UNIVERSITY OF MUMBAI
No.UG / 21 of 2008

CIRCULAR :-

A reference is invited to the Ordinances, Regulations and Syllabi relating to the B.Sc. degree course ***vide*** this office Circular No.UG/86 of 2006 dated 22nd March,2006 and the Directors/Heads of the recognized Institutions concerned and the Principals of the affiliated colleges in Science 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 examination for the M.Sc. degree course in Bio-analytical Sciences, at its meeting held on 14th September,2007 has been accepted by the Academic Council at its meeting held on 14th December,2007 ***vide*** item No.4.11 and that, in accordance therewith, the syllabus for the M.Sc. degree course in Bio-analytical Sciences has been modified as per ***Appendix*** and that, the same will be brought into force with effect from the academic year 2008-2009.

MUMBAI-400 032
25th January,2008

for I/c. REGISTRAR

To,

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

A.C./4.11/14.12.2007

No.UG/ 21-A of 2008, MUMBAI-400 032 25th January,2008

Copy forwarded with compliments for information to :-

1) The Dean , Faculty of Science
2) The Chairman, Ad-hoc Committee in Bio-analytical Sciences
3) The Offg. Controller of Examinations,
4) The Co-Ordinator, University Computerization Centre,

for I/c. REGISTRAR

Copy to :-

The Director, Board of College and University Development, , the Deputy Registrar (Eligibility and Migration Section), the Director of Students Welfare, the Executive Secretary to the Vice-Chancellor, the Pro-Vice-Chancellor, the Registrar and the Assistant Registrar, Administrative sub-center, Ratnagiri for information .

The Offg. Controller of Examinations (10 copies), the Finance and Accounts Officer (2 copies), Record Section (5 copies), Publications Section (5 copies), the Deputy Registrar, Enrolment, Eligibility and Migration Section (3 copies), the Deputy Registrar, Statistical Unit (2 copies), the Deputy Registrar (Accounts Section),Vidyanagari (2 copies), the Deputy Registrar, Affiliation Section (2 copies), the Director, Institute of Distance Education,(10 copies) the Director University Computer Center (IDE Building), Vidyanagari, (2 copies) the Deputy Registrar (Special Cell), the Deputy Registrar,(PRO) , the Assistant Registrar, Academic Authorities Unit (2 copies)and the Assistant Registrar, Executive Authorities Unit (2 copies) . They are requested to treat this as action taken report on the concerned resolution adopted by the Academic Council referred to in the above Circular and that, no separate Action Taken Report will be sent in this connection. the Assistant Registrar Constituent Colleges Unit (2 copies), BUCT(1 copy), the Deputy Account, Unit V(1 copy), the In-charge Director, Centralize Computing Facility (1 copy), the Receptionist (1 copy), the Telephone Operator (1 copy), the Secretary MUASA (1 copy), the Superintendent, Post-Graduate Section (2 copies), the Superintendent, Thesis Section (2 copies)

Enclosure to item No. 4.11
14/12/07

University of Mumbai

Modified Syllabus of M.Sc.degree course in Bioanalytical Sciences

(to be effective from the academic year 2008 – 2009)

R. details of the Syllabus

SYLLABUS IN A NUT SHELL

M.Sc. Part I

- Four Theory Papers — 120 lectures each
- Four practical
  With Industrial Visit

M.Sc. Part II

- Four Theory Papers — 120 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	120
	II	Patents, Drug Act and Quality Management	120
	III	Chromatography and Spectroscopy	120
	IV	Proteomics, Bioinformatics & Pharmacokinetics	120
Part II	V	Basic Microbiology, Genomics, CE and Toxicology	120
	VI	MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques	120
	VII	Standardization of ASU drugs, Statistics & GMP	120
	VIII	BA/ BE Studies, GCP and Method Validation	120

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

DISTRIBUTION OF TOPICS

M. Sc. PART I

PAPER I - Different Medicinal Systems, Pharmacognosy & Extraction Techniques

UNIT 1 – FIRST YERM	UNIT 1 – SECOND TERM
1.1 Indian Systems of Medicine – Ayurved (15)	1. 2 Modern Medicine (15)
1. 3 Growth of Indian pharmaceutical Industry (15)	1.4 Principles of Extraction (15)
1.5 Pharamacognacy (15)	1.6 Isolation of Analytes (15)
1.7 Solid Phase Extraction (15)	1.8 Super Critical Fluid [SCF] Extraction (15)

PAPER II – Patents, Drug Act and Quality Management

UNIT 2 – FIRST YERM	UNIT 2 – SECOND TERM
2.1 IPR Issues of New Drugs(15)	2.2 Patenting and Registration of NewDrugs (15)
2.3 QC & QA of Pharmaceutical Formulations (15)	2.4 Stability Studies (15)
2.5 Drug Act & Regulations(15)	2.6 Good Laboratory Practice [GLP] (15)
2.7 Quality Assurance [QA] (15)	2.8 Quality Control [QC] (15)

DISTRIBUTION OF TOPICS

M. Sc. PART I

PAPER III Chromatography and Spectroscopy

UNITS 3 – FIRST YERM	UNIT 3 – SECOND TERM
3.1 Theory of Chromatographic Separation & TLC (15)	3.2 HPTLC (15)
3.3 HPLC (15)	3.4 HPLC (15)
3.5 GC - I (15)	3.6 GC - II (15)
3.7 Spectroscopy – I (15)	3.8 Spectroscopy – II (15)

PAPER IV Proteomics, Bioinformatics and Quality Management

UNIT 4 – FIRST YERM	UNIT 4 – SECOND TERM
4.1 Proteomics (15)	4.2 Enzymology (15)
4.3 Electrophoresis (15)	4.4 Immunoassay & ELISA (15)
4.5 Bioinformatics (15)	4.6 Basic Pharmacokinetics (15)
4.7 R & D in Pharma Industry (15)	4.8 Drug Properties (15)

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

DISTRIBUTION OF TOPICS

M. Sc. PART II

PAPER V - Basic Microbiology, Genomics, CE and Toxicology

UNIT 5 – FIRST YERM	UNIT 5 – SECOND TERM
5.1 Basic Microbiology & Its Application in Pharmaceuticals (15)	5.2 Bio Assays in Pharmaceutical Evaluation (15)
5.3 Genomics & DNA fingerprinting (15)	5.4 PCR Applications (15)
5.5 Basic Toxicology (15)	5.6 Regulatory toxicology (15)
5.7 Capillary Electrophoresis [CE] (15)	5.8 Automation in Sample Preparation (15)

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

UNIT 6 – FIRST YERM	UNIT 6 – SECOND TERM
6.1 MS Basics (15)	6.2 Metabolite Isolation (15)
6.3 LC / MS Applications (15)	6.4 Metabolite Identification (15)
6.5 LC/MS/MS (15)	6.6 Thermal Analysis (15)
6.7 GC/ MS & HS-GC/MS (15)	6.8 Tracer Techniques in Bioanalytical Assays (15)

DISTRIBUTION OF TOPICS

M. Sc. PART II

PAPER VII – Standardization of ASU drugs, Statistics and GMP

UNIT 7 – FIRST YERM	UNIT 7 – SECOND TERM
7.1 Standardisation of Ayurvedic, Unani & Siddha Drugs (15)	7.2 Projects related to Standardization (15)
7.3 General Statistical Methods (15)	7.4 Projects related to Standardization (15)
7.5 Concepts of Biostatistics (15)	7.6 Electronic Data Management (15)
7.7 Good Manufacturing Practice [GMP] – 1 (15)	7.8 Good Manufacturing Practice [GMP] in ASU Drugs – 2 (15)

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

UNIT 8 – FIRST YERM	UNIT 8 – SECOND TERM
8.1 Ethical Issues in Clinical Trials (15)	8.2 Regulatory Aspects of ASU Drugs (15)
8.3 Good Clinical Practice [GCP] – 1 (15)	8.4 Good Clinical Practice [GCP] – 2 (15)
8.5 Bioavailability [BA] & Bioequivalence Studies [BE] – 1 (15)	8.6 Bioavailability [BA] & Bioequivalence Studies [BE] Studies – 2 (15)
8.7 Analytical Method Validation (15)	8.8 QC / QA of ASU Drugs (15)

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

120 Lectures / paper

PAPER I

Different Medicinal Systems, Pharmacognosy & Extraction Techniques

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

1.1 Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani (15)

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

1.2 Modern Medicine (15)

- 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 (15)

- 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 (15)

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

1.5 Pharmacognacy (15)

- 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 (15)

- 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) (15)

- 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) (15)

- 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 unitized Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

2.1 IPR issues of new Drugs (15)

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

2.2 Patenting & Registration of New Drugs (15)

- 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 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.

2.4 Stability Studies (15)

- 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

2.5 Drug Act & Regulations (15)

- 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) (15)

- 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) (15)

- 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) (15)

- 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 unitized Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

3.1 Theory of Chromatographic separation and TLC (15)

- 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 (15)

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

3.3 HPLC – 1 (15)

- 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 (15)

- 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 (15)

- 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 (15)

- 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 (15)

- 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 (15)

- Theory and applications of :
  i. Circular Dichroism (CD)
  ii. Optical Rotary Dispersion (ORD)
- Emission spectroscopy
  Principles, instrumentation and applications of
  i. Flame photometry
  ii. Atomic Emission Spectroscopy
- 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 & Pharmacokinetics

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

4.1 Proteomics (15)

- 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 (15)

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

4.3 Electrophoresis (15)

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

4.4 Immunoassay & ELISA (15)

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

4.5 Bioinformatics (15)

- What is bioinformatics ?
- Databases and Search Tools
- Different Search Engines
- Applications of bioinformatics
- Using various libraries
- Internet Applications in bioinformatics
- Inter protocols & Search tools
- Genome & Proteome Analysis

4.6 Basic Pharmacokinetics (15)

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

4.7 R and D in Pharma industry (15)

- 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 Drug properties (15)

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

DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES

120 Lectures / paper

PAPER V

Basic Microbiology, Genomics, CE & Toxicology

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

5.1 Basic Microbiology and its application in pharmaceuticals (15)

- 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 (15)

- 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 (15)

- 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 (15)

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

5.5 Basic Toxicology (15)

- 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 (15)

- 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 (15)

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

5.8 Automation in Sample preparation (15)

- 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
- Exarnple 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 unitized Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

6.1 MS basics (15)

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

6.2 Metabolite isolation (15)

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

6.3 LC/MS Application (15)

- 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 (15)

- 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 (15)

- 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 (15)

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

6.7 GC/MS & HS-GC/MS (15)

- 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 (15)

- 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 unitized Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

7.1 Standardization of ASU drugs (15)

- 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 & 7.3 PROJECTS related to Standardisation (15) + (15)

- Students should carry out a project of standardization of ASU formulations as per the guidelines of Department of AYUSH, Ministry of Health, Govt. of India. They must work on any of the following formulations;
    - Herbo-mineral preparation (Bhasma) containing calcium or Iron.
    - Any Oil based preparation or Ayurvedic Taila preparation.
    - Any Vati (Ayurvedic) or Guliga (Siddha)
    - Any preparation from Unani e.g.-
        - Habb-e-Muquil (contains guggul)
        - Habb-e-shabyar (contains guggul)
        - Laooq-e-khiyar shambar (contains *Cassia fistula*)
        - Raughan-e-Haft Barg (contains *Calotropis*)
- The Project must involve standardization of raw materials / finished formulation (comparison of different sources or different manufacturers) and report on its quality assurance methods.
- The methods used shall involve either all or at least any two of the following;
    - modern chromatographic separation techniques,
    - microscopic evaluations,
    - chemical and physical tests.

7.4 General Statistical Methods (15)

- 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 (15)

- 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 (15)

- 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) (15)

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

7.8 GMP in ASU Drugs (15)

- 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 unitized Distribution)
(Lecture allotment includes periods for Seminars and Discussions)

8.1 Ethical Issues in Clinical Trials (15)

- 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 (15)

- 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 (15)

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

8.4 Good Clinical Practice (GCP) – 2 (15)

- 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 (15)

- 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 (15)

- 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 (15)

- 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 (15)

- 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, Glimiperide, Aceclofenac, Metformin etc.)
- SPE of a modern drug from formulation (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.)
- SPE of a modern drug from plasma (e.g. Atorvastatin, Diclofenac sodium, Sibutramine etc.)
- Separation of human serum / plasma proteins / egg white using PAGE (Protein molecular weight determination kit may be used)
- Separation of proteins using 2D gel electrphoresis
- Immunoassay of HEPALISA in serum.
- Immunoassay for HCG in urine
- IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)
- Determination of percentage purity of $CaCO_3$/$MgCO_3$ by
  - i)Titrimetry
  - ii) Complexometry
  - iii) IE chromatography

PRACTICAL II

- HPTLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
- HPTLC fingerprinting of Herbal raw material (e.g. *Asteracantha longifolia, Ricinus cummunis, Calotropis gigantia*)
- HPTLC detection of herbal raw material from its formulations (e.g. *Asteracantha longifolia* from LUKOL / SPEMAN, *Vitex nigundo* from PANCHGUN TAILA, *Glycerrizha glabra* from ANU TAILA)
- Gas Chromatographic separation of solutes from their matrix (e.g. Diclofenac sodium from its formulation, Methanol from plasma etc.)

- Gas Chromatograhic separation of solvent mixtures (e.g. Menthol & Ethanol, Toluene & Methanol etc.)
- HPLC separation of a modern drug from plasma and its formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)
- HPLC separation of modern drugs from their combination formulation (e.g. Diclofenac Sodium & Paracetamol, Metformin & Glimiperide etc.)
- 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.)
- Determination of Caffeine from a given sample by
  i) uv spectrophotometry
  ii)HPTLC
  iii)HPLC

PRACTICAL III

- Students must submit a Report of the Industrial Visits and a Field Note Book of their field excursion.
- Marks will be allotted as follows;
  - 10 marks for Report of Industrial visit & Field Note Book of field excursion
  - 15 marks for presentation on topics allotted for seminar
  - 25 marks for viva based on entire Syllabus of Part I

PRACTICAL IV

- Microscopic evaluation of sections and powders of the following medicinal plants;

1) *Emblica officinalis* – (Amla - dried fruit)
2) *Glycerrhiza glabra* (Yeshtimadhu) - Rhizome
3) *Vitex nigundo* - Leaves
4) *Ricinus communis* - Leaves
5) *Tinospora cordifolia* – Stem
6) *Asteracantha Longifolia* – Whole plant

7) *Achyranthas aspera* - Whole plant
8) *Calotropis gigantea* – Leaves
9) *Colocasia* (Arum) – Leaves
10) *Phyllanthus amarus* – Whole plant

- Calculation in terms of percent occurrence of key anatomical characteristics in the powder to be recorded.
- Individual student must report findings of ANY THREE from the above list but in each institution evaluation on all the listed plants must be carried out.

- Preparation of Herbarium of following medicinal plants;
  1) *Asteracantha longifolia*
  2) *Trigonella foenum*
  3) *Clitoria ternatea*
  4) *Coriandrum sativum*
  5) *Achyranthus aspera*
  6) *Scoparia dulcis*
  7) *Amaranthus spinosa*
  8) *Phyllanthus amarus*
  9) *Calotropris gigantea*
  10) *Vitex nigundo*
  - Individual student must **submit** herbaria of ANY THREE from the above list but in each institution herbarium of all the listed plants must be prepared.

- Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans, steroids and glycosides using TLC. Compare the results using standards (if available).
- Evaluate the given data of protein and nucleic acid sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis of the findings.

7) *Achyranthas aspera* - Whole plant
8) *Calotropis gigantea* – Leaves
9) *Colocasia* (Arum) – Leaves
10) *Phyllanthus amarus* – Whole plant

- Calculation in terms of percent occurrence of key anatomical characteristics in the powder to be recorded.
- Individual student must report findings of ANY THREE from the above list but in each institution evaluation on all the listed plants must be carried out.

- Preparation of Herbarium of following medicinal plants;
  1) *Asteracantha longifolia*
  2) *Trigonella foenum*
  3) *Clitoria ternatea*
  4) *Coriandrum sativum*
  5) *Achyranthus aspera*
  6) *Scoparia dulcis*
  7) *Amaranthus spinosa*
  8) *Phyllanthus amarus*
  9) *Calotropris gigantea*
  10) *Vitex nigundo*
  - Individual student must **submit** herbaria of ANY THREE from the above list but in each institution herbarium of all the listed plants must be prepared.

- Prepare specific reagents and conduct qualitative test for the presence of alkaloids, tannins, lignans, steroids and glycosides using TLC. Compare the results using standards (if available).
- Evaluate the given data of protein and nucleic acid sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis of the findings.

- Evaluate the given data of peptide sequence using a global database with appropriate search engine / software (e.g. BIOEDIT). Prepare a report stating the steps involved and a brief analysis on the functional annotation of the peptide.
- Separation of plant pigments using paper chromatography.
- Carry out Friability Test. Hardness test & dissolution test on any one tablet preparation
- Preparation of calibration graphs for Li, Na, and K by flame Photometry using their solutions of appropriate concentrations and studying interference of

  i) K in Na estimation

  OR

  ii) Na in Li estimation

  OR

  iii)Li in K estimation

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

Part II Practical (V to VIII)

PRACTICAL V

- Plant DNA extraction and separation using agarose Gel
- PCR (PCR Kit may be used) for Plant DNA and RFLP (RFLP kit may be used) (e.g. *Phyllanthus* sps.)
- DNA sequencing using sample from a suitable organism

  OR

  Identification of Genetically Modified Organism (GMO identification kit may be used)
- DNA fingerprint (Genomic DNA isolation kit may be used) of two bacterial strains (e.g. Resistant and wild strains of *E. coli*)
- Study of matrix effect on IR spectra using solution IR technique and quantitate the solute from a given sample. Identify solute from a given solution using IR library and carry out quantitative assay.
- IR patterns of an Ayurvedic Bhasma preparation (e.g. calcium containing shanka bhasma – comparison with pure $CaCO_3$ and formulations like Calcium supplement tablets)
- CE separation of a modern drug from plasma and its formulation (e.g. Diclofenac sodium)
- CE separation of peptides (e.g. erythropoietin as per E.P.)
- CE separation of N. Acids
- BA & BE of a modern drug (Demonstration – witnessing an actual trial)

PRACTICAL VI

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

PRACTICAL VII

- REPORT OF PROJECTS UNDERTAKEN
  - The project should involve industrial training of 8 to 12 weeks period
  - Data evaluation must involve application of biostatistics.
  - The above two will be presented and defended before the panel of examiners.

PRACTICAL VIII

- LD_{50} evaluation using a suitable model (e.g. Daphnia / rice weevil)
- CCl_4 liver dysfunction in rats and evaluation using liver function tests (An experimental comparison using suitable groups of controls, natural recovery and treatment with known hepatoprotectants to be carried out)
- Sterility testing (Microbial load) of drug formulations
- Zone of inhibition assay for penicillin (using spiked plasma and formulation)
- Zone of exhibition assay for Vitamin B_{12}
- AAS of a suitable Ayurvedic metal bhasma preparation (e.g *Tamara bhasma*)
- Determination of iron from a given sample / sample solution by
  i) Redox titration
  ii)Colorimetry
  iii)Atomic Absorption Spectroscopy
- Gram staining of bacteria and mounting of filamentous and non-filamentous fungi (*Staphylococcus aureus*, *E. coli*, *Candida albicans*, *Penicillium sps*, *Lactobacillus sps* etc.)

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 75 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 units of FIRST TERM

SECTION II

Five Questions from units 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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