SIES College of Arts, Science & Commerce

RISE WITH EDUCATION

Sion (West), Mumbai – 400022

(Autonomous)

Faculty: Science

Program: M.Sc-I

Subject: BIOANALYTICAL SCIENCES

Academic Year: 2022 – 2023

Credit Based Semester and Grading System approved by Board of Studies in Bioanalytical Sciences to be brought into effect from August 2022

M.Sc - Part I in Bioanalytical Sciences Syllabus (Autonomous)
Semester I and Semester II
(Credit Based Semester and Grading System, with effect from academic year 2022-2023)

Preamble

"The advantage of the analytical approach is that it is widely applicable, and it can provide a considerable amount of quantitative information even with a relatively poor resolving power" – Christian de Duve (Nobel Laureate in Physiology or Medicine in 1974)

Academic freedom is a privilege entitled with Academic Autonomy. This paradigm shift served as an impetus for restructuring and refining the curriculum for the postgraduate program in the subject of Bioanalytical Sciences.

A new and relevant topic has been included in the syllabus in the form of Research Methodology with the purpose and rationale to not only inculcate amongst students a research aptitude, but also develop and enhance their research skills in order to make them adapt to the research culture. It also aims to nurture critical thinking and develop analytical reasoning amongst students. Some topics like Drug invention and Pharmaceutical Industry, Pharmacokinetics, Pharmacodynamics and Drug properties have been redesigned with the purpose to understand the process by which drugs are sculpted and brought into being, based on experimentation and optimization of many independent properties. The inclusion of Internet of Things (IOT) will help the students to correlate and recognize the link between pharmacology and related sciences such as Bioinformatics, Proteomics, and Pharmacogenomics. It will help students recognize and reinterpret the actions and uses of drugs in light of advances in medicine and the basic biomedical sciences. The topics on Chromatography and Spectroscopy have been restructured, whereby, they will give the students exposure to the vast arena of technological improvements in method development and method validation of drugs in pharmaceutical industries.

The revised syllabus is a collective and constructive effort of the faculty, experts from industry and research institutions, alumni and the board members, whose valuable suggestions and expertise were instrumental in drafting this syllabus. The comments 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, in the meeting held on 13th August 2022 at SIES College of Arts, Science and Commerce (Autonomous), Sion, Mumbai.

In conclusion, we hope this syllabus will not only fulfil the aspirations of postgraduate students who want to pursue careers in fields related to Pharmaceuticals, Nutraceuticals and allied Industries, but it will also inculcate an interdisciplinary approach in students and develop a mind for scientific inquiry aspiring to explore new dimensions of the subject. Moreover, this course will also facilitate training and developing skills related to Instrumentation amongst the students, whereby, it will enable to bridge the gap between the domain wise demand and supply for skilled manpower in areas related to Bioanalytical Method Development and Life Sciences Sector Skill Development.

Dr. Satish Sarfare
Chairman,
Board of Studies in the subject of Bioanalytical Sciences
Email: satishs@sies.edu.in

M.Sc Part I – Bioanalytical Sciences Syllabus (Autonomous) – Semester I Credit Based Semester and Grading System (With effect from academic year 2022-23)				
Paper Code	**Unit No.**	**Unit Name**	**Credits**	**Lectures/week**
SIPSBN11	**1**	Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani	**4**	**1**
	2	Modern Medicine		**1**
	3	Pharmacognosy		**1**
	4	Principle of extraction and Isolation of analytes		**1**
SIPSBN12	**1**	Good Laboratory Practice (GLP)	**4**	**1**
	2	Pharmacopeial standards and Testing Procedure		**1**
	3	Drug Act & Regulations		**1**
	4	Quality Control (QC) and Quality Assurance (QA)		**1**
SIPSBN13	**1**	Theory of Chromatographic separation and TLC	**4**	**1**
	2	HPLC – 1		**1**
	3	GC – I		**1**
	4	Spectroscopy – I		**1**
SIPSBN14	**1**	OMICS	**4**	**1**
	2	Electrophoresis		**1**
	3	Bioinformatics		**1**
	4	Environmental Issues of Bioanalytical laboratory		**1**

SIPSBNP11	Different Medicinal Systems, Pharmacognosy & Extraction Techniques	**2**	**4**
SIPSBNP12	GLP, Drug Act and Quality Management	**2**	**4**
SIPSBNP13	Chromatography and Spectroscopy-I	**2**	**4**
SIPSBNP14	Proteomics, Bioinformatics & Environmental Issues	**2**	**4**
	Total	**24**	**32**

M.Sc Part I – Bioanalytical Sciences Syllabus (Autonomous) – Semester II Credit Based Semester and Grading System (With effect from academic year 2022-23)				
Paper Code	**Unit. No.**	**Unit Name**	**Credits**	**Lectures/week**
SIPSBN21	**1**	R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry	**4**	**1**
	2	Solid Phase Extraction (SPE)		**1**
	3	Phytochemistry		**1**
	4	Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography)		**1**
SIPSBN22	**1**	Research Methodology	**4**	**1**
	2	Stability Studies		**1**
	3	IPR and Patenting		**1**
	4	Packaging in Pharma industry		**1**
SIPSBN23	**1**	HPTLC	**4**	**1**
	2	HPLC – 2		**1**
	3	GC – II		**1**
	4	Spectroscopy – II		**1**
SIPSBN24	**1**	Drug Invention and Pharmaceutical Industry	**4**	**1**
	2	Pharmacokinetics		**1**
	3	Pharmacodynamics and Drug properties		**1**

	4	Immunoassay & ELISA		**1**
SIPSBNP21	Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques		**2**	**4**
SIPSBNP22	Research methodology, Intellectual Property Rights, Stability Studies and Packaging		**2**	**4**
SIPSBNP23	Chromatography and Spectroscopy-II		**2**	**4**
SIPSBNP24	Drug development, Pharmacokinetics, Pharmacodynamics, Drug properties and Immunoassays		**2**	**4**
	Total		**24**	**32**

Program Specific Outcomes

- *A Bioanalytical Sciences student will have Knowledge of both traditional or alternative medicinal System as well as modern medicinal system giving them an advantage in both traditional as well as modern pharmaceutical industries*
- *A Bioanalytical Sciences student will be more employable as he/she is well versed with Good Laboratory Practices, Pharmacopeial Standards and testing methods, Drug Acts and Regulations and Concepts of Quality Control and Quality Assurance*
- *A Bioanalytical Sciences student will have expertise on Chromatographic and Spectroscopic separation techniques along with the instrumentation knowledge and result interpretational talent.*
- *A Bioanalytical Sciences student shall have acquired the knowledge about OMICS, Electrophoresis, Bioinformatics and Environment Issues of Laboratory.*
- *A Bioanalytical Sciences Student will have mastery in the phytochemistry and various extraction techniques*
- *A Bioanalytical Sciences Students would have developed research aptitude and scientific temper to understand and conduct research project*
- *A Bioanalytical Science student will develop Entrepreneurship Skills as he/she is familiar with the Intellectual Property Rights and Concept of Patenting*
- *A Bioanalytical Sciences student will have an edge over other students as he/she is more adept with modern instrumentation techniques*
- *A Bioanalytical Sciences student will have comprehension about new drug development, immunoassays, Pharmacological Studies along with Laboratory Safety Precautions.*
- *A Bioanalytical Sciences student will have practical inputs about microbiological techniques, molecular biology and Toxicological Studies*
- *A Bioanalytical Sciences student will have command over hyphenated techniques*
- *A Bioanalytical Sciences student has understanding about Standardization methods of ASU drugs, Statistics and Good Manufacturing Practice*
- *A Bioanalytical Sciences Student will be employable in Pharmaceutical Sector because of his/ her proficiency about ethics, Good Clinical practice, Bioavailability and Bioequivalence studies and Analytical Method validation.*

Paper Code: SIPSBN11
Different Medicinal Systems, Pharmacognosy & Extraction Techniques

Course Outcomes paper 1 (SIPSBN11)

- Explain and recall the Traditional medicinal systems of Ayurveda, Siddha and Unani
- Compare and contrast the Traditional medicinal system and Modern Medicines with respect to principle, practice, formulation types
- Identify various terms and concepts associated with Pharmacognosy and its significance in the process of standardization and characterization.
- Investigate various extraction and isolation of analyte techniques

Learning Objectives

- ✓ *To understand what are traditional medicines.*
- ✓ *Traditional and Modern medicines comparison with respect to formulation, types and dosage.*
- ✓ *To understand the importance of Pharmacognosy in drug preparation.*
- ✓ *Introduction to various theoretical concepts related to extraction and isolation of drug formulation.*

Unit 1: Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani **15 Lectures**

1.1 Principles and Practice (*History and current scenario, basic principles*)
1.2: Types of drug formulation (*At least 4 from each branch in detail and various other formulations*)
1.3: Methods of manufacture – raw material to finished product (*AYUSH Guidelines*)
1.4: Types of drugs *(Elaboration of 1.2*)
1.5: Excipients in various dosage forms (*What are excipients, excipients used in ASU drugs, general dosage of ASU drugs*)

Unit 2: Modern Medicine **15 Lectures**

2.1: Principles and Practice (*History and current scenario, basic principles*)
2.2: API and concept of its formulation into a dosage form (*Definition, difference between API and formulation w.r.t to WHO guidelines. API and dosage general concept*)
2.3: Different types Drug Formulations (Various forms, at least 4 in detail)
2.4: Excipients in various dosage forms (*Definition of excipient, its role in formulation and dosage*)
2.5: Disease Management (Comparison of ASU and Modern Drugs) (*Comparison of unit 2.1 and 2*)

a. Diabetes
b. Tuberculosis
c. Hypertension
d. Hepatitis
e. Malaria
f. Dengue
g. Influenza

Unit 3: Pharmacognosy **15 Lectures**

3.1: Introduction, Plants and their medicinal uses example of one plant to be given (*Examples of plants in practical)*
3.2: Concepts of ethanobotany, ethno medicines and pharmacology *(definition, general concept*)
3.3: Phytogeographical regions to be explained with respect to endemism and hot spots (explain only concepts) (*Concepts of endangered plants, endemic plants and hot spots in India*)
3.4: Herbaria evaluation to include Plant collection, Authentication, storage and drying techniques. (*Basic concept, BSI, role of Herbaria in drug preparation)*
3.5: Raw material evaluation to include Microbial load, Raw material characterization, proximate evaluation, photomicrography (*Assays to be done, basic microbiology*)
3.6: Concepts of GAP and GHP for medicinal plants (only introduction) *(w.r.t AYUSH or WHO guidelines)*

Unit 4: Principle of extraction and Isolation of analytes **15 Lectures**

4.1: Introduction
4.2: Physico-chemical properties of drugs and solvents
4.3: Concept of partition & Partition Coefficient
4.4: Solvent properties
4.5: Selection of solvent
4.6: Extraction efficiency
4.7: Introduction to classical methods of extraction
4.8: Introduction to modern methods of extraction- advantages & disadvantages - Include LLE (Soxhlet) and LME
4.9: Applications of extraction
4.10 : Microwave assisted extraction its advantages and disadvantages
4.11 : Ionization and its effect on the extraction of drugs
4.12 : The 'First law of drug metabolism'
4.13 : Matrix components & analyte isolation
4.14 : Concentration of extracts
4.15: Isolations of fractions
4.16: Purification of isolate

References:

- A.F.Rudole Hoernle, Vaidya Bhagwan Dash, *Studies in the Medicine of Ancient India*, Concept Publisher Co.
- Prof. (Mrs) Asima Chatterjee, Dr.Satyesh Chandra Prakash, *The Treatise on Indian Medicinal Plants* Vol 1, Publications & Information Direct
- V.V.Sivarajan, Indira Balachandran, *Ayurvedic Drugs and Their Plant Sources*, Oxford and IBH
- L.D.Kapoor, *Handbook of Ayurvedic Medicinal Plants*, CRP Press
- www.indianmedecine.nic.in
- Howard C.Ansel, *Introduction to Pharmaceutical Dosage Forms* 4th ed., Lea & Febiger
- H.J.Roth, A.Kleemann, *Pharmaceutical Chemistry* Vol 1, Ellis Horwood
- John B. Taylor, Peter D. Kennewell, *Modern Medicinal Chemistry*, Ellis Horwood Ltd
- D.R.Karsa, R.A.Stephenson, *Excipients & Delivery Systems for Pharmaceutical Formulations*, The Royal Society of Chemistry
- Varro E.Tyler, Lynn R.Brody, James E.Robbers, *Pharmacognosy* 9th ed., Lea and Febiger
- Tatsuya Sekine, Yuko, Hasegawa, Dr.V.Mshinde, *Solvent Extraction Chemistry Fundamentals and Applications*, Marcel Dekker Inc

Paper Code: SIPSBN12
GLP, Drug Act and Quality Management

Course Outcomes for Paper 2 (SIPSBN12): -

- Introduce students to the regulatory aspects of the pharmaceutical industry like GLP, Pharmacopoeias, QA/QC, etc.
- Make the students develop an understanding of some of the regulatory guidelines in the pharmaceutical industry, both in India and around the world.
- Reintroduce students to some of the basic QC techniques in the pharmaceutical industry and also introduce some of the other techniques like friability, hardness testing, disintegration testing and dissolution testing.

Learning Objectives:

- ✓ *To familiarize students with basic concept of Good Laboratory Practices, Laboratory Safety Measures, Drug Acts.*
- ✓ *Pharmacopeias, Quality management and Quality assurance (various stages involved), various schedules, electronic signatures and the current regulations pharmaceutical industry.*
- ✓ *To give an insight to students about various rules and regulations regarding which Pharmaceutical industries have to follow.*

- ✓ *To reintroduce students with some of the basic Quality Control techniques and introduce some new ones like Friability, Dissolution, etc.*

Unit 1: Good Laboratory Practice (GLP) 15

Lectures Laboratory Safety Measures w.r.t handling of chemicals and biological materials

1.1: What is GLP? (*Definition, importance)*
1.2: Practicing GLP
1.3: Guidelines to GLP
1.4: Documentation of Laboratory work
1.5: Preparation of SOPs
1.6: Calibration records (*implementation in laboratory)*
1.7: significance of validation in GLP
1.8: Transfer of methods
1.9: Documentation of results
1.10: General Precautions, labels and signage
1.11: Material handling and disposal
1.12: Material Safety Data Sheets (MSDS) and SOP (Standard Operating Procedure)
1.13: Personal safety & Clothing
1.14: Levels of safety
1.15: Fire safety and fire fighting
1.16: Working in Biosafety Cabinets and hoods

Unit 2: Pharmacopeial standards and Testing Procedure 15

Lectures 2.1: Introduction to WHO guidelines
2.2: Introduction to Pharmacopoeias IP, BP, USP (JP, EP, AP where ever applicable)
2.3: Specified test in Monographs w.r.t liquid formulation (injectable) and solid dosage form (USP, EP, BP, IP)
2.4: Include AP, Indian HP and AFI (wherever applicable)

Unit 3: Drug Act & Regulations 15 Lectures

3.1: Indian Drugs and Cosmetics Act w.r.t Schedule Y, M, H. Include Schedule A, S (introduction)
3.2: Introduction to foreign guidelines w.r.t US, EU, Australia & Japan
3.3: Introduction to CFR 21 part 11
3.4: Current guidelines in the pharmaceutical industry (Indian and also global)

Unit 4: Quality Control (QC) and Quality Assurance (QA) 15

Lectures

4.1: Introduction
4.2: What is QC? What is QA?
4.3: Requirements for implementing QC & QA
4.4: QC & QA concepts in ASU drugs
4.5: Standardizing an Analytical method
    a. Introduction to standardization
    b. Steps involved in standardization of an analytical method
4.6: Introduction to some basic Quality Control (QC) techniques: -
    a. pH meter
    b. Karl-Fischer (KF) Titration
    c. Friability Testing, Hardness Testing, Disintegration Testing and Dissolution Testing
4.7: Support work & documentation
4.8: Introduction to validation and it's types
4.9: Audit requirements, audits and audit reports
4.10: Personnel Responsibility in QA

References:

- Tatsuya Sekine, Yuko, Hasegawa, Dr.V.Mshinde, *Solvent Extraction Chemistry Fundamentals and Applications*, Marcel Dekker Inc
- F.Bloomfield, R.Baird, R.E.Leak, R.Leech, *Microbial Quality Assurance in Pharmaceuticals,Cosmetics and Toiletries* ,Ellis Horwood
- Dr.C.R.Karnick, Pharmacopoeial Standards of Herbal Plants Vol I, Sri Satguru Publisher
- Regional Research Lab & IDMA, Indian Herbal Pharmacoepoeia Vol II, Regional Research Lab
- Dr.C.R.Karnick, Pharmacopoeial Standards Of Herbal Plants Vol II, Sri Satguru Publisher .
- Dr.V.Rajpal, Standardization of Botanicals Vol I, Eastern Publishers
- R.S.Iyer, Schedule M and Beyond Good Manufacturing Practices, Indian Drug Manufacturers Association

Paper Code: SIPSBN13
Chromatography & Spectroscopy-I

Course outcomes for Paper 3 (SIPSBN13): -

- Introduce (in more detail) analytical techniques like Chromatography and Spectroscopy.
- Develop an understanding of the basic principles, instrumentation, working and other aspects of various chromatography (like HPLC and GC) and spectroscopy (like UV-Visible Spectroscopy, Fourier Transform Infrared (FTIR) Spectroscopy, etc.
- Make students realize the importance and also the practical aspects of analytical techniques like chromatography and spectroscopy.

Learning Objectives:

- ✓ *Introduce students to analytical chemistry and Instrumentation.*
- ✓ *To make students understand general concept of Chromatography and Spectroscopy in terms of principle and instrumentations involved.*
- ✓ *To introduce students to chromatographic techniques along with its application in Thin Layer Chromatography. Familiarize students with all components of Thin Layer Chromatography.*
- ✓ *To understand general concepts of HPLC along with its instrumentation and various types Recent development in HPLC.*
- ✓ *To understand general concepts of GC along with its instrumentation factors affecting it.*
- ✓ *To introduce students to basic concepts of spectroscopy and various instruments which follow principles of spectroscopy*

Unit 1: Theory of Chromatographic separation and TLC **15 Lectures**

1.1: Principles of chromatographic separation (*general concepts, terminology*)
1.2: Introduction to chromatographic separation techniques
1.3: Classification of chromatography (*partition adsorption chromatography)*
1.4: Principles and Practice of TLC (*types: planar*)
1.5: Uses of TLC (*applications*)
1.6: Some recommended solvents systems (*mobile systems*)
1.7: Detection of compounds on TLC plates (*detecting reagents*)

Unit 2: HPLC – 1 (*General concepts elaboration w.r.t practicals***)** **15 Lectures**

2.1: Principles and Instrumentation
2.2: The chromatographic process
2.3: The chromatogram
2.4: Separation mode
2.5: Column chemistry
2.6: System parameters
2.7: Reverse-phase HPLC
2.8: Introduction to various HPLC techniques:
- **a)** Ion-pair HPLC

b) Ion-exchange HPLC
c) Normal-phase HPLC
d) Affinity Chromatography
e) Gel permeation Chromatography

2.9: Recent advances (Fast LC, online extractions, add on pumps, online derivatization, multi-dimensional LC)

Unit 3: GC – I (*General concepts elaboration w.r.t practicals)* **15 Lectures**

3.1: Principles and Instrumentation
3.2: Factors that affect the chromatographic separation (Temperature, Type of column etc.)
3.3: GC techniques
3.4: Types of columns and their application
3.5: Selection of liquid stationary phases (Packed and capillary columns)
3.6: GC hardware
a) Introduction to flow and pressure controllers
b) Injection techniques- on column injection, large volume injection, split - split less, PTV and various auto injectors- gas sampling as well as liquid sampling
c) Column Oven- temperature programming, (High /cryogenic oven temperature)

Unit 4: Spectroscopy – I (*General concepts elaboration w.r.t practicals*) **15 Lectures**

4.1: Introduction to atomic and molecular Spectroscopy (*Differences between the two*)

4.2: UV, Visible and fluorescence
a) Principles & Instrumentation
b) Applications
4.3: Nephelometry
a) Principles & Instrumentation
b) Applications
4.4: Turbidometry
a) Principles & Instrumentation
b) Applications
4.5: IR
a) Principles & Instrumentation
b) Applications
4.6: FTIR
a) Principles and Instrumentation
b) Applications
4.7: Basic concepts of NMR spectroscopy
4.8: Raman spectroscopy

References:

- Douglas A.Skoog, *Principles of Instrumental Analysis,* Saunders College Publishing
- Robert White, *Chromatography / Fourier Transform Infrared Spectroscopy and its Applications*,
- Marcel Dekker Inc
- R.W.Hannah, J.S.Swinehart, *Experiments in Techniques of Infrared Spectroscopy,* Perkin Elmer
- Patrick Hendra, Catherine Jones, Gavin Warnes, *Fourier Transform Raman Spectroscopy Instrumentation and Chemical Applications*, Ellis Horwood
- Gordon M.Barrow, *Introduction to Molecular Spectroscopy*, McGraw Hill
- Stephen G.Schulman, *Molecular Luminescence Spectroscopy Methods and Applications Part I,*
- John Wiley and Sons
- George G.Guilbault, *Practical Fluorescence*, Marcel Dekker
- B.J.Clark, T.Frost ,M.A.Russell ,*UV Spectroscopy Techniques Instrumentation Data Handling*.Chapman and Hall
- W.O.George, H.A.Willis, *Computer Methods in UV Visible and IR Spectroscopy*, Royal Society of Chemistry
- B.Ravindranath, Principles and Practice of Chromatography, Ellis Horwood Ltd

- Roger M.Smith, Gas and Liquid Chromatography in Analytical Chemistry, John Wiley and Sons
- Edward Johnson, Robert Stevenson, Basic Liquid Chromatography, Varian Associate
- B.Ravindranath, Principles and Practice of Chromatography, Ellis Horwood Ltd
- Hobart H.Williard, Lynne Merritt, John Dean, FrankSettle, Instrumental Methods of Analysis 6th Ed.,CBS Publishers and Distributors
- Douglas A.Skoog, Principles of Instrumental Analysis, Saunders College Publishing
- Dennis J. Runser, Maintaining and Troubleshooting HPLC Systems, John Wiley and Sons
- Douglas A.Skoog, Principles of Instrumental Analysis, Saunders College Publishing
- Dr.P.D.Sethi, Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography, CBS Publishers and Distributors
- B.Ravindranath, Principles and Practice of Chromatography, Ellis Horwood Ltd
- I.P.Alimarin,V.I.Fadeeva ,E.N.Dorokhora, Lecture Experiments in Analytical Chemsitry ,Mir Publishers, Moscow
- William David Cooper,Albert D.Helfrick ,Electronic Instrumentation and Measurement Technique, Prentice Hall of India Pvt.Ltd
- Hobart H.Williard, Lynne Merritt, John Dean, FrankSettle, Instrumental Methods of Analysis 6th Ed.,CBS Publishers and Distributors
- P.D.Sethi ,Dilip Charegaokar ,Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography, CBS Publishers and Distributors
- H.Wagner, S.Bladt , Zgainski, Plant Drug Analysis A Thin Layer Chromatography Atlas, Springer Veriag

Paper Code; SIPSBN14
Proteomics, Bioinformatics & Environmental Issues

Course Outcomes paper 4 (SIPSBN14)

- Outline and Discuss various OMICS technologies with emphasis on Proteomics
- Categorize various Electrophoretic techniques, its detection, standardization and applications
- Examine Bioinformatics and investigate its role in OMICS technology and drug discovery
- Compare various types and sources of Bioanalytical Laboratory wastes, its handling, control and regulations and inspect the environmental issues associated with it.

Learning Objectives:

- ✓ *To provide students with basic insights to the terms "OMICS". To make students understand various concepts related to OMICs with emphasis on Proteomics.*
- ✓ *To familiarize students with concepts of Electrophoresis, its principle and applications.*
- ✓ *To make students competent in applying computer skills in field of drug discovery by using tools like Bioinformatics.*
- ✓ *To understand environmental issues related to Bioanalytical laboratory, rules and regulations to be followed.*

Unit 1: OMICS **15 Lectures**

1.1:Introduction to Omics:

a. Central Dogma of Molecular Biology
b. Genomics
c. Proteomics
d. Metabolomics
e. Lipidomics (*basic introduction and application*)

1.2: Overview of proteomics

a. Basic Protein Chemistry
b. Modification of proteins (Post Translational and Chemical)
c. Methods for cell disruption/protein extraction
d. Protein purification/ Fractionation
e. Protein identification and characterization
f. Significance of proteome

1.3 :"Introduction to Internet of Things"

- **a)** Overview of Internet of Things
- **b)** Applications of Internet of Things in Health sector (Clinical Practice and Patient Management along with case studies)
- **c)** Advantages and Challenges associated with use of Internet of Things in Health Sector in India

Unit 2: Electrophoresis **15 Lectures**

2.1 Principles of electrophoretic separation
2.2: Equipment and process
2.3: Agarose gel electrophoresis
2.4: PAGE – Native & SDS, 2DGE, Extensions of Electrophoresis -Immunoelectrophoresis/pulsefield
2.5: Standardization of electrophoretic technique
2.6: Detection techniques
2.7: Applications of electrophoresis

Unit 3: Bioinformatics **15 Lectures**

3.1: What is bioinformatics?
3.2: Databases and Search Tools
3.3: Applications of bioinformatics

a. Genomics
b. Proteomics
c. Drug discovery (Docking software)

3.4: Using various libraries & tools w.r.t structure/ literature to drug development/ proteins
3.5: Introduction to Chemi-informatics

Unit 4: Environmental Issues of Bioanalytical laboratory **15 Lectures**

4.1: Introduction to types and sources of Bioanalytical Laboratory waste

4.2: Chemical & Biological materials: Hazards and Handling

a) Chemical Storage and Segregation
b) Chemical Laboratory Emergency Response
c) Equipment Safety
d) Laboratory Inspections
e) Transportation and Receiving of Hazardous Materials

4.3: Hazard Controls & Information (Workplace Hazardous Materials Information System {WHMIS} as example)
4.4: Introduction to: Regulations of Pollution Control Board for Laboratories.

References:

- Rastogi, *Bioinformatics: Methods and applications- Genomics, Proteomics and Drug Discovery*
- Gopal, *Bioinformatics with fundamentals of genomics and proteomics*
- Allen J.Bard, *Electroanalytical Chemistry*,A series of Advances Volume –5,Marcel Dekker, Inc; New York
- Allen J.Bard , *Electroanalytical Chemistry*,A series of Advances Volume – 12,Marcel Dekker, Inc; New York
- Allen J.Bard, *Electroanalytical Chemistry*, A series of Advances Volume – 13, Marcel Dekker, Inc; New York
- Norberto A.Guzman, *Capillary Electrophoresis Technology*, Marcel Dekker Inc
- Dale R Baker, *Capillary Electrophoresis*, John Wiley and Sons
- H.E.Schwartz, R.H.Palmieri, *Introduction to Capillary Electrophoresis of Proteins and Peptides*, Beckman
- Kelvin Altria and Manus Rogan, *Introduction of Quantitative Applications of C.E in Pharmaceutical Analysis*, Beckman
- Rastogi, *Bioinformatics: Methods and applications- Genomics, Proteomics and Drug Discovery*

- Gopal, *Bioinformatics with fundamentals of genomics and proteomics*
- Central Pollution Control Board Guidelines

Semester I - Practicals

Semester I – Practical I (SIPSBNP11) Based on SIPSBN11

1. Liquid – liquid extraction of a modern drug from plasma and formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
2. Microscopic evaluation of sections and powders with adulteration and formulation comparision of the following medicinal plants;
   - **a)** *Emblica officinalis* – (Amla - dried fruit)
   - **b)** *Vitex nigundo* - Leaves
   - **c)** *Asteracantha Longifolia* – Whole plant
   - **d)** *Calotropis gigantea* – Leaves
   - **e)** *Phyllanthus amarus* – Whole plant

   Calculation in terms of percent occurrence of key anatomical characteristics in the powder to be recorded.
3. Individual student must report findings of ANY THREE from the above list but in each institution evaluation on all the listed plants must be carried out.
4. Separation of plant pigments using paper chromatography
5. Determination of sugars /plant pigments) by paper chromatography.

Semester I – Practical II (SIPSBNP12) Based on SIPSBN12

a) Students must submit a Field Note Book of their field excursion including Presentation of the field visit
b) Research Paper Review
c) Carry out dissolution test, disintegration, hardness and friability on any one tablet preparation
d) Modification by using Sodium dodecyl sulphate buffer and other buffer system (for water soluble and water insoluble drug). And with one modification that student should carry out tablet preparation with the help of IR Punch and then study all the test w.r.t. different parameters.

Semester I – Practical III (SIPSBNP13) Based on SIPSBN13

1. Gas Chromatograhic separation of solvent mixtures (e.g. Menthol & Ethanol, Toluene & Methanol etc.)
2. HPLC separation of herbal raw material from its formulation (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Phyllanthus amarus* from LIV 52, *Tribulus terrestris* from Ghokshuradi guggul etc.)
3. HPLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
4. HPLC separation of modern drugs from their combination formulation (e.g. Diclofenac Sodium &Paracetamol, Metformin & Glimiperide etc.)
5. Determination of Caffeine from a given sample by
   i) UV spectrophotometry
   ii) HPLC
6. IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)
7. Derivatization in GC

Semester I – Practical IV (SIPSBNP14) Based on SIPSBN14

1. Separation of human serum / plasma proteins / egg white using PAGE((Protein molecular weight determination kit may be used)
2. Evaluate the given data of protein and nucleic acid sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis of the findings.
3. Evaluate the given data of peptide sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis on the functional annotation of the peptide.
4. Bioinformatics : Clustal W. omega, BLAST A, Blast O, Fasta, Alignment, Prosite, SCOP, Rasmol, CATH, Identification of Protein,
5. Separation of proteins using 2D gel electrophoresis
6. Calculation of Ka, Ke, t ½, Cmax and Tmax from the given data (2 expts.)
7. Protein profiling of plant seed by SDS-PAGE

Semester II – Theory
Paper Code: SIPSBN21
Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques

Course outcomes for Paper 1 (SIPSBN21): -

- Develop an understanding of the various aspects of the Indian Pharmaceutical industry like its history, the current market trends and activities, Drug pricing policy, etc.
- Introduce students to Solid Phase Extraction (SPE) and develop an understanding of its history, the various steps in SPE, etc.
- Gain an insight into the various naturally occurring metabolites, their synthesis, applications, develop an understanding of the interconnectedness of the various metabolic pathways and learn the various techniques for extraction of these metabolites.
- Introduce students to Supercritical Fluid Extraction (SCFE) and Supercritical Fluid Chromatography (SCFC) and develop an understanding of various aspects like the basic principle, instrumentation, factors affecting them, etc.

Learning Objectives:

- ✓ *To understand the dynamics of Pharmaceutical industry. Its current trend, government policies and parameters affecting Pharmaceutical industry in India.*
- ✓ *Understanding basis of Solid Phase Extraction, strategies involved, methods and current development.*
- ✓ *Introduce students to basics of Phytochemistry, plant metabolites, its classification and different extraction techniques.*
- ✓ *Introduce students to Super Critical Extraction, its basic concepts, instrumentation and factors affecting it, benefits and future prospects.*

Unit 1: R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry
15 Lectures

1.1: Historical background with emphasis on Post 1947 period
1.2: Market trends and activities
1.3: Govt. initiatives and the public sector in Pharmaceutical Industry
1.4: The role of Drug Pricing policy in India and its impact on the Indian Pharmaceutical Industry
1.5: Role of Analytical chemist in Pharmaceutical Industry
1.6: R&D strategies of Indian Pharma
1.7: Pharma R&D
1.8: Bulk Drug manufacturing & its R&D
1.9: Varied Dosage forms and its R&D

Unit 2: Solid Phase Extraction (SPE) **15 Lectures**

2.1: Introduction
2.2: General properties of bonded silica sorbents
2.3: Sorbent/analyte interactions
2.4: Sample pretreatment of different biological matrices
2.5: Developing SPE methods
2.6: Example of an SPE method (introduction of SPME)
2.7: Disc cartridges
2.8: 96-Well Format (e.g. Porvair Microsep TM system)
2.9: Direct injection of plasma
2.10 : Other new developments

Unit 3: Phytochemistry **15 Lectures**

3.1: Natural drug substances from plants (primary and secondary metabolites)
3.2: Broad classification of secondary metabolites

a. Nitrogenous
b. Non nitrogenous

c. Isoprenoids

3.3: Secondary drug metabolite production with special reference with integrated pathway
3.4: Key Factors affecting synthesis of secondary metabolites
3.5: Choice of solvent for extraction of phytoconstituents
3.6: Extraction Techniques of Crude plant material w.r.t
a) maceration (Types- Kwatha and Swarasa)
b) percolation
c) steam distillation

Unit 4: Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography)
15 Lectures

4.1 The concept of SCFE & SCFC
4.2: Instrumentation of SCFE & SCFC
4.3: Factors affecting SCFE & SCFC
4.4: Benefits of SCFE & SCFC
4.5: Application of SCFE for natural products and Application of SCFC
4.6: Conclusions and future perspectives

References:

- Larry T.Taylor, *Supercritical Fluid Extraction*, John Wiley and Sons
- Prof. Dr.F.C.Czygan, D.Frohne, C.Hohxel, A.Nagell, H.J., Pfainder, G.Willuhn , W.Buff, Herbal Drugs and Phytopharmaceuticals, CRC Press
- Douglas A.Skoog, Principles of Instrumental Analysis, Saunders College Publishing
- R.S.Iyer, Schedule M and Beyond Good Manufacturing Practices, Indian Drug Manufacturers Association

Paper Code: SIPSBN22

Research methodology, Intellectual Property Rights, Stability Studies and Packaging

Course Outcomes paper 2 (SIPSBN22)

- To introduce students to various stages, types, terminologies involved in Research so as to develop a research aptitude in them.
- Illustrate IPR and Patenting terminologies with a perspective of India's stature in World
- Identify and recommend various strategies for stability studies for different formulations
- Identify and assess IPR and Patents and be able to compose a patent claim.
- Examine the role of packaging in pharmaceutical industries.

Learning Objectives:

- ✓ *To provide an overview of Research methodology so as to give students insights of concept of what and how research is carried out*
- ✓ *To familiarize students with IPR, Patenting. Basic concepts of TRIPS, International Agreements and current scenario.*
- ✓ *To teach students importance of drug stability and its comparison with ASU drugs.*
- ✓ *To provide insights on IPR with respect to India and world.*
- ✓ *To familiarize students with packaging in Pharmaceutical Industry with respect to needs, rules and regulations.*

Unit 1: Research Methodology **15 Lectures**

1.1 Basic concepts in research – scientific research method, types of research, significance/relevance of research, research methods versus research methodology
1.2 Research process – Literature review/survey/search, primary stages of research process, steps in research process, developing and testing hypothesis
1.3 Research problem – formulating research problem, meaning and statement of research problem, identification and selection of research problem, types of variables (experimental and control groups etc)
1.4 Research design – types of research design, nature and importance of research design, qualitative versus quantitative research design, design of research posters/research presentations
1.5 Scientific research writing – writing a research article/paper/manuscript, types of research articles, writing an abstract, types of abstracts, selection of key words, citing references/bibliography (Harvard

style, Numeric style, APA style, end note/foot note),

1.6 Research review and journals – critique and review of research paper/manuscript, overview of types of research journals and publications (peer-reviewed, open access etc)

1.7 Research grants/funds – Overview of funding agencies (government and private organizations), brief of writing a research proposal/research project to funding agencies

1.8 Research ethics – Avoiding plagiarism, Awareness of misconduct or fraud, Acknowledgement/Declaration of conflict of interest, overview of ethics in animal research/preclinical trials and clinical trials

Unit 2: Stability Studies **15 Lectures**

2.1 : Factors that influence stability of drug formulations

2.2 : Types of Stability chambers and their design considerations

2.3 : Stability issues of ASU raw materials and finished products

2.4 : Guidelines on Stability evaluations

2.5 : Approaches to stability studies of ASU formulations

Unit 3: IPR and Patenting **15 Lectures**

3.1 Concept of IPR - Understanding the meaning of IPR & its significance in knowledge-based economy.

3.2 Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, Geographical indications, Protection of New Plant Varieties, Copyright.

3.3 Global Harmonization - Impact of IPR on global trade and the need for harmonization, WTO and its role in a global harmonization,

a) TRIPS and introduction to the articles in TRIPs document as well as the flexibilities provided by TRIPS.
b) How India has leveraged the flexibilities provided by TRIPS to safeguard the industry and prevent ever-greening of patents.
c) Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance.

3.4 IPR as a strategic tool –

d) Concepts of piracy, reverse engineering and knowledge worker.
e) Benefits of creating and/or owning patents and other IPR.

3.4 International Agreements related to IPR & patents - Paris Convention, PCT.

3.5 Indian Patent Act -

f) Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step, useful/capable of industrial application.
g) Non-patentable subject matter - what is not patentable.
h) Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, servicing of patents.
i) Provisional Patents, Divisional Patents & Patents of Addition.
j) Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check

Unit 4: Packaging in Pharma industry **15 Lectures**

4.1 : Introduction to Packaging

4.2 : Fundamentals of Distribution

4.3 : Packaging Forms & their Significance

4.4 : Packaging Materials (covering basic manufacturing process, applications and significance)

4.5 : Paper, Paper Board and CFB Glass,metals, Basic Polymer based materials, Polymer based composite materials

4.6 : Ancillary Mats

4.7 : Package Material Testing

4.8 : Compatibility & Migration Studies

4.9 : Accelerated Shelf Life Testing - Theory and Problems

4.10 : GMP

4.11 : Packaging Validation

4.12 : Packaging Laws and regulatory compliance

4.13 : Labeling and Inserts

References:

- H.Jackson Knight, *Patent Strategy for Researchers and Research Managers* 2nd ed, John Wiley and Sons
- S.F.Bloomfield, R.Baird, R.E.Leak, R.Leech, *Microbial Quality Assurance in Pharmaceuticals,Cosmetics and Toiletries* ,Ellis Horwood
- William Hewitt, Stephen Vincent, *Theory and Application of Microbiology Assay*, Academic Press
- Jens T. Carstensen, *Drug Stability Principles & Practices* 2nd e.d.,Marcel Dekker
- Kenneth A.Connors, Gordon L.Amidon, Valentino J.Stella, Chemical Stability of
- *Pharmaceuticals*, John Wiley & Sons
- Hamed M.Abdon, *Dissolution Bioavailbaility and Bioequivalence*, MACK Publishers
- Richard Friary, *Jobs in the Drug Industry*, Academic Press
- Nicholas Walliman, Research Methods – the basics, Routledge, 2011
- George Thomas, Research Methodology and Scientific Writing, Ane Books Pvt. Ltd, 2019
- Kenneth Bordens, Bruce Abbott, Research Design and Methods – a process approach, Tata McGraw- Hill, 2011
- Catherine Dawson, Activities for teaching research methods, SAGE publications, 2016
- Priti Majhi, Prafull Khatua, Research methodology – concepts, methods, techniques and SPSS – texts and cases, Himalaya Publishing House, 2013
- Spikard James, Research Basics
- Mcburney, Donald, Research methods
- Hilary Glasman, Scientific research writing
- C. R. Kothari, Research methodology, methods and techniques
- Paul Leedy, Practical research planning and design

Paper Code: SIPSBN23
Chromatography & Spectroscopy-II

Course outcomes for Paper 3 (SIPSBN23): -

- Introduce students to High Performance Thin Layer Chromatography (HPTLC) and develop an understanding of it's principle, it's comparison with TLC, etc.
- Develop an understanding of High Performance Liquid Chromatography (HPLC) and Gas Chromatography (GC) in even further detail, particularly with respect to their types, detectors, applications, etc.
- Develop an understanding of the principles, instrumentation of other spectroscopy techniques (like Atomic Absorption Spectroscopy (AAS), Flame Photometry, etc.) and their importance/ applications.

Learning Objectives:

- ✓ *To familiarize students with HPTLC, HPLC, GC, AAS, ICP, CD, ORD, X-ray diffraction with emphasis being on instrumentation, its application and troubleshooting.*
- ✓ *To introduce students to Hyphenated techniques*

Unit 1: HPTLC **15 Lectures**

1.1 : Principles and Instrumentation
1.2 : HPTLC vs TLC
1.3 : Densitometry & quantitation in HPTLC
1.4 : HPTLC in fingerprinting & QC
1.5 : Troubleshooting
1.6 : Applications of HPTLC

Unit 2: HPLC - II **15 Lectures**

2.1 : Chiral HPLC
2.2 : Column switching in HPLC
2.3 : Gradient reverse-phase HPLC
2.4 : Column conditions
2.5 : Automation in HPLC

2.6 : HPLC detectors
   a) Introduction
   b) Principles of detection
   c) Universal and Specific Detectors
   d) Detector response
   e) Sensitivity considerations Selectivity

2.7 : Manual and Electronic data Processing
2.8 : Troubleshooting
2.9 : Applications of HPLC
2.10 : UPLC
2.11: LC
2.12 : 2D chromatography
2.13 : Preparative chromatography

Unit 3: GC - II **15 Lectures**

3.1 : Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD)
3.2 : Derivatization for GC
3.3 :GC strategy for analysis involving biological matrices
3.4 : Troubleshooting
3.5 : Applications

Unit 4: Spectroscopy - II **15 Lectures**

4.1 : Theory and applications of;
   a) Circular Dichroism (CD)
   b) Optical Rotary Dispersion (ORD)

4.2 : Emission spectroscopy
4.3 : Principles, instrumentation and applications of
   a)Flame photometry
   b) Atomic Emission Spectroscopy

4.4 : AAS
   a) Principles & Instrumentation
   b) Applications

4.5 : ICP
   a)Principles & Instrumentation
   b) Applications

4.6 : X – Ray diffraction
   a)Principles & Instrumentation
   b) Applications

References:

- Douglas A.Skoog, *Principles of Instrumental Analysis,* Saunders College Publishing
- Roy M.Harrison ,Spyridon Rapsomanikis ,*Environmental Analysis Using Chromatography Interfaced with Atomic Spectroscopy* ,Ellis Horwood Ltd
- James W.Robinson, *Practical Handbook of Spectroscopy,* Crc Press
- G.L.Moore, *Introduction to Inductively Coupled Plasma Atomic Emission Spectrometry*, Elsevier
- Richard D Beaty, Concepts, *Instrumentation and Techniques in Atomic Absorption Spectrophotometry*. Perkin-Elmer
- A-Knowles, C.Burgess, *Practical Absorption Spectrometry*,Chapman & Hall
- Takekiyo Matsoo, Richard M.Capridi, Michael L.Gross ,Yousuke Seyama, *Biological Mass Spectrometry Present and Future*, John Wiley and Sons
- Barbara Stuart, *Modern Infrared Spectroscopy* - ACOL, John Wiley and Sons
- Irving Sunshine, *Handbook of Spectrophotometric Data of Drugs*, CRC Press
- Douglas A.Skoog, Principles of Instrumental Analysis, Saunders College Publishing
- Chung Chow Chan, Y.C.Lee, Analytical Method Validation and Instrumental Performance Verification, Wiley Interscience

- Raymond P.W.Scott, Chromatographic Detectors Design Function Function and Operation, Marcel Dekker Inc
- D.J.David, Gas Chromatographic Detectors, John Wiley & Sons
- G.Subramanian, Preparative and Process Scale Liquid Chromatography, Ellis Horwood
- W.M.A.Niessen, Liquid Chromatography Mass Spectrometry 2nd ed, Marcel Dekker Inc
- Dr.P.D.Sethi, HPTLC High Performance Thin Layer Chromatography
- Garry D.Christian , Analytical Chemistry 5th ed ,John Wiley and Sons Inc
- Karel Eckschlager ,Klans Danzer,Information Theory in Analytical Chemistry ,John Wiley and Sons
- Chung Chow Chan, Y.C.Lee, Analytical Method Validation and Instrumental Performance Verification, Wiley Interscience

Paper Code: SIPSBN24

Drug development, Pharmacokinetics, Pharmacodynamics, Drug properties and Immunoassays

Course Outcomes paper 4 (SIPSBN24)

- To examine how a New Chemical /Molecular Entity becomes a drug invention and the different stages , approach of pharmaceutical industries and role of regulatory bodies involved in it.
- Examine immunoassays and ELISA and its applications
- Outline Pharmacokinetics and Pharmacodynamics concepts, terminologies, models and examine its role in drug properties
- Investigate Drug properties and be able to categories the Adverse Drug reaction or Serious Adverse Events.

Learning Objectives:

- ✓ *To introduce and familiarize students to the concept of New Chemical/ Molecular Entity and how it become a marketable drug.*
- ✓ *To familiarize students with basic concepts of Immunoassay and Eliza and its practical applications.*
- ✓ *To introduce students to various concepts of Pharmacokinetics and the ADME of drug*
- ✓ *To introduce the concept of pharmacodynamics and drug properties. Parameters, receptors, ligands and drug response involved.*
- ✓ *To introduce students to basic concept of drug, its formulation, concepts of drug metabolism, ADR and SAE*

Unit 1: Drug Invention and Pharmaceutical Industry **15 Lectures**

1.1: Sources of drugs (New Chemical Entity or New Molecular Entity)
- a) Small molecules are the tradition
- b) From Hits to Leads
- c) Importance of Large molecules

1.2: Targets of Drug Action
- a) Is the target drugable?
- b) Has the target been validated?
- c) Is this drug invention effort economically viable?

1.3: Preclinical research and trials

1.4: Clinical trials
- a) Role of the Drug Regulatory Authority/Agency
- b) The conduct of clinical trials
- c) Determining 'Safe' and 'Effective'

1.5: Public policy considerations and criticisms of the pharmaceutical industry
- a) Who pays?
- b) Drug promotion
- c) Product liability
- d) 'Me too' versus 'True Innovation' – the pace of new drug development

1.6: Personalized Medicine

Unit 2: Pharmacokinetics **15 Lectures**

2.1: Passage of drugs across membrane barriers
- a) Plasma membrane is selectively permeable,
- b) Modes of permeation and transport

2.2: Drug absorption and Routes of administration
- a) Absorption and Bioavailability,
- b) Routes of administration

2.3: Distribution of drugs
- a) Binding of drugs to plasma proteins,
- b) Tissue binding

2.4: Metabolism of drugs
- a) few principles of metabolism,
- b) First order kinetics,
- c)Zero order kinetics,
- d) Phases of drug metabolism,
- e) Sites of drug metabolism

2.5: Excretion of drugs
- a) Renal excretion,
- b) biliary and faecal excretion,
- c) excretion by other routes

2.6: Clinical pharmacokinetics
- a) Clearance,
- b) Volume of Distribution,
- c)Steady-State Concentration,
- d) Half-Life,
- e) Extent and Rate of Absorption
- f) Nonlinear Pharmacokinetics
- g) Design and Optimization of dosage regimens

Unit 3: Pharmacodynamics and Drug properties **15 Lectures**

3.1: Pharmacodynamic concepts
- a) Physiological receptors
- b) Specificity of drug responses
- c) Structure-Activity relationship and drug design
- d)Quantitative aspects of drug interactions with receptors
- e) Pharmacodynamic variability – individual and population pharmacodynamics

3.2: Mechanisms of drug action
- a) Receptors that affect concentration of endogenous ligands
- b) Drug receptors associated with extracellular processes
- c) Intracellular pathways activated by physiological receptors
- d)Structural and functional families of physiological receptors

3.3: General classification of Drugs and their formulations, Spurious and Misbranded drugs, Orphan drugs

3.4: Adverse Drug reactions (ADRs)

3.5: Serious Adverse Events (SAEs)

Unit 4: Immunoassay & ELISA **15 Lectures**

4.1: Introduction

4.2: Definitions

4.3: Theory

4.4: Requirements for immunoassay

4.5: Practical aspects

4.6: Requirements for immunoassay

4.7: Practical aspects

4.8: Data handling

4.9: Advantages of immunoassay

4.10: Principles and instrumentation in ELISA
4.11: Applications of ELISA
4.12: Types of Detection systems

References:

- Goodman and Gilmans, The pharmacological basis of therapeutics, Edited by Laurence Brunton and other, McGraw Hill Education, 2018
- Lippincotts Illustrated Reviews on Pharmacology, Edited by Richard Harvey, Lippincotts, Williams and Wilkins, 2008
- WHO, *Specification for the Identity and Purity of some enzymes and certain other substances*,W.H.O
- Richard A.Guarino, *New Drug Approval Process*, Marcel Dekker
- Michael G.Palfregman , Peter McCann ,Walter Lovenberg ,Joseph G.Temple ,Albert Sjoerdsrna
  Enzymes as Targets for Drug Design, Academic
- Alice J.Cunningham, *Introduction to Bioanalytical Sensors*, John Wiley and Sons
- Randoll C.Baset, *Advances in Analytical Toxicology* Vol 2, Year Book Medical Publishers
- Aspi F.Golwalla ,Sharukh A.Golwalla, *ABC of Medicine*, A.F.Golwalla
- Codric M.Smith, Alan M.Reynard, *Textbook of Pharmacology*, W.B.Saunders Comp
- Milo Gibaldi, *Biopharmaceutics and Clinical Pharmacokinetics* 4th ed., Lea and Febiger
- David B.Jack, *Handbook of Clinical Pharmacokinetic Data*, Macmillan Publisher
- Betram G.Katzung, *Basic and Clinical Pharamcology* 4th ed., Prentice-Hall
- Peter G.Welling, P*harmacokinetics*, Marcel Dekker
- Lily Y.Young,*Microbial Transformation and Degradation of Toxic*, Dermot Diamond, John Wiley & Sons
- M.D.B.Stephens, *Detection of New Adverse Drug Reactions*, Macmillan Publisher
- Ivan H.Stockley, Drug Interactions -*A Source Book of Adverse Interactions their Mechanisms Clinical Importance & Management*, Blackwell Scientific Publications
- Gene S.Gilbert, *Drug Safety Assessment in Clinical Trials*, Marcel Dekker

Semester II- Practical

Semester II – Practical I (SIPSBNP21) Based on SIPSBN21

1. SPE of a modern drug from formulation (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.
2. SPE of a modern drug from plasma (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.)
3. Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans, steroids and glycosides using TLC. Compare the results using standards (if available).
4. Preparation of Herbarium of following medicinal plants;
- **a)** *Asteracantha longifolia*
- **b)** *Trigonella foenum*
- **c)** *Clitoria ternatea*
- **d)** *Coriandrum sativum*
- **e)** *Achyranthes aspera*
- **f)** *Scoparia dulcis*
- **g)** *Amaranthus spinosa*
- **h)** *Phyllanthus amarus*
- **i)** *Calotropis gigantea*
- **j)** *Vitex negundo*

Individual student must **submit** herbaria of ANY THREE from the above list but in each institution herbarium of all the listed plants must be prepared.

5. Determination of percentage purity of CaCO3/MgCO3 by
- **a)**Titrimetry
- **b)** Complexometry
- **c)** IE chromatography

6. Comparison of classical and modern method of extraction of phytoconstituent of medicinal plants

7. Effect of drying on phytoconstituents. (Terpenes, alkaloids, tannins
8. Phytochemical variation within a species using HPLC/HPTLC

Semester II – Practical II (SIPSBNP22) Based on SIPSBN22

1. Students must submit a Report of the Industrial Visits including Presentation of the industrial visit.
2. Patent Claim Drafting
3. Accelerated stability studies of various formulations or drugs with respect to Temperature (b) Effect of buffers / pH dependent (2 – 4 Expts.)
4. Test for degradation of compounds using TLC for any two drugs.
5. Stability testing of solution and solid dosage forms for photo degradation. (2 experiments).
6. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
7. Stability studies of drugs in dosage forms at 25oC, 60% RH and 40oC, 75% RH and at different Pressure

Semester II –Practical III (SIPSBNP23) Based on SIPSBN23

1. 1. HPTLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
2. HPTLC fingerprinting of Herbal raw material (e.g. *Asteracantha longifolia, Ricinus communis, Calotropis gigantia*)
3. HPTLC detection of herbal raw material from its formulations (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Vitex nigundo* from PANCHGUN TAILA, *Glycyrrizha glabra* from ANU TAILA)
4. Gas Chromatographic separation of solutes from their matrix (e.g. Diclofenac sodium from its formulation, Methanol from plasma etc.)
5. Determination of Caffeine from a given sample by HPTLC
6. Preparation of calibration graphs for Li, Na, and K by flame Photometry using their solutions of appropriate concentrations and studying interference of

a. K in Na estimation

OR

b. Na in Li estimation

OR

c. Li in K estimation

Semester II – Practical IV (SIPSBNP24) Based on SIPSBN24

1. Immunoassay of HEPALISA in serum.
2. Immunoassay for HCG in urine
3. Immunoassay of T3 and T4 by RIA/IRMA
4. Calculation of different Pharmacokinetic parameters like Ka, Ke, t½, C max, Tmax and AUC from the given blood data.

M.Sc Part I in Bioanalytical Sciences Syllabus (Autonomous)
Credit Based Semester and Grading System
(With effect from academic year 2022-23)
Semester I and Semester II

Scheme of Examination

The performance of learners will be evaluated in two parts for the Theory component of the Course:
1. Internal Assessment with 40% marks
2. Semester End Examination (written) with 60% marks

The Practical component of the Course will be evaluated by conducting Semester End Practical Examination of 50 marks.

Internal Assessment Theory (40%)

It is the assessment of learners on the basis of continuous evaluation as envisaged in the Credit Based System by way of participation of learners in various academic and correlated activities in the given semester of the program.

Seminar Marks: 20

Evaluation will be conducted on the basis of Seminar/ Presentation given by the student on a topic chosen from the syllabus for each paper. The marking scheme shall be:

- Content of Presentation: **05 marks**
- Quality of Presentation: **05 marks**
- Presentation skills: **05 marks**
- Question-Answer discussion: **05 marks**

Assignment Marks: 20

Evaluation will be conducted on the basis of Research paper review / Book review / Poster presentation / Abstract writing / Preparation of Standard Operating Procedure or Calibration of Analytical Instruments for each paper.

Semester End Assessment Theory (60%)

Marks: 60
Duration: 2.5 hours
Theory question paper pattern:

- There shall be five questions of 12 marks each. On each unit there will be one question and the 5^{th} question will be based on the entire syllabus.
  OR
  There shall be four questions of 15 marks each, each question based on one unit.
- All questions are compulsory with internal choice within the questions.
- Questions may be subdivided and the allocation of marks depends on the weight age of the topic.

Semester End Assessment Practical

Marks: 50
Duration: 5 hours

****

SIES

College of Arts, Science & Commerce

RISE WITH EDUCATION

Sion (West), Mumbai – 400022

(Autonomous)

Faculty: Science

Program: M.Sc.-II

Subject: BIOANALYTICAL SCIENCES

Academic Year: 2020 – 2021

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

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

Preamble

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

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

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

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

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

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

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

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

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

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

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

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

Learning objectives

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

301.1 Basic Microbiology and its application in Pharmaceuticals (15)

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

301.2 Genomics (15)

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

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

301.3 Basic and Regulatory Toxicology (15)

Principles of toxicology – Different areas of toxicology – Descriptive, Mechanistic and Regulatory

Characteristics of Exposure – Duration of exposure, frequency of exposure, site of exposure and routes of exposure

Dose Response relationship – Individual/ Graded dose response relationships, Quantal dose response relationships, shape of dose response curves, Concept of LD_{50}, LC_{50}, ED_{50}, Therapeutic index, Margin of safety and exposure

Descriptive animal toxicity tests – Acute toxicity testing, Skin and Eye irritations, Subacute (Repeat-Dose Study), Subchronic, Chronic, Developmental and Reproductive toxicity

Absorption, Distribution and Excretion of toxicants – absorption of toxicants by gastrointestinal tract, lungs, skin; volume of distribution of toxicants, urinary excretion, fecal excretion.

Biotransformation of xenobiotics – xenobiotic biotransformation by Phase I enzymes and Phase II reactions (examples of carbon tetra chloride and acetaminophen).

Dose translation from animals to human – Concept of extrapolation of dose, NOAEL (No Observed Adverse Effect Level), Safety factor, ADI (Acceptable Daily Intake)

OECD guidelines for testing of chemicals

CPCSEA guidelines for animal testing centre, ethical issues in animal studies

Animal models used in regulatory toxicology studies

Alternative methods to animal testing in toxicology (in vitro / in silico approach)

Schedule Y and its interpretation

Case studies – Sulfanilamide, Thalidomide, Diethylstilbestrol, Saccharin

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

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

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

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

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

Learning objectives

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

302.1 MS basics (15)

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

302.2 Hyphenated techniques (15)

1. LC/MS and LC/MS/MS
2. GC/MS and GC/MS/MS
3. Scan events in TQ and other tandem systems and hybrid systems
4. ICP/MS and its applications in pharmaceuticals and food
5. Recent advances in the field of mass spectrometry
6. Introduction to Head space technology.

302.3 Thermal analysis (15)

1. Principles of Thermal Analysis
2. Instrumentation Requirements

3. Applications of Thermal Analysis

4. Thermal analysis of Bhasma preparations

5. Thermal Analysis Techniques

302.4 Bioanalytical Methods (15)

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

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

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

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

303.1 Standardization of ASU drugs (15)

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

303.2 General Statistical Methods (15)

1. Basic concepts of sample statistics

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

303.3 Concepts of Biostatistics (15)

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

303.4 Good Manufacturing Practices (15)

1. What is GMP?
2. Requirements of GMP implementation
3. Documentation of GMP practices
4. Regulatory certification of GMP
5. GMP in production of ASU drugs
6. Harmonization of SOP of manufacture
7. Audit for GMP compliances

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

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives:

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

304.1 Ethical Issues in Clinical Trials (15)

Subtopics:

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

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

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

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

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

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

304.4 Analytical Method Validation (15)

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

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

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

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

401.1 Title: Bio assays in Pharmaceutical evaluation (15)

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

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

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

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

401.3 Automation and analysis (15)

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

401.4 Capillary Electrophoresis (15)

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

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

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

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

metabolite studies

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

402.1 Applications of Quantitative Analysis (15)

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

402.2 Applications of Qualitative Analysis (15)

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

402.3 LC/MS/MS (15)

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

402.4 Tracer techniques in Bioanalytical assays (15)

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

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

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

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

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

403.1 Regulatory Aspects of ASU drugs (15)

1. National initiatives for regulation of ASU drugs
2. Schedule T and Schedule Y of Drugs and Cosmetics Act
3. International initiatives for regulation of ASU drugs with special reference to

- WHO guidelines on traditional medicine
- Approaches of US and EU to ASU drug regulation

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

403.2 Environmental Safety in Bioanalytical laboratory (15)

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

403.3 Electronic Data Management (15)

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

403.4 Regulatory Issues (15)

1. OTC drugs
2. Cosmetics

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

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

(Lecture allotment includes periods for Seminars and Discussions)

Learning objectives

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

404.1 Therapeutic drug monitoring and Pharmacovigilance (15)

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

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

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

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

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

404.4 QC and QA of ASU drugs (15)

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

M.Sc. Semester III PRACTICAL SIPSBNP 31

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

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

- Sterility testing (Microbial load) of drug formulations (According to IP 2013)
- CCl4 liver dysfunction in rats and evaluation using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out)
- LD 50 evaluation using a suitable model (e.g. *Daphnia* / rice weevil)
- Isolation & screening of industrially important microorganisms
- Sterility testing of laminar airflow bench top.
- Strain improvement by mutation (by UV radiation & Chemical mutagens)
- Central streak with Bacillus species isolated from soil

M.Sc. Semester III PRACTICAL SIPSBNP 32

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

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

M.Sc. Semester III PRACTICAL SIPSBNP 33

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

M.Sc. Semester III PRACTICAL SIPSBNP 34

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

i) Redox titration ii) Colorimetry

iii) Atomic Absorption Spectroscopy

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

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

M.Sc. Semester IV PRACTICAL SIPSBNP 41

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

M.Sc. Semester IV PRACTICAL SIPSBNP 42

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

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

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

M.Sc. Semester IV PRACTICAL SIPSBNP 43

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

M.Sc. Semester IV PRACTICAL SIPSBNP 44

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