SIES College of Arts, Science & Commerce (Autonomous)

RISE WITH EDUCATION

NAAC REACCREDITED - 'A' GRADE

(***Affiliated to University of Mumbai***)

Faculty: Science

Program: M.Sc. - I

Subject: Bioanalytical Sciences

Academic Year: 2023 – 2024

Revised Syllabus in Bioanalytical Sciences under
Choice Based Credit System (CBCS)
Approved by the Board of Studies in Bioanalytical Sciences
Effective from academic year 2023-24 under the aegis of
National Education Policy

Preamble

"Where the mind is without fear and the head is held high …."

— A poem written by Nobel Laureate Rabindranath Tagore (Nobel Prize in Literature in 1913), the poem represents Tagore's vision of a new and awakened India (it is quoted in this preamble in the context of National Education Policy – New Education Policy).

The implementation of India's National Education Policy 2020, the first education policy of the 21st century which aims to address the growing developmental imperatives of our country. Universal high-quality education is fundamental for achieving full human potential, besides developing an equitable and just society, and promoting national development. It is the best way forward for developing and maximizing our country's rich talents and resources which eventually will determine the future of our country. Therefore, in this context, the current backdrop of our institutions 'Empowered Autonomous Status' becomes all the more relevant, in terms of our contribution as an educational institution to 'Achieving the full potential of every student'.

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'. One of the ways to achieve this is through fine-tuning the curriculum. Thus, in addition to enable students to acquire an in depth knowledge of the Core/Mandatory subject, the current syllabus also attempts to integrate a few courses under Department Specific Electives, which will help students to be equipped with the necessary skills to enhance their core competencies in understanding synergism of pure and applied sciences, in order to make them self-sufficient and build a future. Some of the key features of this revised syllabus are as follows:-

- ✓ *Industry Internship / Apprenticeship / On Job Training – A course requiring students to participate in a professional activity or work experience, with an entity external to the educational institution. Internships will involve working with local industry, government or private organizations, etc. to provide opportunities for students to actively engage in on-site experiential learning. Moreover, it will also strengthen academia-industry linkage and increase employability of students.*
- ✓ *Research Methodology – A course requiring students to inculcate research aptitude, enhance research skills and adapt to research culture, to develop an open, inquiring mind that is willing to explore new territories and learn new things. It will also encourage the spirit of curiosity of students, who are also potential problem solvers and scientific investigators in their own way. It will also nurture critical thinking and develop analytical reasoning amongst students. Moreover, this course will serve as a stepping stone/foundation for execution of a Research Project in their final year.*
- ✓ *Drug invention and Pharmaceutical Industry, Pharmacokinetics, Pharmacodynamics and Drug properties – A course that has 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) – A course which 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.*
- ✓ *Department Specific Elective in the form of Chromatography and Spectroscopy - A course which has been restructured, whereby, it will give the students exposure to the vast arena of technological improvements in method development and method validation of drugs in pharmaceutical industries.*

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

In conclusion, we hope this syllabus will inculcate an interdisciplinary approach in students and develop a mind for scientific inquiry aspiring to explore new dimensions of the subject. Moreover, this syllabus will also encourage and maximize learning among students to develop open, inquiring minds for holistic development thereby justifying the essence and spirit of National Education Policy.

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Chairman
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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)*

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

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

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

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

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

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

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

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M.Sc. Part I – Bioanalytical Sciences – Semester I (Syllabus Grid)

THEORY			
Course name and code	**Unit**	**Topic Headings**	**Credits**
SEMESTER I			
A) Major			
a) Mandatory/Core Papers			
Paper I: Different Medicinal Systems, Phytochemistry and Extraction Techniques			
SIPBACC511	1	Indian Systems of Medicine (ASU) – Ayurveda, Siddha & Unani	**4**
	2	Modern Medicine	
	3	Phytochemistry	
	4	Principle of extraction and Isolation of analytes	
Paper II: Basic Microbiology, Proteomics and Bioinformatics			
SIPBACC512	1	Basic Microbiology	**4**
	2	OMICS	
	3	Electrophoresis	
	4	Bioinformatics	
Paper III: Quality Management and Biostatistics			
SIPBACC513	1	Quality Management	**2**
	2	Biostatistics	
b) Electives			
Paper IV: Chromatography and Spectroscopy – I			
SIPBAEL511	1	Theory of Chromatographic Separation and TLC	**3**
	2	HPLC and GC	
	3	Spectroscopy	
B) Research Methodology			
Paper V: Research Methodology			
SIPBARM511	1	Basic concepts in research, research methods and methodology	**3**
	2	Scientific research writing, research review and research ethics	
	3	Research grants, funding agencies and research projects	
PRACTICAL			
SIPBACCP511	1	Based on Core course-1 (SIPBACC511)	**2**
SIPBACCP512	2	Based on Core course-2 (SIPBACC512)	**2**
SIPBAELP511	3	Based on DSE (SIPBAEL511)	**1**
SIPBARMP511	4	Based on RM (SIPBARM511)	**1**
		Total	**22**

M.Sc. Part I – Bioanalytical Sciences – Semester II (Syllabus Grid)

THEORY			
Course name and code	**Unit**	**Topic Headings**	**Credits**
SEMESTER II			
A) Major			
a) Mandatory/Core Papers			
Paper I: Indian Pharmaceutical Industry, Stability Studies, Packaging and Extraction Techniques			
SIPBACC521	**1**	Research and Development in Pharma industry and Recent trends in Indian Pharmaceutical Industry	**4**
	2	Stability Studies	
	3	Packaging in Pharmaceutical Industry	
	4	Solid Phase Extraction (SPE), Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography)	
Paper II: Drug Development, Pharmacokinetics, Pharmacodynamics, and Immunoassays			
SIPBACC522	**1**	Drug Invention and Pharmaceutical Industry	**4**
	2	Pharmacokinetics	
	3	Pharmacodynamics and Drug Properties	
	4	Immunoassay & ELISA	
Paper III: Intellectual Property Rights, Drug Act and Pharmacopeial Standards			
SIPBACC523	**1**	IPR and Patenting	**2**
	2	Drug Act and Pharmacopeial Standards	
b) Electives			
Paper IV: Chromatography and Spectroscopy - II			
SIPBAEL521	**1**	HPTLC	**3**
	2	HPLC and GC	
	3	Spectroscopy	
B) On Job training or Field project			
Paper V: On Job Training			
SIPBAOJ521	**1**	**No Theory Paper**	**-**
PRACTICAL			
SIPBACC521	**1**	Based on Core course-1 (SIPBACC521)	**2**
SIPBACCP522	**2**	Based on Core course-2 (SIPBACC522)	**2**
SIPBAELP521	**3**	Based on DSE (SIPBAEL521)	**1**
SIPBAOJP521	**4**	Based on OJ (SIPBAOJ521)	**4**
		Total	**22**

MSc – Part I - Bioanalytical Sciences Syllabus - Semester I

CORE / MANDATORY PAPER 1: SIPBACC511

Different Medicinal Systems, Phytochemistry and Extraction Techniques

Theory Credits	Practical Credits
4	2

Course Outcomes	• To be able to 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 their significance in theprocess of standardization and characterization. • To gain an insight into the various naturally occurring metabolites, their synthesis, and applications, to develop an understanding of the interconnectedness of the various metabolic pathways and learn the various techniques for extraction of these metabolites • Investigate various extraction techniques involving in isolation of analytes of interest.
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. Introduce students to the basics of Phytochemistry, plant metabolites, their classification, anddifferent extraction techniques.* ✓ *Introduction to various theoretical concepts related to drug formulation extraction and isolation*

Unit 1 **15 Lectures**

Indian Systems of Medicine (ASU) – Ayurveda, Siddha & Unani

- Traditional Medicinal Systems in India, its Principles and Practice (*History and current scenario, Diagnosis and Treatment*)
- Different types of drug formulations (*At least 4 from each branch in detail)*
- Methods of manufacture – raw material to finished product (*AYUSH Guidelines*)
- Excipients in various dosage forms (*What are excipients, excipients used in ASU drugs, and generaldosage of ASU drugs*)

Unit 2 **15 Lectures**

Modern Medicine

- Principles and Practice of Modern Medicinal System (*History and current scenario, basic principles*)
- API and concept of formulation, Various types of drug formulations and dosage forms (*Definition, difference between API andformulation w.r.t to WHO guidelines. API and dosage general concept*)
- Excipients in various dosage forms (*Definition of excipient, its role in formulation and*

dosage)

- Disease management: Comparison of ASU and Modern Drugs in case of Diabetes, Tuberculosis, Hypertension, Hepatitis, Malaria, Dengue, Influenza (any four diseases)

Unit 3 **15 Lectures**

Phytochemistry

- Introduction to Plants and their medicinal uses
- Concept of ethnobotany, ethnomedicines, and pharmacology *(definition and general concept*)
- Phytogeographical regions to be explained with respect to endemism and hot spots in India *(Understanding concepts of endangered plants, endemic plants and hot spots)*
- Herbaria and its role in drug preparation *(Steps involving Plant collection, Authentication, storage and drying techniques. Role of BSI)*
- Raw material evaluation, concept of Microbial load, Raw material characterization, proximate evaluation, photomicrography
- Introduction to concept of GAP and GHP for medicinal plants (*based on Guidelines by WHO and AYUSH*)
- Natural drug substances from plants (primary and secondary metabolites)
- Broad classification of secondary metabolites (Nitrogenous, Non-nitrogenous, Isoprenoids)
- Secondary drug metabolite production with special reference with integrated pathways
- Key factors affecting synthesis of secondary metabolites including choice of solvent for extraction of phytoconstituents
- Extraction Techniques of crude plant material w.r.t maceration, percolation, steam distillation

Unit 4 **15 Lectures**

Principle of extraction and Isolation of analytes

- Introduction to Physico-chemical properties of drugs and solvents
- Concept of Partition & Partition Coefficient
- Solvent properties
- Selection of solvent
- Extraction efficiency
- Introduction to classical methods of extraction
- Introduction to modern methods of extraction- advantages & disadvantages - Include LLE (Soxhlet) andLME
- Applications of extraction
- Microwave-assisted extraction its advantages and disadvantages

- Ionization and its effect on the extraction of drugs
- The 'First law of drug metabolism'
- Matrix components & analyte isolation
- Concentration of extracts
- Isolations of fractions
- Purification of isolate

References:

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- Prof. (Mrs) Asima Chatterjee, Dr.Satyesh Chandra Prakash, *The Treatise on Indian MedicinalPlants* 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
- 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
- Prof. Dr.F.C.Czygan, D.Frohne, C.Hohxel, A.Nagell, H.J., Pfainder, G.Willuhn , W.Buff, HerbalDrugs and Phytopharmaceuticals, CRC Press
- 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 Fundamentalsand Applications*, Marcel Dekker Inc

CORE /MANDATORY PAPER 2: SIPBACC512

Basic Microbiology, Proteomics and Bioinformatics

Theory Credits	Practical Credits
4	2

Course outcomes	• Examine various basic microbiological concepts and techniques and its application in Pharmaceuticals • 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
Learning Objectives	✓ *To understand the basics of microbiology and recognize its application in pharmaceuticals* ✓ *To provide students with basic insights to the terms "OMICS". To make studentsunderstand 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 usingtools like Bioinformatics.*

Unit 1 **15 Lectures**

Basic Microbiology and its Application in Pharmaceuticals

- Microbes & their environment, significance and scope of microbiology, biodiversity and types of microorganisms, visualization of microorganisms: staining, simple and compound microscopy, Electron Microscopy
- Growth of microorganisms, methods to study the growth of microorganisms, preservation of microorganisms, maintenance media, etc.
- 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)
- 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

Unit 2 **15 Lectures**

OMICS

- Introduction to Omics:

a. Central Dogma of Molecular Biology

b. Genomics

c. Proteomics

d. Metabolomics

e. Lipidomics (*basic introduction and application*)

- 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

Unit 3 **15 Lectures**

Electrophoresis

- Principles of electrophoretic separation
- Equipment and process (electrophoretic apparatus)
- Agarose Gel Electrophoresis
- PAGE – Native & SDS, 2DGE, Extensions of Electrophoresis for example Immuno-electrophoresis/pulse-field
- Standardization of electrophoretic technique
- Detection techniques
- Applications of electrophoresis

Unit 4 **15 Lectures**

Bioinformatics

- What is bioinformatics?
- Databases and Search Tools
- Applications of bioinformatics

a. Genomics

b. Proteomics

c. Drug discovery (Docking software)

- Using various libraries & tools w.r.t structure/ literature to drug development/ proteins
- Introduction to Chemi-informatics
- **"**Introduction to Internet of Things"

a. Overview of Internet of Things

b. Applications of Internet of Things in Health sector (Clinical Practice and Patient Managementalong with case studies)

c. Advantages and Challenges associated with use of Internet of Things in Health Sector in India

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

CORE / MANDATORY PAPER 3: SIPBACC513

Quality Management and Biostatistics

Theory Credits	Practical Credits
2	-

Course Outcomes	• Introduce students to the regulatory aspects of the pharmaceutical industry like GLP,Pharmacopoeias, QA/QC, etc • 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 testingand dissolution testing. • Compare various types and sources of Bioanalytical Laboratory wastes, its handling, control andregulations and inspect the environmental issues associated with it. • To familiarize students with fundamentals of Biostatistics
Learning Objectives	✓ *To familiarize students with basic concept of Good Laboratory Practices, Laboratory SafetyMeasures, Drug Acts.* ✓ *To reintroduce students with some of the basic Quality Control techniques and introduce somenew ones like Friability, Dissolution, etc.* ✓ *To understand environmental issues related to Bioanalytical laboratory, rules and regulationsto be followed.* ✓ *To introduce students to basic concepts and applications of general statistics methods and to make them competent in Biostatistics*

Unit 1 **15 Lectures**

Quality Management

- What is GLP? (*Definition, importance)*
- Practicing GLP and Guidelines to GLP
- Documentation of Laboratory work
- Preparation of Standard Operating Procedure (SOP)and Calibration records
- Significance of validation in GLP
- Transfer of methods
- Documentation of results
- General Precautions, labels and signage
- Material handling and disposal, Material Safety Data Sheets (MSDS) , GHS
- Safety Practices: Personal safety & Clothing, Levels of safety, Fire safety and fire fighting, Working in Biosafety Cabinets and hoods
- Introduction to Quality Control (QC) and Quality Assurance (QA)
- Requirements for implementing QC & QA, QC & QA concepts in ASU drugs
- Standardizing an Analytical method (including the concept and steps involved in standardization of an analytical method
- Introduction to some basic Quality Control (QC) techniques: - (such as pH meter, Karl-Fischer (KF) Titration, Friability Testing, Hardness Testing, Disintegration Testing and Dissolution Testing
- Introduction to validation and it's types, Audit requirements, audits and audit reports
- Personnel Responsibility in QA
- Introduction to Types and Sources of Bioanalytical Laboratory waste
- Chemical & Biological materials: Hazards and Handling (including Chemical Storage and Segregation, Chemical Laboratory Emergency Response, Equipment Safety, Laboratory Inspections, Transportation and Receiving of Hazardous Materials)
- Hazard Controls & Information (Workplace Hazardous Materials Information System {WHMIS} asexample)
- Introduction to: Regulations of Pollution Control Board for Laboratories.

Unit 2 **15 Lectures**

Concepts in Statistics and Biostatistics

- Basic concepts of sample statistics (Mean, Median, Mode, Standard Deviation)
- Concept of sample size and power
- Concept of randomization and sampling techniques
- Concept of significance and confidence limits

- Introduction to Various statistical tests - parametric and non-parametric
- Use of Statistical Packages for Data evaluation
- Concept of level of significance, power of test and confidence limits
- Application of normal distribution Statistical approach to biological samples
- Introduction to Data collection techniques
- Design of experiments, for e.g. Block designs, Latin square
- COV and ANOVA (one way ANOVA and two way ANOVA)
- Concept of correlation, coefficient of correlation and its calculation by using Pearson's coefficient of correlation
- Regression analysis with application to Standard Graph
- Nonparametric tests with examples (Sign Test, Run Test, Kruskal Wallis Test, Spearman's rank coefficient of correlation)
- Statistical Guidance from regulatory agencies
- Student's t-test, chi square test, z test, and f test
- Use of statistical packages for data analysis and an introduction to SAS and SPSS

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- Central Pollution Control Board Guidelines
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- Le, Chap T. (2003) Introductory Biostatistics. Hoboken: John Wiley & Sons, Inc.

ELECTIVE PAPER: SIPBAEL511

Chromatography & Spectroscopy - I

Theory Credits	Practical Credits
3	1

Course Outcomes	• 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 likechromatography and spectroscopy.
Learning Objectives	✓ *Introduce students to analytical chemistry and Instrumentation.* ✓ *To make students understand general concept of Chromatography and Spectroscopy in terms ofprinciple and instrumentations involved.* ✓ *To introduce students to chromatographic techniques along with its application in Thin LayerChromatography. Familiarize students with all components of Thin Layer Chromatography.* ✓ *To understand general concepts of HPLC along with its instrumentation and various types Recentdevelopment 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 followprinciples of spectroscopy*

Unit 1 **15 Lectures**

Theory of Chromatographic Separation and TLC

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

Unit 2 **15 Lectures**

HPLC and GC- I

- Principles and Instrumentation of HPLC
- The chromatographic process
- The chromatogram
- Separation mode
- Column chemistry
- System parameters
- Reverse-phase HPLC
- Introduction to various HPLC techniques:

a. Ion-pair HPLC

b. Ion-exchange HPLC

c. Normal-phase HPLC

d. Affinity Chromatography

e. Gel permeation Chromatography

- ❋ Recent advances (Fast LC, online extractions, add on pumps, online derivatization, multi-dimensional LC)
- ❋ Principles and Instrumentation of GC
- ❋ Factors that affect the chromatographic separation (Temperature, Type of column etc.)
- ❋ GC techniques
- ❋ Types of columns and their application
- ❋ Selection of liquid stationary phases (Packed and capillary columns)
- ❋ GC hardware

a. Introduction to flow and pressure controllers

b. Injection techniques- on column injection, large volume injection, split - split less, PTVand various auto injectors- gas sampling as well as liquid sampling

c. Column Oven- temperature programming, (High /cryogenic oven temperature)

Unit 3 **15 Lectures**

Spectroscopy- I

- ❋ Introduction to atomic and molecular Spectroscopy (*Differences between the two*)
- ❋ UV, Visible and fluorescence
  - **a.** Principles & Instrumentation
  - **b.** Applications
- ❋ Nephelometry
  - **a.**Principles & Instrumentation
  - **b.** Applications
- ❋ Turbidometry
  - **a.** Principles & Instrumentation
  - **b.** Applications
- ❋ IR
  - **a.** Principles & Instrumentation
  - **b.** Applications
- ❋ FTIR
  - **a.** Principles and Instrumentation
  - **b.** Applications
- ❋ Basic concepts of NMR spectroscopy
- ❋ Raman spectroscopy

References:

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- ❖ Robert White, *Chromatography / Fourier Transform Infrared Spectroscopy and its Applications*,
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- 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
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- H.Wagner, S.Bladt , Zgainski, Plant Drug Analysis A Thin Layer Chromatography Atlas, SpringerVeriag

RESEARCH METHODOLOGY: SIPBARM511

Theory Credits	Practical Credits
3	1

Course Outcomes	• Inculcate research aptitude and to develop analytical skills amongst students • Encourage interdisciplinary approach and critical thinking amongst students • Inspire and motivate students to think of research as one of the career option
Learning Objectives	✓ *To inculcate in students 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, in order to develop the potential to be problem solvers and scientific investigators in their own way.* ✓ *To develop and enhance their research skills in order to make them adapt to the research culture* ✓ *To nurture critical thinking and develop analytical reasoning amongst students* ✓ *To equip students with essential concepts and necessary skills for execution of a research project in their final year*

Unit 1 **15 Lectures**

Basic concepts in research, research methods and methodology

- Basic concepts in research - meaning of research, objectives of research, characteristics and purposes of research, significance and relevance of research
- Research process or the process of Science – Scientific inquiry, Steps of scientific inquiry or flow diagram for the scientific method, Observation, Developing and Testing Hypothesis, Inductive reasoning, Predictions & Experiments, Deductive reasoning, Presenting & Analyzing the data, Scientific theory, Example / Case study of the Scientific method, Example / Case study of Hypothesis testing.
- Types of research – fundamental research, applied research, translational research, etc and comparison of types of research – descriptive versus analytical, fundamental versus applied, qualitative versus quantitative, conceptual versus empirical; research methods versus research methodology.
- Research problem – meaning and statement of research problem, formulating research problem, identification and selection of research problem, techniques involved in defining a research problem, types of variables (experimental and control groups etc)
- Research design – meaning of research design, nature and importance of research design, concepts related to research design, types of research design, experimental designs for examples – informal experimental design, formal experimental design etc.
- Methods of data collection, data presentation and data analysis – types of data (primary and secondary data), data collection methods (primary and secondary), tabulation and presentation of data, Hypothesis testing – overview of parametric test, non-parametric tests

(chi-square test, analysis of variance, non-parametric tests), overview of multivariate analysis techniques (correlation analysis, regression analysis).

Unit 2 **15 Lectures**

Scientific research writing, research review and research ethics

- Report writing – meaning of report, meaning of research report and report writing, different steps in report writing, characteristic of report, significance of report
- 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), overview of science communication organisations/companies or forums, opportunities as professional writers (examples such as Cactus Communications, India BioScience Newsletter etc).
- Literature review – Introduction to literature review, steps in writing a literature review, relevance of literature review, primary research article/original research article, secondary research article/review article.
- Research review and journals – critique and review of research paper/manuscript, overview of types of research journals and publications (examples of peer-reviewed, open access journals) relevance of impact factor, h-index, citations, overview of ResearchGate (professional network for researchers and scientists)
- Model organisms in research and guidelines – Concept of model organisms, recommended laboratory animal models, Purpose bred species, Animal study design/preclinical trials, Organization for Economic Cooperation and Development (OECD) guidelines, Committee for Control and Supervision of Experiments on Animals (CCSEA) guidelines, Alternative to animal models.
- Research ethics – Avoiding plagiarism, Awareness of misconduct or fraud, Acknowledgement / Declaration of conflict of interest; Plagiarism checker software (Examples – Turnitin, Urkund etc); Overview of composition and responsibilities of Institutional Animal Ethics Committee (IAEC), Overview of composition and responsibilities of Institutional Ethics Committee (IEC), Overview of Indian Council of Medical Research guidelines (ICMR) for Biomedical research, Overview of International Conference on Harmonization – Good Clinical Practices (ICH-GCP) guidelines.

Unit 3 **15 Lectures**

Research grants, funding agencies and research projects

- Research grants/funds – concept of getting research grants or funds or research projects.
- Research projects – writing a research proposal / project; components of research

proposal/project; major/minor research projects (University Grants Commission, University of Mumbai etc), components of research grants (for example - consumables, contingency grants, utilization certificate etc)

- Funding agencies in India – overview of government and nongovernment funding agencies in India (Examples such as Department of Science & Technology; Department of Biotechnology; Indian Council of Medical Research; Council of Scientific & Industrial Research; Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homeopathy; Indian National Science Association; etc);
- Research fellowships in India – concept of research fellowship, research fellows – junior research fellow, senior research fellow, research associate etc; Examples of fellowships – Prime Ministers Research Fellowship, ICMR JRF, CSIR-UGC JRF, DBT-JRF, TATA Innovation Fellowships, DST- INSPIRE, DBT- Ramanujan fellowships etc.
- Global funding agencies/Research fellowships worldwide – overview of international funding agencies, how to apply to global funding agencies, examples such as Fulbright Program, United States India Educational Foundation (USIEF), British Council Fellowship, Humbolt Research Fellowship etc.

References

- Research Methodology: Methods and Techniques; C.R. Kothari; Wiley Eastern Ltd. Mumbai
- Priti Majhi, Prafull Khatua, Research methodology – concepts, methods, techniques and SPSS – texts and cases, Himalaya Publishing House, 2013
- George Thomas, Research Methodology and Scientific Writing, Ane Books Pvt. Ltd, 2019
- Nicholas Walliman, Research Methods – the basics, Routledge, 2011
- 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
- Research Basics - Spikard James,
- Research methods - Mcburney, Donald,
- Research methodology in medical and biological sciences - Peter Laake, Benestad
- The craft of research - Wayne Booth
- Research design: Qualitative, Quantitative and Mixed Methods Approaches - John Crewel
- Introducing Research Methodology: A Beginner's Guide to Doing a Research Project - Uwe Flick
- Research Methods A Practical Guide for Students and Researchers - Willie Tan
- A Manual for Writers of Research Papers, Theses, and Dissertations, Ninth Edition: Chicago Style for Students and Researchers (Chicago Guides to Writing, Editing, and Publishing - Kate L. Turabian
- Writing scientific research articles - Margaret Cargill
- Writing a Postgraduate Thesis or Dissertation – Hammond, Michael

MSc – Part I - Bioanalytical Sciences Syllabus - Semester II

CORE / MANDATORY PAPER 1: SIPBACC521

Indian Pharmaceutical Industry, Stability Studies, Packaging and Extraction Techniques

Theory Credits	Practical Credits
4	2

Course outcomes	• 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 • Identify and recommend various strategies for stability studies for different formulations • Examine the role of packaging in pharmaceutical industries. • Introduce students to Solid Phase Extraction (SPE) and develop an understanding of its history, thevarious steps in SPE, etc • 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 outcomes	✓ *To understand the dynamics of the Pharmaceutical industry. Current trends, government policies and parameters affecting the Pharmaceutical industry in India.* ✓ *To teach students the importance of drug stability and stability study trends for ASU drugs* ✓ *To familiarize students with packaging in Pharmaceutical Industry with respect to needs,rules and regulations.* ✓ *Understanding basics of Solid Phase Extraction, strategies involved, methods andcurrent development.* ✓ *Introduce students to Super Critical Extraction, its basic concepts, instrumentation andfactors affecting it, benefits and future prospects.*

Unit 1 **15 Lectures**

R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry.

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

Unit 2 **15 Lectures**

Stability Studies

- Factors that influence the stability of drug formulations
- Types of Stability chambers and their design considerations
- Stability issues of ASU raw materials and finished products
- Guidelines on Stability evaluations
- Approaches to stability studies of ASU formulations

Unit 3 **15 Lectures**

Packaging in Pharma Industry

- Introduction to Packaging
- Fundamentals of Distribution
- Packaging Forms & their Significance
- Packaging Materials (covering basic manufacturing process, applications and significance)
- Paper, Paper Board and CFB Glass, metals, Basic Polymer-based materials, Polymer-based compositematerials
- Ancillary Mats
- Package Material Testing
- Compatibility & Migration Studies
- Accelerated Shelf Life Testing - Theory and Problems
- GMP
- Packaging Validation
- Packaging Laws and regulatory compliance
- Labelling and Inserts

Unit 4 **15 Lectures**

Solid Phase Extraction (SPE), Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography)

- Introduction to SPE
- General properties of bonded silica sorbents
- Sorbent/analyte interactions
- Sample pretreatment of different biological matrices
- Developing SPE methods
- Example of an SPE method (introduction of SPME)
- Disc cartridges
- 96-Well Format (e.g. Porvair Microsep TM system)
- Direct injection of plasma

- Other new developments
- The concept of SCFE & SCFC
- Instrumentation of SCFE & SCFC
- Factors affecting SCFE & SCFC
- Benefits of SCFE & SCFC
- Application of SCFE for natural products and Application of SCFC
- Conclusions and future perspectives

References

- Larry T. Taylor, *Supercritical Fluid Extraction*, John Wiley and Sons
- Jens T. Carstensen, *Drug Stability Principles & Practices* 2nd e.d.,Marcel Dekker
- Richard Friary, *Jobs in the Drug Industry*, Academic Press
- Kenneth A.Connors, Gordon L.Amidon, Valentino J.Stella, Chemical Stability of *Pharmaceuticals*, John Wiley & Sons

CORE / MANDATORY PAPER 2: SIPBACC522

Drug Development, Pharmacokinetics, Pharmacodynamics, and Immunoassays

Theory Credits	Practical Credits
4	2

Course Outcomes	• To examine how a New Chemical /Molecular Entity becomes a drug invention and the differentstages, approaches of pharmaceutical industries and the role of regulatory bodies involved in it. • Examine immunoassays and ELISA and their applications • Outline Pharmacokinetics and Pharmacodynamics concepts, terminologies, and models and examine their role in drug properties • Investigate Drug properties and be able to categorize the Adverse Drug reaction or Serious Adverse Events.
Learning Outcomes	✓ *To introduce and familiarize students to the concept of the New Chemical/ Molecular Entity and howit become a marketable drug.* ✓ *To familiarize students with basic concepts of Immunoassay and ELISA and theirpractical 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 **15 Lectures**

Drug Invention and Pharmaceutical Industry

- ❋ Sources of drugs (New Chemical Entity or New Molecular Entity)
- ❋ Small molecules are the tradition
- ❋ From Hits to Leads
- ❋ Importance of Large molecules
- ❋ Targets of Drug Action

a. Is the target drugable?

b. Has the target been validated?

c. Is this drug invention effort economically viable?

- ❋ Preclinical research and trials
- ❋ Clinical trials

a. Role of the Drug Regulatory Authority/Agency

b. The conduct of clinical trials

c. Determining 'Safe' and 'Effective'

- ❋ 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

- ❋ Personalized Medicine

Unit 2 **15 Lectures**

Pharmacokinetics

- ❋ Passage of drugs across membrane barriers

a. Plasma membrane is selectively permeable,

b. Modes of permeation and transport

- ❋ Drug absorption and Routes of administration

a. Absorption and Bioavailability,

b. Routes of administration

- ❋ Distribution of drugs

a. Binding of drugs to plasma proteins,

b. Tissue binding

- ❋ 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

❋ Excretion of drugs

a. Renal excretion,

b. biliary and faecal excretion,

c. Excretion by other routes

❋ Clinical pharmacokinetics

a. Clearance,

b. Volume of Distribution, Steady-State Concentration

c. Half-Life,

d. Extent and Rate of Absorption,

e. Nonlinear Pharmacokinetics,

f. Design and Optimization of dosage regimens

Unit 3 **15 Lectures**

Pharmacodynamics and Drug Properties

❋ 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

❋ Mechanisms of drug action

a) Receptors that affect the concentration of endogenous ligands

b) Drug receptors associated with extracellular processes

c) Intracellular pathways activated by physiological receptors

d) Structural, functional families of physiological receptors

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

❋ Adverse Drug reactions (ADRs)

❋ Serious Adverse Events (SAEs)

Unit 4 **15 Lectures**

Immunoassay & ELISA

- Introduction
- Definitions
- Theory
- Requirements for immunoassay
- Practical aspects
- Data handling
- Advantages of immunoassay
- Principles and instrumentation in ELISA
- Applications of ELISA
- 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 MechanismsClinical Importance & Management*, Blackwell Scientific Publications
- Gene S.Gilbert, *Drug Safety Assessment in Clinical Trials*, Marcel Dekker

CORE / MANDATORY PAPER 3: SIPBACC523

Intellectual Property Rights, Drug Act and Pharmacopeial Standards

Theory Credits	Practical Credits
2	-

Course Outcomes	• Illustrate IPR and Patenting terminologies with a perspective of India's stature in the World • Identify and assess IPR and Patents and be able to compose a patent claim. • Make the students develop an understanding of some of the regulatory guidelines in thepharmaceutical industry, both in India and around the world.
Learning Objectives	✓ *To familiarize students with IPR, Patenting. Basic concepts of TRIPS, International Agreements and current scenario.* ✓ *To introduce students to Pharmacopoeias, 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 provide insights on IPR with respect to India and world.*

Unit 1 **15 Lectures**

IPR and Patenting

- ❋ Concept of IPR - Understanding the meaning of IPR & its significance in knowledge-based economy.
- ❋ Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, GeographicalIndications, Protection of New Plant Varieties, Copyright.
- ❋ Global Harmonization - Impact of IPR on global trade and the need for harmonization, WTO and its rolein 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 the ever-greening of patents.

c. Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance.

- ❋ IPR as a strategic tool –

a. Concepts of piracy, reverse engineering, and knowledge worker.

b. Benefits of creating and/or owning patents and other IPRs.

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

a. Indian Patent Act -

b. Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step,

useful/capableof industrial application.

c. Non-patentable subject matter - what is not patentable.

d. Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, and servicing of patents.

e. Provisional Patents, Divisional Patents & Patents of Addition.

f. Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check

Unit 2 **15 Lectures**

Drug Act & Pharmacopeial Standards

- Indian Drugs and Cosmetics Act w.r.t Schedule Y, M, H. Include Schedule A, S (introduction)
- Introduction to foreign guidelines w.r.t US, EU, Australia & Japan
- Introduction to CFR 21 part 11
- Current guidelines in the pharmaceutical industry (Indian and also global)
- Introduction to WHO guidelines
- Introduction to Pharmacopoeias IP, BP, USP (JP, EP, AP where ever applicable)
- Specified test in Monographs w.r.t liquid formulation (injectable) and solid dosage form (USP, EP, BP,IP)
- Include AP, Indian HP and AFI (wherever applicable)

References

- 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 Publishers.
- Dr. V .Rajpal, Standardization of Botanicals Vol I, Eastern Publishers
- H .Jackson Knight, *Patent Strategy for Researchers and Research Managers* 2nd ed, John Wiley

ELECTIVE PAPER: SIPBAEL521

Chromatography and Spectroscopy – II

Theory Credits	Practical Credits
3	1

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

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

Unit 1 **15 Lectures**

HPTLC

- Principles and Instrumentation
- HPTLC vs TLC
- Densitometry & quantitation in HPTLC
- HPTLC in fingerprinting & QC
- Troubleshooting
- Applications of HPTLC

Unit 2 **15 Lectures**

HPLC and GC -II

- Chiral HPLC
- Column switching in HPLC
- Gradient reverse-phase HPLC
- Column conditions
- Automation in HPLC
- HPLC detectors

a. Introduction

b. Principles of detection

c. Universal and Specific Detectors

d. Detector response

e. Sensitivity considerations Selectivity

- Manual and Electronic data Processing
- Troubleshooting
- Applications of HPLC
- UPLC
- LC
- 2D chromatography
- Preparative chromatography
- Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD)
- Derivatization for GC
- GC strategy for analysis involving biological matrices
- Troubleshooting

- ❋ Applications

Unit 3 **15 Lectures**

Spectroscopy- II

- ❋ Theory and applications of;

a. Circular Dichroism (CD)

b. Optical Rotary Dispersion (ORD)

- ❋ Emission spectroscopy
- ❋ Principles, instrumentation and applications of

a. Flame photometry

b. Atomic Emission Spectroscopy

- ❋ AAS

a. Principles & Instrumentation

b. Applications

- ❋ ICP

a. Principles & Instrumentation

b. Applications

- ❋ 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 AtomicAbsorption Spectrophotometry*. Perkin-Elmer
- ❖ A-Knowles, C.Burgess, *Practical Absorption Spectrometry*,Chapman & Hall
- ❖ Barbara Stuart, *Modern Infrared Spectroscopy* - ACOL, John Wiley and Sons
- ❖ Irving Sunshine, *Handbook of Spectrophotometric Data of Drugs*, CRC Press
- ❖ Chung Chow Chan, Y.C.Lee, Analytical Method Validation and Instrumental PerformanceVerification, 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 andSons
- Chung Chow Chan, Y.C.Lee, Analytical Method Validation and Instrumental PerformanceVerification, Wiley Interscience

ON JOB TRAINING: SIPBAOJ521

Course Outcomes	• As a part of the M.Sc Degree program in the subject of Bioanalytical Sciences 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 • Partial evaluation of the performance of the student by the competent authority at the industry where the student is placed • To make students practice and maintain the Industrial Diary
Learning Outcomes	✓ *To understand the inner workings of industries or research institutes in the field of Bioanalytical Sciences.* ✓ *To gain experience of hands-on work in a structured organization.*

Practical Component MSc Bioanalytical Sciences Part 1 - Semester I

Based on Core/ Mandatory Paper 1: SIPBACCP511

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 comparison of thefollowing 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

3. Calculation in terms of the percent occurrence of key anatomical characteristics in the powder to berecorded.

4. Separation of plant pigments using paper chromatography

5. Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans,steroids and glycosides using TLC. Compare the results using standards.

6. Comparison of classical and modern methods 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

9. Preparation of Herbarium of the 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

Based on Core/ Mandatory Paper 2: SIPBACCP512

1. Gram staining of soil microflora

2. Demonstrate the effect of media on the growth curves of a given microorganism, using two different media (minimal and enriched).

3. Separation of human serum / plasma proteins / egg white using PAGE ((Protein molecular weightdetermination kit may be used)

4. 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 analysisof the findings

5. Bioinformatics: Clustal W. omega, BLAST A, Blast O, Fasta, Alignment, Prosite, SCOP, Rasmol,CATH, Identification of Protein,

6. Separation of proteins using 2D gel electrophoresis

7. Calculation of Ka, Ke, t ½, Cmax and Tmax from the given data (2 expts.)

Note: There are no practical's based on Core/ Mandatory Paper 3: SIPBACC513

Based on Elective Paper: SIPBAELP511

1. Gas Chromatographic 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

a) UV spectrophotometry

b) HPLC

6. IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)

7. Derivatization in GC

Practical Based on Research Methodology: SIPBARMP511

1. Students will be provided with a sample research paper, whereby, the title, abstract, key words will be masked, and the student will be required to frame a title for that research paper, choose key words and write an abstract for the sample research paper. Then, the student will be given the same sample research paper, however, now it will be unmasked and the student will be asked to compare the accuracy of their title, keywords, abstract with the sample research paper.

2. Students will be provided with a sample research paper, and the students will prepare a poster on a chart paper, for poster presentation of that research work. The poster must include the following: introduction, objectives, materials and methods, observation, results, conclusion and discussion, relevance/impact, bibliography.

3. Students will be provided with a sample research paper, and the students will prepare a power point presentation, for presentation of that research work. The presentation must include the following: introduction, objectives, materials and methods, observation, results, conclusion and discussion, relevance/impact bibliography.

4. Students will be provided with a sample research paper, and the students will write a review for that research paper. The review must include the following: overview of the research paper, advantages or impact of research paper, limitations or shortcomings of the research paper, future plan or extension of the research work.

5. Students will be given a research topic, and the students will write a research proposal, giving outline/scheme for execution of the proposed research work. The outline/scheme of the proposed research work must include: literature review, objectives, purpose and rationale, materials and methodology, results, conclusion and discussion, bibliography

Practical Component MSc Bioanalytical Sciences Part 1 - Semester II

Based on Core/ Mandatory Paper 1: SIPBACCP521

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. Determination of percentage purity of $CaCO_3$/$MgCO_3$ by

a) Titrimetry

b) Complexometry

c) IE chromatography

4. Determination of percentage purity of CaCO3/MgCO3 by

a) Titrimetry

b) Complexometry

c) IE chromatography

5. Accelerated stability studies of various formulations or drugs with respect to Temperature (b) Effect ofbuffers / pH dependent (2 – 4 Expts.)

6. Test for degradation of compounds using TLC for any two drugs.

7. Stability testing of solution and solid dosage forms for photodegradation. (2 experiments).

8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugsin solution at elevated temperatures and room temperature. (2 experiments).

9. Stability studies of drugs in dosage forms at 25oC, 60% RH and 40oC, 75% RH and at different Pressure

10. Carry out hardness and friability on any one tablet preparation

Based on Core/ Mandatory Paper 2: SIPBACC522

1. Immunoassay of HEPALISA in serum.

2. Immunoassay for HCG in urine

3. Immunoassay of T3 and T4 by RIA/IRMA

4. Carry out dissolution test and disintegration test on any one tablet preparation

5. Calculation of different Pharmacokinetic parameters like Ka, Ke, t½, C max, Tmax and AUC from thegiven blood data.

Note: There are no practical's based on Core/ Mandatory Paper 3: SIPBACC523

Based on Elective Paper: SIPBAELP521

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

Practical based - On Job Training/Field Project (SIPBAOJ121)

- As a part of the M.Sc Degree program in the subject of Bioanalytical Sciences 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
- There will be evaluation of the performance of the student by the competent authority at the industry, where the student is placed and an evaluation by examiners at the college during their semester end examination.
- Scheme 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.

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