA isolation kit might be used)
- Gram staining of soil microflora
- Demonstrate the effect of media on the growth curves of a given microorganism, using two different media (minimal and enriched).
- Isolation & screening of industrially important microorganisms
- Sterility testing (Microbial load) of drug formulations (According to IP 2013) (sterile water/eye drops)
- $CCl_4$ 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 using a suitable model (e.g., *Daphnia* / *Chironomus larva*)

**M.Sc. Semester III Practical's of SIPSBNP32**

(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.
- Quantitative determination of residual solvents (Carbon tetrachloride, etc.) by static headspace GC-MS
- Identification of organic compounds from their GC-MS spectra

**M.Sc. Semester III Practical's of SIPSBNP33**

- 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.
- Calibration of an instrument. (Calibration of visible spectrophotometer using $KMnO_4$ and checking various validation parameters)

**SIPSBNP34 - Industrial Training/Internship/Apprenticeship**

**Background:** As a part of the M.Sc. Degree program in the subject of Bioanalytical Sciences, the M.Sc. Part 2 students are required to complete an Internship / Training / Apprenticeship program at Industry / Company / Research Institute / Organization for gaining industrial experience related to the subject and or the area of specialization. This exercise carries a total of 150 marks which is partly based on the evaluation of the performance of the student by the competent authority at the industry where the student is placed and an evaluation by a team of examiners at the college during their semester end examination.

**Modalities of Evaluation:**

**1. Industry Diary / Rough Journal:**

Each student will maintain an Industry Diary / Rough Journal for keeping a record of daily activities carried out during the working period at the industry. The diary entries are to be evaluated and approved by a competent authority at the department / section where the student is placed. The diary entries must **NOT** contain any confidential information or any information that may infringe the intellectual property rights of the industry. The diary entries should be general with no details of specifics.

**2. Continuous Evaluation:**

The student needs to be continually evaluated for his / her performance at the industry. This evaluation may be based on a suitable criteria and modality as found appropriate and feasible at the industry. The evaluation may be best made by the immediate superior or the departmental / sectional head to whom the student reports. The evaluator may also keep regular record of the evaluations made.

**3. End of Program Evaluation;**

At the end of period, the immediate superior or the departmental / sectional head to whom the student reports, should make an evaluation report in the format attached with this document. The evaluation document will be approved by a competent authority at the senior managerial level, directly in the same vertical, where the student is placed.

**M.Sc. Semester IV Practical's on SIPSBNP41**

- PCR (PCR Kit may be used) for a given DNA sample
- RFLP (RFLP kit may be used)
- 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 $B_{12}$

**M.Sc. Semester IV Practical's of SIPSBNP42**

- Problems based on biostatistics
- IR patterns of an Ayurvedic Bhasma preparation (e.g., calcium containing Shankha Bhasma – comparison with pure CaCO3)
- AAS of a suitable Ayurvedic metal Bhasma preparation (e.g., Tamra Bhasma/Paracetamol)
- Environment audit report
- Problems based on calculation of carbon credit and carbon footprint

**M.Sc. Semester IV Practical's of SIPSBNP43**

- 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 (by culturing in selective media and Gram staining)

**SIPSBNP44 - Research Project**

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

**Details of Research project component for Semester IV 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.
4. 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.
6. The mentor will prepare, guide and supervise the group by giving orientation / instructions about writing the project proposal.
7. 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 in the subject of Bioanalytical Sciences)
8. 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.
9. 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.
10. The mentor for the respective group will keep a track of the actual execution of the project.
11. 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.
12. 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 |

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