UNIVERSITY OF MUMBAI

No.UG/ 361 of 2004

CIRCULAR :

Attention of the Directors/Heads recognised Institutions concerned and Principals of the affiliated colleges in the Faculty of Science is hereby invited to the Ordinances Regulations and syllabi relating to the Master of Science (M.Sc.) (Part-I & II) vide Page-Set No. 175 and to this office Circular No. UG/168 of 2004 dated 20th April 2004 and they are hereby informed that the Proposal for introduction of two years MSc. Course in Bio-analytical Instrumentation has been accepted by the Academic Council at its meeting held on 18th June, 2004 vide item No.4.15 and has subsequently been approved by the Management Council at its meeting held on 31st July, 2004 vide item No. 17 and that in accordance therewith the two year M.Sc. degree course in Bio-analytical Instrumentation has been introduced with effect from the academic year 2004-2005.

They are further informed that in exercise of the powers conferred upon Management Council under sub Section (i) of Section 54 of the Maharashtra Universities Act.1994, the Management Council has made the Ordinance 5447 and in exercise of the powers conferred upon the Management Council under Section 55 (i) of the Maharashtra Universities Act. 1994 the Management Council has approved the Regulations 4793, 4794, 4795, 4796, 4797 and 4798 relating to the Syllabus and standard of passing for the two year M.Sc. degree course in Bio-analytical Instrumentation is passed as per Appendix and that the same has been brought into force with effect from the academic year 2004-2005.

Mumbai 400 032.
26th August, 2004

for I/c REGISTRAR.

To.

The Directors/Heads of the recognised institutes concerned and the Principals of the affiliated colleges in Science.

A.C.4.15.13.6.2004
M.C.17/31.7.2004

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No.UG/361-A of 2004 25th August, 2004.

Copy forwarded with Compliments to the Dean, Faculty of Science, for information.

for I/c REGISTRAR.

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A.C. Item No. 4.15 dt. 18/6/2004

UNIVERSITY OF MUMBAI

Ordinances & Regulations
Relating to
Master of Science
in
Bioanalytical Sciences

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Preamble:

Indian PharmacueticalIndustry:

Indian Pharmaceutical industry has long proved its mite both at national and international arena. With the *WTO* regime just rising in the horizon our pharma companies are in for a great boom especially in manufacturing and marketing generics which would be out of patent regime during 2005 to 2007. The market for these molecules is expected to be around 100 billion dollars. Even if our companies make a share of 01 % percent, substantial revenue is in the offering. Coupled with this they can strive to have few new molecules up their scheme

*Ayurveda, Sidha and Unan (**ASU**) Medicines - Our rich heritage:*

The Indian sub-continent houses one of the world's richest flora & fauna and has one of the world's oldest medicinal systems - Ayurveda. Ayurveda (Ayurlife; Veda - knowledge) is an encyclopedia of the Indian medicinal system, which has a history of over 3000 years. It reflects the law of nature, inherent to life of all living beings. Along with Ayurveda other systems of medicine like the folk medicines, Unani and Siddha are also being practiced in the subcontinent. Ayurveda, Unani and Siddha (ASU) medicines are quit popular among the Indians, and have been followed for over several hundred years.

Department of Indian Systems of Medicine and Homeopathy, Government of India recognizes Ayurveda, Sidha and Unani as standard systems of medicine. Having given the recognition and since these medicines are gaining the trust of people the world over, the Government is trying to implement regulatory guidelines to ensure consistent quality of efficacy & quality. Therefore, standardization of herbal medicines is the need of the hour. This will help not only lead to better acceptance of medicines of Indian systems by the people but will also help to bring these systems on par with the modern medicines where modern scientific principles and techniques are employed to ensure quality and efficacy of the drug formulations.

Inadequacy of Trained personnel:

Major hurdle faced by the R&D centers at various Pharma laboratories is the lack of adequately trained and GLP oriented personnel. This forms a major set back when the application of sophisticated technology especially in the bio analytical field is concerned. The lacunae become more evident when dealing with newer dosage forms and peptide based drugs.

Indian ASU formulations are already in great demand. There is, however, a dire need for standardization techniques based on modern instrumental procedures and principles. A major hurdle in achieving this is the lack of adequate expertise among the manufacturers of ASU drugs. The same inadequacy is seen even among the national laboratories and other Testing and research centers.

This lacunae needs to addressed very diligently and the proposed programme is a step in this direction. Bioanalytical evaluations are interdisciplinary programmes and require highly skilled personnel with strong background of Bio-analytical techniques. There is no programme available today for such a training to generate such expertise in analysts. Though

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industry uses sophisticated instruments in QC and drug development, there is a dire need of technical personnel with an overall expertise in various bioanalytical techniques including biological techniques to be able to take up R&D in newer formulations and standardization of ASU formulations to come up with meaningful evaluations.

The proposed programme has been planned to address this need of trained personnel. Ramnarain Ruia College has an elaborate facility with various bioanalytical instruments in evaluation of modern drugs including human volunteer studies and has been using many sophisticated techniques in standardization of ASU medicines. Our laboratory has been undertaking standardization of ASU drugs especially those, which are of plant (herbal) and mineral (bhasma) origin. We have developed expertise in different stages involved in standardization and have been extending these expertises to the industry.

Objectives of the Course

- Develop trained manpower in the field of Bio-analytical Sciences with specific emphasis for exploitation of ASU system of medicine as well as its need for changing trends of modern pharmaceutical Industries
- Amalgamate traditional analytical chemical techniques with modern genomic and proteomic technologies of manufacturing and analysis
- Introduce the powerful tools of informatics in routine use at manufacturing, QC and research.
- Exposure to National & International regulatory affairs with reference to drugs

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O. 5447 **Eligibility**: **B.Sc.** in any one of the following subjects: Chemistry, Botany, Zoology, Microbiology, Life Sciences, Biochemistry, Biotechnology **and** have offered **Chemistry** as one of the subject **till S Y B Sc** (total **5 units**) or equivalent

R. 4793 **Fee**: Rs.25, 000/- per year

R. 4794 **No of Lectures**: 100 lectures / paper; 4 papers in Part I, 4 papers in Part II

R. 4795 **No of Practical periods:** 4 practical of per year

Work Load :

Four periods per week per paper where each period is of ONE hour duration

Four practical per week. Each practical is of Four periods Where each period is of ONE hour duration.

One Seminar per Week. Each seminar is of ONE hour Duration for a batch of TEN students.

Guidance to the students for projects

R. 4796 **Passing Standard** : Minimum 25 % marks in each paper and each practical and minimum 40 % marks in aggregate in Theory and Practical separately.

R. 4797 **Duration**: 2 Years

Number of Students 20 per batch

Selection Entrance Test

Faculty

Post-graduate degree in the subject of Chemistry / Botany / Zoology, Microbiology / Biochemistry / Biotechnology with B+ and NET / SET

Visiting Faculty from Industry & Research Institutes

The visiting Faculty will be from a post equivalent to that of Senior Lecturer level with Ph. D and not less than 5 years of research experience or with experience in industry not below Assistant Manager Level.

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R. 4798 details of the Syllabus

SYLLABUS IN A NUT SHELL

M.Sc. Part I

- Four Theory Papers — 100 lectures each
- Four practical
  With Industrial Visit

M.Sc. Part II

- Four Theory Papers — 100 lectures each
- Four practical
  With Project

M. Sc.	Paper.	Title	Lectures
Part I	I	Different Medicinal Systems, Pharmacognosy & Extraction Techniques	100
	II	Spectroscopy, Pharmacokinetics, Drug Act and Quality Management	100
	III	Chromatography and Bioinformatics	100
	IV	Proteomics, Patents and Data Management	100
Part II	V	Microbiology, Genomics, CE and Toxicology	100
	VI	MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques	100
	VII	Standardization of ASU drugs & GMP	100
	VIII	GCP & BA/ BE Studies	100

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SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART I

PAPER I - Different Medicinal Systems, Pharmacognosy & Extraction Techniques

MODULE I - FIRST YERM	MODULE II – SECOND TERM
1.1 Indian Systems of Medicine – Ayurved (13)	1. 2 Indian Systems of Medicine – Unani & Siddha (12)
1. 3 Modern Medicine (13)	1.4 Pharmacognosy (12)
1.5 Principles of Extraction (13)	1.6 Isolation of Analytes (12)
1.7 Solid Phase Extraction (13)	1.8 Super Critical Fluid [SCF] Extraction (12)

PAPER II - Spectroscopy, Pharmacokinetics, Drug Act and Quality Management

MODULE III - FIRST YERM	MODULE IV – SECOND TERM
2.1 Spectroscopic methods of analysis – Uv-Vis (3), Nephalometry (2), Turbidometry (2), IR (6) (12)	2.2 Spectroscopic methods of analysis – AAS (4), ICP (4), X-ray Diffraction (4) (12)
2.3 Pharmacokinetics (13)	2.4 Drug Properties (12)
2.5 Drug Act & Regulations(13)	2.6 Good Laboratory Practice [GLP] (12)
2.7 Quality Assurance [QA] (13)	2.8 Quality Control [QC] (12)

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MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART I

PAPER III (100) Chromatography and Bioinformatics

MODULE V - FIRST YERM	MODULE VI – SECOND TERM
3.1 TLC (13)	3.2 HPTLC (12)
3.3 HPLC (13)	3.4 HPLC (12)
3.5 GC (13)	3.6 GC (12)
3.7 Bioinformatics (13)	3.8 Bioinformatics (12)

PAPER IV (100) Proteomics, Patents and Data Management

MODULE VII - FIRST YERM	MODULE VIII – SECOND TERM
4.1 Proteomics (13)	4.2 Enzymology (12)
4.3 Electrophoresis (13)	4.4 Immunoassay & ELISA (12)
4.5 IPR (13)	4.6 Patenting & Registration of Drugs (12)
4.7 Electronic Data Management (13)	4.8 Statistical Analysis & Evaluation of data (12)

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SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART II

PAPER V - Microbiology, Genomics, CE and Toxicology

MODULE IX - FIRST YERM	MODULE X – SECOND TERM
5.1 Basic Microbiology (13)	5.2 Microbiological Testing (12)
5.3 Genomics & DNA fingerprinting (13)	5.4 PCR Applications (12)
5.5 Basic Toxicology (13)	5.6 Regulatory toxicology (12)
5.7 Capillary Electrophoresis [CE] (13)	5.8 Automation in Sample Preparation (12)

PAPER VI MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques

MODULE XI - FIRST YERM	MODULE XII – SECOND TERM
6.1 MS Basics (13)	6.2 Metabolite Isolation (12)
6.3 LC / MS Applications (13)	6.4 Metabolite Identification (12)
6.5 LC/MS/MS (13)	6.6 Thermal Analysis (12)
6.7 GC/ MS & HS-GC/MS (13)	6.8 Tracer Techniques in Bioanalytical Assays(12)

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MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART II

PAPER VII – Standardization of ASU drugs & GMP

MODULE XIII - FIRST YERM	MODULE XIV – SECOND TERM
7.1 Standardisation of Ayurvedic Drugs – 1 (13)	7.2 Standardisation of Ayurvedic Drugs – 2 (12)
7.3 Standardisation of Siddha Drugs – 1 (13)	7.4 Standardisation of Siddha Drugs – 2 (12)
7.5 Standardisation of Unani Drugs – 1 (13)	7.6 Standardisation of Unani Drugs – 2 (12)
7.7 Good Manufacturing Practice [GMP] – 1 (13)	7.8 Good Manufacturing Practice [GMP] in ASU Drugs – 2 (12)

PAPER VIII – GCP & BA/ BE Studies

MODULE XV - FIRST YERM	MODULE XVI – SECOND TERM
8.1 Ethical Issues in Clinical Trials (13)	8.2 Ethical Issues in Bio Studies (12)
8.3 Good Clinical Practice [GCP] – 1 (13)	8.4 Good Clinical Practice [GCP] – 2 (12)
8.5 Bioavailability [BA] Studies – 1 (13)	8.6 Bioavailability [BA] Studies – 2 (12)
8.7 Bioequivalence [BE] Studies – 1 (13)	8.8 Bioequivalence [BE] Studies – 2 (12)

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DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

100 Lectures / paper

PAPER I

Different Medicinal Systems, Pharmacognosy & Extraction Techniques

(The programme to be conducted as per the Modular Distribution)

1.1 Indian systems of Medicine (ASU) – Ayurveda (13)

- Principles and practice of Ayurveda
- Types of Drug Formulation
- Methods of Manufacture – Raw Material To Finished Product

1.2 Indian systems of Medicine (ASU) – Unani & Siddha (12)

- Principles and practice of Unani
- Principles and Practice of Siddha
- Types of Drug Formulation
- Methods of Manufacture – Raw Material To Finished Product

1.3 Modern Medicine (13)

- Principles and practice
- NCE and its evolution into a Drug Molecule
- API
- Drug Formulations
- Excipients

2.2 Pharmacognacy (12)

- Introduction, Plants and their medicinal uses
- Plant identification & Authentication
- Concepts of ethanobotany
- Medicinal plants in India, Indian Phyto-geographical regions, Plant collection techniques, Herbaria and its evaluation, Anatomical studies on plant material
- Anatomical, Raw material characterization, Proximate evaluation
- Introduction to Cultivation & production of Natural Drug substances
- Photomicrography

2.2 Principles of Extraction (13)

- Introduction
- Physico-chemical properties of drugs and solvents
- Concept of partition & Partition Coefficient
- Solvent properties
- Selection of solvent
- Extraction efficiency

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2.2 Isolation of analytes (12)

- Ionisation 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 isolates

2.2 Solid Phase Extraction (SPE) (13)

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

2.2 Super Critical Fluid Extraction (SCFE) (12)

- The concept of SCFE
- Instrumentation
- Factors affection SCFE
- Benefits of SCFE
- Application of SCFE for natural products Conclusions and future perspectives

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DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

PAPER II

Spectroscopy, Phrmacokinetics, drug Act and Quality Management

(The programme to be conducted as per the Modular Distribution)

2.2 Spectroscopy – I (13)

- Introductory Principles (01)
- UV & Visible (02)
  - i. Principles & Instrumentation
  - ii. Applications
- Nephalometry (02)
  - i. Principles & Instrumentation
  - ii. Applications
- Turbidometry (02)
  - i. Principles & Instrumentation
  - ii. Applications
- IR (06)
  - i. Principles & Instrumentation
  - ii. Applications

2.2 Spectroscopy – II (12)

- AAS (04)
  - i. Principles & Instrumentation
  - ii. Applications
- ICP (04)
  - i. Principles & Instrumentation
  - ii. Applications
- X – ray diffraction (04)
  - i. Principles & Instrumentation
  - ii. Applications

2.3 Pharmacokinetics (13)

- Principles of Pharmacokinetcs
- Different pharmacokinetic parameters
- Evaluation of Pharmacokinetic parameters
- Different types of model for pharmacokinetics

2.4 Drug properties (12)

- Types of Drugs
- Drug – Route of entry, Absorption and Distribution
- Drug Metabolism & elimination

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2.5 Drug Act & Regulations (13)

- Indian Drug Act
- ICMR guidelines
- Registration requirements for a new drug
- Guidelines regarding Bioanalytical studies
- Introduction to foreign guidelines
- CFR 21 part 11

2.6 Good Laboratory Practice (GLP) (12)

- What is GLP?
- Practicing GLP
- Guidelines to GLP
- Documentation of Laboratory work
- Preparation of SOPs
- Calibration records
- Validation of methods
- Transfer of methods
- Documentation of results
- Audits
- Audit reports

2.7 Quality Assurance (QA) (13)

- Introduction
    - What is QA?
    - Requirements for implementing QA
    - QA concepts in ASU drugs
- Support work & documentation
- Audit requirements
- Personnel Responsibility in QA

2.8 Quality Control (QC) (12)

- Introduction
    - What is QC?
    - Requirements for implementing QC
    - QC concepts in ASU drugs
- Standardizing an Analytical method
    - Preliminary requirements of a discriminatory quantitaion
    - Detection of the analyte of interest
    - Separation of analyte form the matrix components
    - Sample preparation for quantitation
- Factors for standardization
    - Solid-phase extraction
    - Extraction sequence
    - Liquid/liquid extraction
    - Quantification
- Validation
- Support work & documentation

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DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

PAPER III
Chromatography & Bioinformatics

(The programme to be conducted as per the Modular Distribution)

3.1 TLC (13)

- Principles of chromatographic separation
- Introduction to chromatographic separation techniques
- Principles and Practice of TLC
- Uses of TLC
- Some recommended solvents systems
- Detection of compounds on TLC plates

3.2 HPTLC (12)

- Principles and Instrumentation
- HPTLC vs TLC
- Densitometry & quantitaion in HPTLC
- HPTLC in fingerprinting & QC
- Troubleshooting

3.3 HPLC – 1 (13)

- Applications
- Apparatus
- The chromatographic process
- The chromatogram
- Separation mode
- Column care
- System parameters
- Reverse-phase HPLC
- Ion-pair HPLC
- Ion-exchange HPLC
- Normal-phase HPLC

3.4 HPLC – 2 (12)

- Chiral HPLC
- Column switching in HPLC
- Gradient reverse-phase HPLC
- Column conditions
- Computerised optimisation of HPLC
- HPLC detectors
    a. Introduction
    b. Principles of detection
    c. Selectivity in detectors

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d. Detector response
e. Detector types
f. Sensitivity considerations
g. Selectivity
h. Detectors problems

- Troubleshooting

3.5 GC (13)

- Why gas chromatography works
- Factors that affect the chromatography
- Choices in GC
- GC hardware

3.6 GC (12)

- Detectors in GC
- Derivatisation for GC
- GC strategy for bioanalysis
- Troubleshooting

3.7 Bioinformatics (13)

- What is bioinformatics ?
- Different Search Engines
- Applications of bioinformatics
- Internet Applications in bioinformatics

3.8 Bioinformatics (12)

- Databases and Search Tools
- Inter protocols & Search tools
- Using various libraries
- Genome & Proteome Analysis

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DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

PAPER IV

Proteomics, Patents & Data Management

(The programme to be conducted as per the Modular Distribution)

4.1 Proteomics (13)

- Protein Extraction & purification
- Protein separation
- Protein identification
- Protein fingerprinting for medicinal plants
- Endogenous peptides,
- Chemical modification of proteins.

4.2 Enzymology (12)

- What are Enzymes ?
- Enzymes as biocatalysts
- Classification of Enzymes
- Kinetics of enzyme catalysed reactions
- Enzymes in diagnostics
- Enzymes in drug industry

4.3 Electrophoresis (13)

- Basic Protein Chemistry
- Priciples of electrophoretic separation
- Equipment and process
- Agarose gel electrophoresis
- PAGE – Native & SDS
- Standardization of electrophoretic technique

4.4 Immunoassay & ELISA (12)

- Introduction
- Definitions
- Theory
- Requirements for immunoassay
- Practical aspects
- Data handling
- Advantages of immunoassay
- Principles and instrumentation in ELISA
- Applications of ELISA

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4.5 IPR issues of new Drugs (13)

- Origin of WTO
- WTO & Its implications (for drugs)
- IPR issues in ASU drugs
- Patenting and IPR

4.6 Patenting & Registration of New Drugs (12)

- Patent acts with emphasis on Indian patent Act
- US & European patent regulations
- Requirements of Patent filing
- Patent protection and Patent servicing
- Requirements for registering a new drug
- Issues in registering new ASU drugs

4.7 Electronic Data Management (13)

- Electronic Acquisition of data
- Management of data in Computers
- Electronic Data Validation and regulatory requirements
- Electronic signatures & its regulation

4.8 Statistical Analysis & Evaluation of Data (12)

- Use of Statistical Packages for Data evaluation
    i. Validated applications for data evaluation
- Generating reports using computers
- Regulatory requirements of Data evaluation

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DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

: 100 Lectures / paper

PAPER V

Microbiology, Genomics, CE & Toxicology

(The programme to be conducted as per the Modular Distribution)

5.1 Basic Microbiology (13)

- Microbes and their environment
- Monitoring Microbial contamination
- Microbial Contamination in ASU preparations
- Some common microbial contaminants

5.2 Microbiological testing (12)

- Sampling for microbiological assays
- Laboratory set up for microbiological testing
- Microbiological Assays
- Microbiological testing in pharmaceuticals
- Fungi and their evaluation

5.3 Genomics & DNA Fingerprinting (13)

- Nucleic Acid chemistry
- Principles of DNA sequencing
- DNA & RNA probes
- Concepts of Gene manipulation (introduction only)
    - Restriction enzymes & their uses
    - Vectors & their uses
    - Producing Transgenic organisms
    - Hybridoma technology
- DNA fingerprinting
    - Instrumentation
    - Applications

5.4 Polymerase Chain Reaction (PCR) Applications (12)

- Principles of Thermal Cycler
- DNA Amplification using PCR technology
- cDNA production & its use
- Gene libraries & their uses
- Production of oligotides.

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5.5 Basic Toxicology (13)

- Introduction, scope and types of toxicological studies.
- Toxicants, their route of entry, distribution
- Metabolism & elimination of toxicants
- Concept of LD_{50}, ED_{50}

5.6 Regulatory Toxicology (12)

- Types of toxicity studies
- Design considerations.
- Evaluation of results
- Extrapolation to man.
- OECD Guidelines on Toxicological studies
- Schedule Y and its interpretation.

5.7 Capillary Electrophoresis (13)

- Introduction
- How capillary electrophoresis works
- Why capillary electrophoresis works
- CE hardware
- Use in bioanalysis

5.8 Automation in Sample preparation (12)

- Introduction
- When to automate ?
- Approaches to automation
- Simple automation
- Column switching
- Prospekt and Merck OSP-2
- Benchtop instruments- sequential sample processing
- Benchtop instruments- parallel sample processing
- Gilson ASTED
- Full robotic systems
- Example methods
- Conclusions and future perspectives

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DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

PAPER VI

MS Applications, Metabolite Studies, Thermal Analysis & Tracer Techniques

(The programme to be conducted as per the Modular Distribution)

6.1 MS basics (13)

- Introduction
- Inlets
- Ion sources
- Analysers
- Detectors
- Data acquisition and processing

6.2 Metabolite isolation (12)

- Objectives
- Introduction
- Bioavailability of drug metabolites
- Principles of isolation of metabolites
- Influence of Biological matrix in isolation

6.3 LC/MS Application (13)

- Quantification of analyte
- Internal standardisation
- Data acquisition
- Developing a quantitative method
- An example of thermospray LC/MS
- Example of API LC/MS
- Impurity profiling

6.4 Metabolite identification (12)

- Principles of Metabolite identification
- Use of Tandem mass spectrometry (MS-MS)
- Isotopically labeled compounds in metabolite identification
- Practical aspects for the identification of metabolites by mass spectrometry

6.5 LC/MS/MS (13)

- Principles of Tandem Mass analysis
- Instrumentation for MS^n
- Applications of MS^n in drug analysis
- Applications of MS^n in proteomics

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6.6 Thermal analysis (12)

- Principles of Thermal Analysis
- Instrumentation Requirements
- Applications of Thermal Analysis
- Thermal analysis of Bhasma preparations

6.7 GC/MS & HS-GC/MS (13)

- Analysis of prostanoids by GC/MS
- GC – MS and use of library
- Principles of HS/GC
- Applications of HS-GC/MS

6.8 Tracer techniques in Bioanalytical assays (12)

- Concept of Radioactivity & Half life
- $\propto$, β, γ emitters and their biological applications
- Using tracers in assays
- Detectors and counters
- Concept of autoradiography
- Radio labeled probes and their uses

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DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

PAPER VII

GMP & Standardization of ASU drugs

(The programme to be conducted as per the Modular Distribution)

7.1 Standardization of Ayurvedic drugs (13)

- Need of standardization of Ayurvedic drugs
- What does standardization involve?
- Bioanalytical tools for standardization
- Clinical studies in Standardization

7.2 Standardization of Ayurvedic drugs (12)

- Approaches to standardization;
    - Raw materials
    - In-process materials
    - Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

7.3 Standardization of Siddha drugs (13)

- Need of standardization of Siddha drugs
- What does standardization involve?
- Bioanalytical tools for standardization
- Clinical studies in Standardization

7.4 Standardization of Siddha drugs (12)

- Approaches to standardization;
    - Raw materials
    - In-process materials
    - Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

7.5 Standardization of Unani drugs (13)

- Need of standardization of Unani drugs
- What does standardization involve?
- Bioanalytical tools for standardization
- Clinical studies in Standardization

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7.6 Standardization of Unani drugs (12)

- Approaches to standardization:
  - Raw materials
  - In-process materials
  - Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

7.7 Good Manufacturing Practice (GMP) (13)

- What is GMP?
- Requirements of GMP implantation
- Documentation of GMP practices
- Regulatory certification of GMP

7.8 GMP in ASU Drugs (12)

- GMP in production of ASU drugs
- Harmonization of SOP of manufacture
- Audit for GMP compliances

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DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

PAPER VIII

GCP & BA / BE Studies

(The programme to be conducted as per the Modular Distribution)

8.1 Ethical Issues in Clinical Trials (13)

- Origin of Ethical Issues
- Dealing with Ethical issues
- Ensuring compliance to ethical issues

8.2 Ethical Issues in Bio studies (12)

- Ethical Committees & their set up
- Regulatory powers of ethical committees
- Ethical issues in animal studies
- Compliance to ethical guidelines

8.3 Good Clinical Practice (GCP) – 1 (13)

- What is GCP?
- Origin of GCP
- Earlier Guidelines for GCP
- Requirements of GCP compliance

8.4 Good Clinical Practice (GCP) – 2 (12)

- GCP guidelines of ICH
- GCP guidelines of ICMR
- Ensuring GCP
- Documentation of GCP practice
- Audit of GCP compliance

8.5 Bioavailability (BA) studies – 1 (13)

- What is BA?
- Parameters to evaluate BA of a drug
- Factors that influence BA of a drug
- Evaluating BA of a drug
- Estimating BA parameters of a drug

8.6 Bioavailability (BA) Studies – 2 (12)

- Design of a BA study
- Conduct of a BA study
- Data collection and evaluation
- Reporting a BA study
- Regulatory requirements of BA

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8.7 Bioequivalence (BE) study – 1 (13)

- What is BE?
- Parameters to evaluate BE of a drug
- Factors that influence BE of a drug
- Evaluating BE of a drug
- Estimating BE parameters of a drug

8.8 Bioequivalence (BE) study – 2 (12)

- Design of a BE study
- Conduct of a BE study
- Regulatory requirements of BA and BE
- Data record and evaluation
- Estimating Pharmacokinetic parameters
- Assessment of Bioequivalence
- Regulatory requirements and their compliance

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SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

PART I (PRACTICALS) (PRACTICAL I TO IV)

PRACTICAL I

- Liquid – liquid extracts of Diclofenac Sodium from plasma and formulations
- SPE of Atorvastatin from formulations
- SPE extraction of atarvostatin from plasma
- PAGE separation of human serum proteins
- 2D gel separation of rice plant proteins
- Immunoassay estimation of T_3, T_4 in serum.
- Immunoassay techniques for HCG.
- IR analysis of Diclofenac Sodium

PRACTICAL II

- HPTLC of Diclofenac Sodium (plasma and formulations)
- HPTLC fingerprinting of Herbs (*A. longifolia*)
- HPTLC of *A. longifolia* formulations
- GC of Diclofenac Sodium from plasma and formulations
- GC separation of CH_3OH in presence of C_2H_5OH
- HPLC of Diclofenac Sodium (plasma and formulations)
- HPLC of Diclofenac Sodium in a combination formulation
- HPLC of *A. longifolia* and formulations

PRACTICAL III

- Report of Industrial Visits and field visits

PRACTICAL IV

- Powder Characteristics of Herbal Raw materials (*A. longifolia*)
- Herbarium preparation of herbs (*A. longifolia*)
- Qualitative tests for alkaloids, tannins, lignins, steroids, glycosides on TLC plates
- Sequences analysis of protein & NA using NCBI & EBI sites
- Submission of sequence data for functional annotation
- Paper Electrophoresis of plant pigments

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Part II practicals (V to VIII)

PRACTICAL V

- Plant DNA extraction and separation of agarose Gel
- PCR using separated Plant DNA and RFLP with primers (*Phyllanthus* sps.)
- DNA sequencing
- DNA fingerprint of resistant bacterial strain.
- IR patterns of Bhasma
- CE of Diclofenac Sodium (plasma and formulations)
- CE separation of peptides (protein)
- CE separation of N. Acids
- BA & BE of Diclofenac Sodium (Demo)

PRACTICAL VI

- LC/MS quantitation of Diclofenac Sodium
- LC/MS/MS qunatitation of Diclofenac Sodium from plasma
- LC/MS/MS quantitation of M F acid from plasma
- Mass Fingerprinting of peptides
- GC/MS separation of plant essential oil (Demo)

PRACTICAL VII

- REPORT OF PROJECTS UNDERTAKEN

PRACTICAL VIII

- LD 50 evaluation using insect model
- CCl_4 liver dysfunction in rats and evaluation of liver function test
- Sterility testing (Microbial load) of drug formulations
- Zone of inhibition assay for erythromycin (plasma and formulation)
- Zone of exhibition – Vitamin D_{12}
- AAS of Bhasma preparation

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SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

EVALUATION

- Theory Examination of all four papers for each year
- Practical Examination
- Successful completion of Industrial Visit / Training
- Successful completion and submission of report of project
- All rules and pattern as per University of Mumbai for M. Sc. courses

THEORY QUESTION PAPER PATTERN

- Each Theory paper will be of 100 marks
- Each Theory paper will be of 3 hr. Duration
- Each Theory paper will have ten question in all divided in two sections

Each Theory Paper will have following pattern;

SECTION I

Five questions from Modules of FIRST TERM

SECTION II

Five Questions from Module of SECOND TERM

- Total of TEN Questions in All
- ANY THREE questions to be answered from each section

PRACTICAL EXAMINATION

- Each Practical paper will be of 50 marks (i.e. 200 marks in all)
- Each Practical paper will be of 6 hr duration on separate days, i.e. Four days in all
- For each Practical there will be 2 experiments with marks suitably assigned for Viva, Journal, project work, industrial visit report and presentation
- For Practical III in Part I the marks will be allotted to the report on the industrial visit and a presentation by the student on the visit.
- For Practical VII in Part II the marks will be allotted to the report on the Project carried out by the student and the report submitted on the project.

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Minimum Infrastructure required for running the course

Sr. No.	Item
a.	Laboratory Space & Furniture – of ~ 900 sq ft carpet area with about 6 sq ft table space /student (Batch of 20 students)
b.	Air-conditioned Instrumentation Room for Analytical Equipments
c.	Library Facilities
d.	Computational Facilities
e.	Animal / Glass House
f.	Water & Electricity
g.	Instrumental Support

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RECOMMENDED EQUIPMENT AND ACCESSORIES

Sr. No	Equipment
1.	Agarose and PAG Electrophoresis systems
2.	Analytical Balance
3.	Autoclave
4.	Capillary Electrophoresis (with PDA & UV detectors)
5.	Computers
6.	Cooling Centrifuge
7.	Counter Current Chromatograph
8.	Deep Freezer
9.	Dissolution Test Apparatus
10.	DNA Sequencer
11.	Flame Photometer
12.	Fourier Transform Infrared Spectrometer
13.	Gas Chromatograph
14.	Gel Documentation
15.	HPLC with various detectors (UVNIS, E.C.D, PDA) & software
16.	HPTLC Densitometer with CATS 3.0software
17.	HPTLC Spotter
18.	LC/MS/MS
19.	Low Volume Evaporator
20.	Melting Point Apparatus
21.	pH - meter
22.	Refrigerators
23.	Solid Phase Extractor
24.	Top pan balance
25.	Ultrasonic bath with Temperature control
26.	UV-Vis Scanning Spectrophotometer
27.	Vacuum Concentrator
28.	Water Distillation Apparatus
29.	Water Purification System

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