UNIVERSITY OF MUMBAI
No.UG/ 86 of 2006

CIRCULAR :-

Attention of the Directors/Heads recognized Institutions concerned and the 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.) (parts I & II) Vide pamphlet No. 175 and to this office circular No.UG 13 of 2006 dated 13th January, 2006 and they are hereby informed that the recommendation made by the Ad-hoc Committee appointed by the Academic Council to advise it on all matters relating to the courses of study and examinations for the M. Sc. Degree course in Bioanalytical Sciences at its meeting held on 1st December. 2005 has been accepted by the Academic Council at its meeting held on 28th December, 2005 vide item 4.17 and subsequently approved by the Management Council at its meeting held on 18th February, 2006 vide item No. 3 and that in accordance therewith the syllabus for the M. Sc. Degree course in Bioanalytical Sciences is revised as per **Appendix*** and that the same will be brought into force with effect from the academic year 2006-2007.

Further that Ordinance 5585 and Regulations 5312, 5313, 5314, 5315, 5316, 5317, 5318, 5319, and 5320 including syllabus, scheme of examination relating to the M. Sc. Degree course in Bioanalytical Sciences is passed as per **Appendix*** and that the same will be brought into force with effect from the academic year 2006-2007.

Mumbai 400 032
22nd March, . 2006

for REGISTRAR.

To,

The Directors/ Heads recognized Institutions concerned and the Principals of the affiliated colleges in the Faculty of Science.

A.C.4.17/28.12.2005
M.C.3/18.02.2006

No.UG/ 86-A of 2006

22nd March, 2006

Copy forwarded with compliments to the :-

1) The Dean, Faculty of Science

for REGISTRAR

Enclosure to item No. 4.17
28/12/05

University of Mumbai

Revised Syllabus

For
Master of Science

In

(Bioanalytical Sciences)

(With effect from the academic year 2006-2007)

R. 5312 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 (involving industrial training of 8 to 2 weeks)

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

Preamble:

Indian PharmacueticalIndustry:

Indian Pharmaceutical industry has long proved its mitc 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

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

O.5585 **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.5313 **Fee: Rs.50, 000/- per year**

❖ Tuition Fee	15,000.00
❖ Laboratory Fee (Wet and Instrument Labs.)	18,000.00
❖ Project / Product Development	02,500.00
❖ On-job training	03,000.00
❖ Industrial Visits	01,000.00
❖ Library	02,000.00
❖ Gymkhana	00,500.00
❖ Utility	00,300.00
❖ Extracurricular	00,200.00
❖ Development Fund	01,000.00
❖ Computer / internet	01,000.00
❖ Other Fees	02,000.00
❖ Miscellaneous	00,500.00
TOTAL :	**50,000.00**

R.5314 **No of Lectures:** 100 lectures / paper; 4 papers in Part I, 4 papers in Part II

R.5315 **No of Practical periods:** 4 practical of four periods each per week

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.5316 **Passing Standard** : Minimum 25 % marks in each paper and each practical and minimum 40 % marks in aggregate in Theory and Practical separately.

R.5317 **Duration**: 2 Years

Number of Students — 20 per batch

Selection — Entrance Test

R. 5319 The following will be the staffing pattern for the course:

- Instrument technician – 01
- Technical Assistant – 02
- Lecturers – 03 (full time)
  01 (part – time)

and remaining workload to be completed using guest faculty.

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.

R. 5319 **Mark-list**

- The mark-list of the students must indicate titles of papers in the syllabus

R.5320 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 (involving industrial training of 8 to 2 wee

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

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 Modern Medicine (12)
1. 3 Growth of Indian pharmaceutical Industry (13)	1.4 Principles of Extraction (12)
1.5 Pharmacognacy (13)	1.6 Isolation of Analytes (12)
1.7 Solid Phase Extraction (13)	1.8 Super Critical Fluid [SCF] Extraction (12)

PAPER II – Patents, Drug Act and Quality Management

MODULE III - FIRST YERM	MODULE IV – SECOND TERM
2.1 IPR Issues of New Drugs(13)	2.2 Patenting and Registration of NewDrugs (12)
2.3 Basic 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)

MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART I

PAPER III (100) Chromatography and Spectroscopy

MODULE V - FIRST YERM	MODULE VI – SECOND TERM
3.1 Theory of Chromatographic Separation & TLC (13)	3.2 HPTLC (12)
3.3 HPLC (13)	3.4 HPLC (12)
3.5 GC - I (13)	3.6 GC - II (12)
3.7 Spectroscopy – I (13)	3.8 Spectroscopy – II (12)

PAPER IV (100) Proteomics, Bioinformatics and Quality 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 Bioinformatics (13)	4.6 QC & QA of Pharmaceutical Formulations(12)
4.7 R & D in Pharma Industry (13)	4.8 Stability Studies (12)

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART II

PAPER V - Basic Microbiology, Genomics, CE and Toxicology

MODULE IX - FIRST YERM	MODULE X – SECOND TERM
5.1 Basic Microbiology & Its Application in Pharmaceuticals (13)	5.2 Bio Assays in Pharmaceutical Evaluation (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)

MODULAR DISTRIBUTION OF TOPICS

M. Sc. PART II

PAPER VII – Standardization of ASU drugs, Statistics and GMP

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

PAPER VIII –BA/ BE Studies, GCP and Method Validation

MODULE XV - FIRST YERM	MODULE XVI – SECOND TERM
8.1 Ethical Issues in Clinical Trials (13)	8.2 Regulatory Aspects of ASU Drugs (12)
8.3 Good Clinical Practice [GCP] – 1 (13)	8.4 Good Clinical Practice [GCP] – 2 (12)
8.5 Bioavailability [BA] & Bioequivaience Studies [BE] – 1 (13)	8.6 Bioavailability [BA] & Bioequivalence Studies [BE] Studies – 2 (12)
8.7 Analytical Method Validation (13)	8.8 QC / QA of ASU Drugs (12)

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)
(Lecture allotment includes periods for Seminars and Discussions)

1.1 Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani (13)

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

1.2 Modern Medicine (12)

- Principles and practice
- NCE and its evolution into a Drug Molecule
- API and concept of its formulation into a dosage form
- Different types Drug Formulations
- Excipients in various dosage forms

1.3 Growth of Indian Pharmaceutical industry (13)

- 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

1.4 Principles of Extraction (12)

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

1.5 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

1.6 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

1.7 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

1.8 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

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

PAPER II

Patents, Drug Act and Quality Management

(The programme to be conducted as per the Modular Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

2.1 IPR issues of new Drugs (13)

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

2.2 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

2.3 Basic Pharmacokinetics (13)

- Basic concepts of Pharmacokinetcs
- Different pharmacokinetic parameters and their meanings
- Basic techniques of evaluating Pharmacokinetic parameters
- Basic types of models in pharmacokinetics

2.4 Drug properties (12)

- General classification of Drugs and their formulations
- Drug – Route of entry, Absorption and Distribution with examples
- Concepts of Drug Metabolism & elimination with examples

2.5 Drug Act & Regulations (13)

- Indian Drugs and Cosmetics 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

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

PAPER III
Chromatography & Spectroscopy

(The programme to be conducted as per the Modular Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

3.1 Theory of Chromatographic separation and 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
- Applications of HPTLC

3.3 HPLC – 1 (13)

- Principles and Instrumentation
- The chromatographic process
- The chromatogram
- Separation mode
- Column care
- 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
- Applications of 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. Universal and Specific Detectors
    d. Detector response
    e. Sensitivity considerations
    f. Selectivity
    g. Manual and Electronic Data processing
- Troubleshooting

3.5 GC – I (13)

- Principles and Instrumentation
- Factors that affect the chromatographic separation (Temperature, Type of column etc.)
- GC and GLC techniques
- Types of columns and their application
- Selection of liquid stationary phases (Packed and capillary columns)
- GC hardware

3.6 GC – II (12)

- Universal and specific Detectors in GC (FID, TCD, ECD, FPD and NPD)
- Derivatisation for GC
- GC strategy for analysis involving biological matrices
- Troubleshooting
- Applications

3.7 Spectroscopy – I (13)

- Introductory Principles
- UV ,Visible and fluorescence
    i. Principles & Instrumentation
    ii. Applications
- Nephalometry
    i. Principles & Instrumentation
    ii. Applications
- Turbidometry
    i. Principles & Instrumentation
    ii. Applications
- IR
    i. Principles & Instrumentation
    ii. Applications
- Basic concepts of NMR spectroscopy

3.8 Spectroscopy – II (12)

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

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

PAPER IV

Proteomics, Bioinformatics & Stability Studies

(The programme to be conducted as per the Modular Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

4.1 Proteomics (13)

- Protein Extraction & purification
- Protein separation
- Protein identification
- Protein fingerprinting for medicinal plants
- Endogenous peptides and concepts of post transitional modifications
- 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

4.5 Bioinformatics (13)

- What is bioinformatics ?
- Databases and Search Tools
- Different Sea[illegible]
- Applications of bioinformatics
- Using va[illegible]
- Internet Applications in bioinformatics
- Inter protocols & Search tools
- Genome & Proteome Analysis

4.6 QC and QA of Pharmaceutical preparations

- Pharmacopeias and their uses
- Different types of Assays and tests for Pharmaceutical preparations
- Specified Tests in Pharmacopeial Monographs
- Packaging standards and their compliances
- Tests on formulations - Content Uniformity, hardness, dissolution etc.

4.7 R and D in Pharma industry (13)

- R & D strategies of Indian Pharma
- GATT and Pharma R & D
- Bulk Drug manufacturing & its R & D
- Varied Dosage forms and its R & D

4.8 Stability Studies (12)

- Factors that influence 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

DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

: 100 Lectures / paper

PAPER V

Basic Microbiology, Genomics, CE & Toxicology

(The programme to be conducted as per the Modular Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

5.1 Basic Microbiology and its application in pharmaceuticals (13)

- General idea about Microbes and their environment
- Microbial Contamination in ASU preparations
- Some common microbial contaminants
- Microbiological Assays for pharmaceutical products
- Regulatory Microbiological testing in pharmaceuticals

5.2 Bio assays in Pharmaceutical evaluation (12)

- General idea about bio assay systems used in pharmaceutical evaluations
- In vitro assays and in vivo assays
- Ethical issues of using animal assay systems
- Alternatives to animal assays – one or two examples

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.

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

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)
(Lecture allotment includes periods for Seminars and Discussions)

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

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
- α, β, γ emitters and their biological applications
- Using tracers in assays
- Detectors and counters
- Concept of autoradiography
- Radio labeled probes and their uses

DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

PAPER VII

Standardization of ASU drugs, Statistics and GMP

(The programme to be conducted as per the Modular Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

7.1 Standardization of ASU drugs (13)

- Need of standardization of Ayurvedic drugs
- What does standardization involve?
- Bioanalytical tools for standardization
- Clinical studies in Standardization
- Approaches to standardization;
    - Raw materials
    - In-process materials
    - Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

7.2 Standardization of Siddha drugs (12)

- Need of standardization of Siddha drugs
- What does standardization involve?
- Bioanalytical tools for standardization
- Clinical studies in Standardization
- Approaches to standardization;
    - Raw materials
    - In-process materials
    - Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

7.3 Standardization of Unani drugs (12)

- Need of standardization of Unani drugs
- What does standardization involve?
- Bioanalytical tools for standardization
- Clinical studies in Standardization
- Approaches to standardization;
    - Raw materials
    - In-process materials
    - Finished products
- Developing standardized QC methods
- Shelf life studies on finished products

7.4 General Statistical Methods (13)

- Basic concepts of sample statistics
- Concept of sample size and power
- Concept of ramdomisation 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

7.5 Concepts of Biostatistics (13)

- Statistical approach to biological samples
- Variations in biological samples & their statistical treatment
- Introduction to Data collection techniques
- Design of experiments with eg. Block designs, Latin square
- COV and ANOVA
- Student's t test and F test
- Regression analysis with application to Std Graph
- Non parametric tests with examples
- Statistical Guidance from regulatory agencies

7.6 Electronic Data Management (12)

- Electronic Acquisition of data
- Management of data in Computers
- Electronic Data Validation and regulatory requirements
- Electronic signatures & its regulation
- Generating reports using computers
- Regulatory requirements of Data evaluation

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

DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

PAPER VIII

BA / BE Studies, GCP & Method Validation

(The programme to be conducted as per the Modular Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

8.1 Ethical Issues in Clinical Trials (13)

- Origin of Ethical Issues
- Dealing with Ethical issues
- Ensuring compliance to ethical issues
- Ethical Committees & their set up
- Regulatory powers of ethical committees
- Ethical issues in animal studies
- Compliance to ethical guidelines

8.2 Regulatory Aspects of ASU drugs (12)

- National initiatives for regulation of ASU drugs
- Schedule T and Schedule Y of Drugs and Cosmetics Act
- International initiatives for regulation of ASU drugs with special reference to
    - WHO guidelines on traditional medicine
    - Approaches of US and EU to ASU drug regulation

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) & Bioequivalence (BE) 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
- 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

8.6 Bioavailability (BA) & Bioequivalence (BE) 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
- 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

8.7 Analytical Method Validation (13)

- Strategies for Method development
- What and Why of method validation
- Regulatory requirements of validation
- IQ, OQ and PQ of analytical instruments
- Use of Reference standards
- Issues of Method transfer
- Intra and inter lab – Validation

8.8 QC and QA of ASU drugs (12)

- Herbal pharmacopoeia and Ayurvedic Formulary of India
- Approaches to Quality control of ASU formulations
- Govt initiatives
- Some Initiatives from manufacturers
- QC of RM and In-process materials (some examples)
- QC / QA for finished products (some examples)

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

PART I (PRACTICAL)
(PRACTICAL I TO IV)

PRACTICAL I

- Liquid – liquid extraction of a modern drug from plasma and formulations (e.g Diclofenac Sodium)
- SPE of a modern drug from formulations (e.g. Atorvastatin)
- SPE extraction of a modern drug from plasma (e.g. Atarvostatin)
- PAGE separation of human serum proteins
- 2D gel separation of proteins from rice plant
- Immunoassay estimation of T_3, T_4 in serum.
- Immunoassay techniques for HCG.
- IR analysis of a modern drug (e.g. Diclofenac Sodium)

PRACTICAL II

- HPTLC of a modern drug from plasma and its formulation (e.g. Diclofenac Sodium)
- HPTLC fingerprinting of a herbal raw material (*Asteracantha longifolia*)
- HPTLC of Herbal raw material from its formulation *(e.g. Asteracantha longifolia)*
- GC of a modern drug from plasma and its formulation (e.g. Diclofenac Sodium)
- GC separation of CH_3OH in presence of C_2H_5OH
- HPLC of a modern drug from plasma and its formulation (e.g. Diclofenac Sodium)
- HPLC of a modern drug from a combination formulation (e.g. Diclofenac Sodium & Paracetamol)
- HPLC of a herbal raw material and its formulation *(e.g. Asteracantha longifolia)*

PRACTICAL III

- Report of Industrial Visits and field visits

PRACTICAL IV

- Powder Characteristics of Herbal Raw materials (e.g. *Asteracantha longifolia*)
- Herbarium preparation of herbs (e.g. *Asteracantha longifolia*)
- Qualitative tests for alkaloids, tannins, lignins, steroids, glycosides on TLC plate
- Sequence analysis of proteins & Nucleic Acids using NCBI & EBI sites
- Submission of a sequence data for functional annotation
- Paper Electrophoresis of plant pigments

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

Part II Practical (V to VIII)

PRACTICAL V

- Plant DNA extraction and separation of agarose Gel
- PCR using separated Plant DNA and RFLP with primers (e.g. *Phyllanthus* sps.)
- DNA sequencing using a suitable sample.
- DNA fingerprint of resistant bacterial strain.
- IR patterns of a Bhasma preparation (e.g. Calcium containing Bhasma – *Shankh Bhasma*)
- CE of a modern drug from plasma and its formulation (e.g. Diclofenac Sodium)
- CE separation of peptides (e.g. erythropoetin)
- CE separation of Nucleic Acids
- BA & BE of a modern drug (Demo)

PRACTICAL VI

- LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium)
- LC/MS/MS quantitation of a modern drug from plasma (e.g. Diclofenac Sodium)
- LC/MS/MS quantitation of metabolite of a modern drug from plasma (e.g. Mycophenolic acid; metabolite of Mycophenolate Mofitil)
- Mass Fingerprinting of peptides using a suitable sample
- GC/MS separation of plant essential oil (Demo)

PRACTICAL Vii

- REPORT OF PROJECTS UNDERTAKEN
  - The Project should involve industrial training of 8 to 12 weeks period.
  - Data evaluation must involve application of bio-statistics.

PRACTICAL VIII

- LD_{50} evaluation of a toxicant using a suitable model (e.g. Daphnia / Rice Weevil)
- CCl_4 liver dysfunction in rats and evaluation of liver function tests
- Sterility testing (Microbial load) of drug formulations
- Zone of inhibition assay for erythromycin (using spiked plasma and formulation)
- Zone of exhibition – Vitamin D_{12}
- AAS of a suitable metal Bhasma preparation (e.g. *Tamra Bhasma*)

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.

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

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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