AC-6-6-12
Item No. 4.122

UNIVERSITY OF MUMBAI

Syllabus for the M.Sc. Part – I&II
Program: M.Sc.
Course : Bioanalytical Sciences

(Credit Based Semester and Grading System with effect from the academic year 2011–2012)

Preamble:

Indian Pharmaceutical industry:

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, Siddha and Unani (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 (Ayur - life; 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, Siddha 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.

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._____ 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.

- **Minimum of 50 % marks in the entrance examination.**

R._____ Fee: **Rs.** **/- per semester**

- Tuition Fee
- Laboratory Fee (Wet and Instrument Labs.)
- Project / Product Development
- On-job training
- Industrial Visits
- Library
- Gymkhana
- Utility
- Extracurricular
- Development Fund
- Computer / internet
- Other Fees
- Miscellaneous

TOTAL : Rs.

R._____ No of Lectures:

60 lectures for each paper per semester .
4 papers per semester

R._____ 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._____ Duration: 2 Years

R. _____Number of Students 20 per batch

Selection Entrance Test

R. _____ 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.

Core 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._____ **Mark-list**

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

SCHEME OF EXAMINATION

1. Each course will have:
   Term work 40% internal assessment and 60% external / University.
   Written examination of TWO hours and Practical examination wherever applicable of six hours duration. All examinations will be held at the end of each semester and will be conducted by the University as per the existing norms.

2. Standard of passing

- The learners shall have to obtain a minimum of 40 % marks in aggregate to qualify the each course where the course consists of internal assessment and semester end examination.

- The learners shall obtain a minimum of 40 % marks(i.e. 16 out of 40) in the internal assessment and obtain a minimum of 40 % marks (i.e. 24 out of 60) in semester end examination.
- To pass the course and minimum grade C shall be obtained in each project wherever applicable in the particular semester.

3. For internal (Continuous) assessment. A teacher may select a variety of procedures for examination such as: 40 marks

    i. Short Quizzes / Viva / Presentations;
    ii. Assignments / Seminars / Laboratory Journal Work ;
    iii. Extension/Field/experimental Work;
    iv. Research Project by individual students or group of students; or
    v. An open Book Test / Review of Research Papers (with the concerned teacher deciding what books / scientific publications / research papers / Chapters from Reference books are to be allowed for this purpose.)
    vi. Two periodical test/case studies/on-line or combination of these
    vii. Overall conduct as a responsible student, mannerism and exhibition of leader ship qualities in organizing co-curricular activities and attendance.

4. End semester examination 60 % 60 marks

- Duration – these examinations shall be of two hours duration.
- Questions paper pattern:-
  There shall be four questions each of 15 marks.
  All questions shall be compulsory with internal choice within the questions.Question may be sub divided into sub- questions a,b,c,d &e only and allocation of marks depends on the weightage of the topic

5. Method to carry forward the marks

- A learner who passes in the internal assessment but fails in the semester end examination of the course shall reappear for the semester end examination of that course. However his/her marks of the internal assessment shall be carried over and he/she shall be entitled for grade obtained by him/ her on passing.

- A learner who fails in the internal assessment but passes in the semester end examination of the course shall resubmit and reappear for the internal assessment on the form of projects of that course. However his/her marks of the semester end examination shall be carried over and he/she shall be entitled for grade obtained by him/ her on passing.

- The evaluation of internal assessment for students who fails and reappear will consist of one project of 40 marks which will be divided into 20 marks for the documentation of the project, 10 marks for the presentation and 10 marks for the viva.

6. ATKT

- A students shall be allowed to keep term for semester II irrespective of the number of heads of failure on the semester I.

- A student shall be allowed to keep term for semester III if she /he passes each of semester I and semester II OR
- A student fails in not more than two courses semester I and semester II taken together.

- A student shall be allowed to keep term for semester IV irrespective of the number of heads of failure on the semester III. However the student has to pass each of semester I and semester II in order to appear for semester IV.

7. Additional examinations

Additional class test or assignment for internal assessment

- There will be one additional class test or assignment for those who have remained absent on valid ground, in such a case student will be allowed to appear for additional class test or assignment by the head of the institution after following necessary formalities.

Semester end examination

- There will be one additional examination for semester I ,II, III and IV for those who have failed or remained absent.
- The absent student will be allowed to appear for the examination by the head of the institution after following necessary formalities.
- This examination will be held 20 days after the declaration of results but not later than 40 days.

8. Project evaluation(if applicable)

- A student who passes in all the courses but does not secures minimum grade of C in project as applicable has to resubmit a fresh project till he/she secures a minimum of grade C.

- The credits and grade points secured by him/her in the other courses will be carried forward and he/she shall be entitled for grade obtained by them on passing.

- The evaluation of project and viva –voce examination shall be by awarding grade in the seven point scale.

- A student shall have to obtain minimum of grade E (or its equivalent marks)in project evaluation and viva-voce taken together to obtain 40 % marks in project work.

9. Conversion of marks to grade and calculations of GPA

Abbreviations and formula's used

G: grade GP:gradepoints C:credits CP:credit points
CG:creditsX grades (product of credits & grades)
ΣCG:sum of product of credits & grades
ΣC: sum of credit points GPA: $\frac{\Sigma CG}{\Sigma C}$
SGPA: semester grade point average shall be calculated for individual semsterd.(it is also designated as GPA)
CGPA: cumulative grade point average shall be calculated for the entire course by taking all semesters taken together.

10. The system of evaluation will be as follows; Each term work module mentioned above will be evaluated in terms of marks first and then to letters grades as shown in the following table.

Marks Out Of 100	Grade	Grade Point
70 & above	O	07
60 to 69.99	A	06
55 to 59.99	B	05
50 to 54.99	C	04
45 to 49.99	D	03
40 to 44.99	E	02
39.99 & below	F	01

11. Grade Point Average (GPA) =Total of product of grade points earned and credits hrs for each course divided by total credit hours.
$GPA=\Sigma G_k * C_k / \Sigma C_k$

12.'B' Grade is equivalent to at least 55% of the marks as per circular No.UGC-1298/[4619] UNI-4 dated December 11,1999.

13. The formula for GPA will be based on Weighted Average. The final GPA will not be printed unless a student passes courses equivalent to minimum 72 credits for B.Sc. and 96 credits for M.Sc.

14. A seen point grade system [guided by the Government of Maharashtra Resolution No.NGV-1298/[4619]UNI.4 dt. December 11, 1999] will be followed. The corresponding grade table is detailed in 09 above.

15. If the GPA is higher than the indicated upper limit in the three decimal digit then the student be awarded higher final grade (e.g. a student getting GPA of 3.491 be awarded 'C')

16. For grade improvement minimum 24 credits (two papers) should be taken by the student for grade improvement. Grade improvement programme will be implemented at the end of the first semester after declaration of the final result. A student can opt for the grade improvement programme only after the declaration of final semester examination.

17. Grade cards

- The grade cards will be printed along with the marks shown for all the concerned courses.
- The grade cards will be issued to all the learners with credits earned and all the remarks
- The SGPA will be calculated only for the learners who will qualify in all the courses and accordingly the grade will be awarded to them.
- The result gazette and the format of the grade cards will be uniform for all the colleges/institutions.

M.Sc. Bioanalytical Sciences: SYLLABUS IN BRIEF

M.Sc. Part I; Semester - I

Paper	Code	Lectures	Credits	Code	Practical	Credits
Different Medicinal Systems, Pharmacognosy & Extraction Techniques-I	PSBN101	60	4	PSBNP101	60	2
Patents, Drug Act and Quality Management-I	PSBN102	60	4	PSBNP102	60	2
Chromatography and Spectroscopy-I	PSBN103	60	4	PSBNP103	60	2
Proteomics, Bioinformatics & Pharmacokinetics-I	PSBN104	60	4	PSBNP104	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			24			

M.Sc. Part I; Semester - II

Paper	Code	Lectures	Credits	Code	Practical	Credits
Different Medicinal Systems, Pharmacognosy & Extraction Techniques-II	PSBN201	60	4	PSBNP201	60	2
Patents, Drug Act and Quality Management-II	PSBN202	60	4	PSBNP202	60	2
Chromatography and Spectroscopy-II	PSBN203	60	4	PSBNP203	60	2
Proteomics, Bioinformatics & Pharmacokinetics-II	PSBN204	60	4	PSBNP204	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			24			

M.Sc. Part II;Semester –III

Note: Industrial Training will be for 8-12 weeks and may be spread out in Semester III and IV for a total of 4 credits.

Paper	Code	Lectures	Credits	Code	Practical	Credits
Basic Microbiology, Genomics, CE and Toxicology-I	PSBN301	60	4	PSBNP301	60	2
MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-I	PSBN302	60	4	PSBNP302	60	2
Standardization of ASU drugs, Statistics & GMP-I	PSBN303	60	4	PSBNP303	60	2
BA/ BE Studies, GCP and Method Validation-I	PSBN304	60	4	PSBNP304	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			24			

M.Sc. Part II; Semester –IV

Note: Industrial Training will be for 8-12 weeks and may be spread out in Semester III and IV for a total of 4 credits.

Paper	Code	Lectures	Credits	Code	Practical	Credits
Basic Microbiology, Genomics, CE and Toxicology-II	PSBN401	60	4	PSBNP401	60	2
MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-II	PSBN402	60	4	PSBNP402	60	2#
Standardization of ASU drugs, Statistics & GMP-II	PSBN403	60	4	PSBNP403	60	2
BA/ BE Studies, GCP and Method Validation-II	PSBN404	60	4	PSBNP404	60	2
TOTAL		240	16		240	8
TOTAL CREDITS			24			

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES
DISTRIBUTION OF TOPICS
M. Sc. PART I

SEMESTER I

PSBN101- Different Medicinal Systems, Pharmacognosy & Extraction Techniques-I
101.1 Indian Systems of Medicine – Ayurved (15)
101.2 Growth of Indian pharmaceutical Industry (15)
101.3 Pharmacognosy (15)
101.4 Solid Phase Extraction (15)

PSBN102- Patents, Drug Act and Quality Management-I
102.1 IPR Issues of New Drugs(15)
102.2 QC & QA of Pharmaceutical Formulations (15)
102.3 Drug Act & Regulations(15)
102.4 Quality Assurance [QA] (15)

PSBN103- Chromatography and Spectroscopy-I
103.1 Theory of Chromatographic Separation & TLC (15)
103.2 HPLC (15)
103.3 GC - I (15)
103.4 Spectroscopy – I (15)

PSBN104- Proteomics, Bioinformatics and Pharmacokinetics-I
104.1 Proteomics (15)
104.2 Electrophoresis (15)
104.3 Bioinformatics (15)
104.4 R & D in Pharma Industry (15)

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES
DISTRIBUTION OF TOPICS
M. Sc. PART I

SEMESTER II

PSBN201- Different Medicinal Systems, Pharmacognosy & Extraction Techniques-II
201.1 Modern Medicine (15)
201.2 Principles of Extraction (15)
201.3 Isolation of Analytes (15)
201.4 Super Critical Fluid [SCF] Extraction (15)

PSBN202- Patents, Drug Act and Quality Management-II
202.1 Patenting and Registration of New Drugs (15)
202.2 Stability Studies (15)
202.3 Good Laboratory Practice [GLP] (15)
202.4 Quality Control [QC] (15)

PSBN203- Chromatography and Spectroscopy-II
203.1 HPTLC (15)
203.2 HPLC-II (15)
203.3 GC - II (15)
203.4 Spectroscopy – II (15)

PSBN204- Proteomics, Bioinformatics and Pharmacokinetics-II
204.1 Enzymology (15)
204.2 Immunoassay & ELISA (15)
204.3 Basic Pharmacokinetics (15)
204.4 Drug Properties (15)

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES
DISTRIBUTION OF TOPICS
M. Sc. PART II

SEMESTER III

PSBN301- Basic Microbiology, Genomics, CE and Toxicology-I
301.1 Basic Microbiology & Its Application in Pharmaceuticals (15)
301.2 Genomics & DNA fingerprinting (15)
301.3 Basic Toxicology (15)
301.4 Capillary Electrophoresis [CE] (15)

PSBN302- MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-I
302.1 MS Basics (15)
302.2 LC / MS Applications (15)
302.3 LC/MS/MS (15)
302.4 GC/ MS & HS-GC/MS (15)

PSBN303- Standardization of ASU drugs, Statistics and GMP-I
303.1 Standardisation of Ayurvedic, Unani & Siddha Drugs (15)
303.2 General Statistical Methods (15)
303.3 Concepts of Biostatistics (15)
303.4 Good Manufacturing Practice [GMP] – 1 (15)

PSBN304-BA/ BE Studies, GCP and Method Validation-I
304.1 Ethical Issues in Clinical Trials (15)
304.2 Good Clinical Practice [GCP] –1 (15)
304.3 Bioavailability [BA] & Bioequivalence Studies [BE] – 1 (15)
304.4 Analytical Method Validation (15)

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES
DISTRIBUTION OF TOPICS
M. Sc. PART II

SEMESTER IV

PSBN401- Basic Microbiology, Genomics, CE and Toxicology-II
401.1 Bio Assays in Pharmaceutical Evaluation (15)
401.2 PCR Applications (15)
401.3 Regulatory toxicology (15)
401.4 Automation in Sample Preparation (15)

PSBN402- MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-II
402.1 Metabolite Isolation (15)
402.2 Metabolite Identification (15)
402.3 Thermal Analysis (15)
402.4 Tracer Techniques in Bioanalytical Assays (15)

PSBN403- Standardization of ASU drugs, Statistics and GMP-II
403.1 Projects related to Standardization (15)
403.2 Projects related to Standardization (15)
403.3 Electronic Data Management (15)
403.4 Good Manufacturing Practice [GMP] in ASU Drugs – 2 (15)

PSBN304-BA/ BE Studies, GCP and Method Validation-II
404.1 Regulatory Aspects of ASU Drugs (15)
404.2 Good Clinical Practice [GCP] – 2 (15)
404.3 Bioavailability [BA] & Bioequivalence Studies [BE] Studies – 2 (15)
404.4 QC / QA of ASU Drugs (15)

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

60 Lectures / paper/semester
SEMESTER I -Theory
PSBN101-Different Medicinal Systems, Pharmacognosy & Extraction Techniques-I
(Lecture allotment includes periods for Seminars and Discussions)

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

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

101.2 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

101.3 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

101.4 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

M.Sc. PART I
Semester I-PRACTICAL

PSBNP101

- 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.)

- 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.

- Separation of plant pigments using paper chromatography.

Semester I-theory
PSBN102-Patents, Drug Act and Quality Management-I
(Lecture allotment includes periods for Seminars and Discussions)

102.1 IPR issues of new Drugs (15)

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

102.2 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.

102.3 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

102.4 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

M.Sc. PART I
Semester I- PRACTICAL

PSBNP102

- Students must submit a Field Note Book of their field excursion including Presentation of the field visit

Semester I- theory
PSBN103-Chromatography & Spectroscopy-I
(Lecture allotment includes periods for Seminars and Discussions)

103.1 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

103.2 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

103.3 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

103.4 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

M.Sc. PART I
Semester I -PRACTICAL

PSBNP103

- Gas Chromatograhic separation of solvent mixtures (e.g. Menthol & Ethanol, Toluene & Methanol 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.)
- 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.)
- Determination of Caffeine from a given sample by
  i) UV spectrophotometry
  ii)HPLC

Semester I-theory

PSBN104-Proteomics, Bioinformatics & Pharmacokinetics-I
(Lecture allotment includes periods for Seminars and Discussions)

104.1 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.

104.2 Electrophoresis (15)

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

104.3 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

104.4 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

M.Sc. PART I
Semester I -PRACTICAL

PSBNP104

- Separation of human serum / plasma proteins / egg white using PAGE (Protein molecular weight determination kit may be used)
- 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).
- Carry out dissolution test on any one tablet preparation
- IR analysis of a modern drug (e.g. Diclofenac Sodium, etc.)

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

60 Lectures / paper/semester
SEMESTER II-theory

PSBN201-Different Medicinal Systems, Pharmacognosy & Extraction Techniques-II
(Lecture allotment includes periods for Seminars and Discussions)

201.1 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

201.2 Principles of Extraction (15)

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

201.3 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

201.4 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

M.Sc. PART I
Semester II -**PRACTICAL**

PSBNP201

- 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.

- Carry out Friability Test, Hardness test & disintegration 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
  - Determination of percentage purity of $CaCO_3$/$MgCO_3$ by
    i)Titrimetry
    ii) Complexometry
    iii) IE chromatography

Semester II-theory
PSBN202-Patents, Drug Act and Quality Management-II
(Lecture allotment includes periods for Seminars and Discussions)

202.1 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

202.2 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

202.3 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

202.4 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

M.Sc. PART I

Semester II -**PRACTICAL**

PSBNP202

- Students must submit a Report of the Industrial Visits including Presentation of the industrial visit.

Semester II-theory
PSBN203- Chromatography & Spectroscopy-II
(Lecture allotment includes periods for Seminars and Discussions)

203.1 HPTLC (15)

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

203.2 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

203.3 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

203.4 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

M.Sc. PART I

Semester II -**PRACTICAL**

PSBNP203

- 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.)

Determination of Caffeine from a given sample by

i)HPTLC

Semester II theory
PSBN204-Proteomics, Bioinformatics & Pharmacokinetics
(Lecture allotment includes periods for Seminars and Discussions)

204.1 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

204.2 Immunoassay & ELISA (15)

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

204.3 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

204.4 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

o

M.Sc. PART I

Semester II **-PRACTICAL**

PSBNP204

- Separation of proteins using 2D gel electrophoresis
- Immunoassay of HEPALISA in serum.
- Immunoassay for HCG in urine
- 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.

DETAILED SYLLABUS FOR M. Sc. Part II BIOANALYTICAL SCIENCES
60 Lectures / paper/semester
SEMESTER III theory

PSBN 301- Basic Microbiology, Genomics, CE & Toxicology-I
(Lecture allotment includes periods for Seminars and Discussions)

301.1 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

301.2 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

301.3 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}

301.4 Capillary Electrophoresis (15)

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

Part II
Semester III Practical

PSBNP301

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

Semester III- theory
PSBN 302 -MS Applications, Metabolite Studies, Thermal Analysis & Tracer Techniques-I
(Lecture allotment includes periods for Seminars and Discussions)

302.1 MS basics (15)

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

302.2 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

302.3 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

302.4 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

Part II
Semester III Practical

PSBNP302

- LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.)
- GC/MS separation of plant essential oil (Demonstration)

Semester III theory

PSBN 303- Standardization of ASU drugs, Statistics and GMP-I

(Lecture allotment includes periods for Seminars and Discussions)

303.1 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
-

303.2 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
-

303.3 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

303.4 Good Manufacturing Practice (GMP) (15)

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

Part II
Semester III Practical

PSBNP303

- The project should involve industrial training of 8 to 12 weeks period
- Data evaluation must involve application of biostatistics

Semester III theory

PSBN304 -BA / BE Studies, GCP & Method Validation-I
(Lecture allotment includes periods for Seminars and Discussions)

304.1 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

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

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

304.3 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

304.4 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

Part II
Semester III Practical

PSBNP304

- LD $_{50}$ evaluation using a suitable model (e.g. *Daphnia* / rice weevil)
- Sterility testing (Microbial load) of drug formulations
- AAS of a suitable Ayurvedic metal bhasma preparation (e.g Tamara bhasma)/ paracetamol
- Gram staining of bacteria and mounting of filamentous and non-filamentous fungi *(Staphylococcus aureus, E. coli, Candida albicans, Penicillium sps, Lactobacillus sps etc.)*

DETAILED SYLLABUS FOR M. Sc. Part I BIOANALYTICAL SCIENCES

60 Lectures / paper/semester
SEMESTER IV theory

PSBN 401- Basic Microbiology, Genomics, CE & Toxicology-II

401.1 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

401.2 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 oligotides.

401.3 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.

401.4 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
- Example methods

- Conclusions and future perspectives

Part II
Semester IV Practical

PSBNP401

- 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)
- 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.
- BA & BE of a modern drug (Demonstration – witnessing an actual trial)

SEMESTER IV theory

PSBN 402-MS Applications, Metabolite Studies, Thermal Analysis & Tracer Techniques-II

402.1 Metabolite isolation (15)

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

402.2 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

402.3 Thermal analysis (15)

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

402.4 Tracer techniques in Bioanalytical assays (15)

- 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

Part II
Semester IV Practical

PSBNP402

- 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.

SEMESTER IV theory

PSBN 403- Standardization of ASU drugs, Statistics and GMP- II

403.1&403.2 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.

403.3 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

403.4 GMP in ASU Drugs (15)

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

Part II
Semester IV Practical

PSBNP403

- The project should involve preparation of herbal formulations and standardization of the same

SEMESTER IV theory

PSBN404 -BA / BE Studies, GCP & Method Validation-II
(Lecture allotment includes periods for Seminars and Discussions)

404.1 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

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

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

404.3 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

404.4 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 / OA for finished products (some examples)

Part II
Semester IV Practical

PSBNP404

- 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)

- Zone of inhibition assay for penicillin (using spiked plasma and formulation)

- Zone of exhibition assay for Vitamin B_{12}

- Determination of iron from a given sample / sample solution by
  i) Redox titration
  ii)Colorimetry
  iii)Atomic Absorption Spectroscopy

SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

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

LIST OF REFERENCE BOOKS

1. Douglas A.Skoog ,Principles of Instrumental Analysis,Saunders College Publihsing
2. Allen J.Bard,Electroanalytical Chemistry,A series of Advances Volume –5,Marcel Dekker, Inc; New York
3. Allen J.Bard ,Electroanalytical Chemistry,A series of Advances Volume – 12,Marcel Dekker, Inc; New York
4. Allen J.Bard, Electroanalytical Chemistry, A series of Advances Volume – 13, Marcel Dekker, Inc; New York
5. I.P.Alimarin,V.I.Fadeeva ,E.N.Dorokhora,Lecture Experiments in Analytical Chemsitry ,Mir Publishers, Moscow
6. William David Cooper,Albert D.Helfrick ,Electronic Instrumentation and Measurement Technique ,Prentice Hall of India Pvt.Ltd
7. Hobart H.Williard, Lynne Merritt, John Dean, FrankSettle, Instrumental Methods of Analysis 6th Ed.,CBS Publishers and Distributors
8. Dale G.Deutsch, Analytical Aspects of Drug Testing, John Wiley and Sons
9. Rober D.Brown ,Introduction to Instrumental Analysis ,Mcgraw-Hill International Ed.
10. C.M.Earnest ,Thermal Analysis of Clays Minerals and Coal, Perkin Elmer
11. Randoll C.Baset ,Advances in Analytical Toxicology Vol 2 ,Year Book Medical Publishers
12. Garry D.Christian , Analytical Chemistry 5th ed ,John Wiley and Sons Inc
13. Karel Eckschlager ,Klans Danzer,Information Theory in Analytical Chemistry ,John Wiley and Sons
14. Alice J.Cunningham ,Introduction to Bioanalytical Sensors ,John Wiley and Sons
15. Peter Roper, Shaura ,Burke, Richard Lawn,Vicki Barwick andRon Walker,Applications of Reference Materials in Analytical Chemistry
16. Royal Society of Chemistry
17. Chung Chow Chan ,Y.C.Lee, Analytical Method Validation and Instrumental Performance Verification, Wiley Interscience
18. G.Schwedt ,Chromatographic Methods in Inorganic Analysis,Dr.Alfred Huthg Verlag
19. Tatsuya Sekine, Yuko ,Hasegawa, Dr.V.Mshinde ,Solvent Extraction Chemistry Fundamentals and Applications ,Marcel Dekker Inc
20. Robert White, Chromatography / Fourier Transform Infrared Spectroscopy and its Applications ,Marcel Dekker Inc
21. Roy M.Harrison ,Spyridon Rapsomanikis ,Environmental Analysis Using Chromatography Interfaced with Atomic Spectroscopy ,Ellis Horwood Ltd
22. Dr.P.D.Sethi ,Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography ,CBS Publishers and Distributors
23. D.Cagniant ,Complexation Chromatography ,Marcel Dekker Inc
24. B.Ravindranath ,Principles and Practice of Chromatography , Ellis Horwood Ltd
25. G.Subramanian ,Preparative and Process Scale Liquid Chromatography ,Ellis Horwood
26. Jack Cazes ,Chromatographic Analysis of Pharmaceuticals ,Marcel Dekker Inc

27. Heman J.cortes ,Multidimensional Chromatography Techniques and Applications ,Marcel Dkker Inc
28. Norberto A.Guzman ,Capillary Electrophoresis Technology ,Marcel Dekker Inc
29. K.Robards ,Principles and Practice of Modern Chromatographic Methods ,Academic Press
30. Walter D.Conway ,Countercurrewnt Chromatography ,VCH
31. Alian P.Foucault ,Centrifugal Partition Chromatography ,Marcel Dekker Inc
32. Yoichiro Ito ,Welter D. Conway ,High Speed Countercurrent Chromatography ,John Wiley and Sons
33. Dr.P.D.Sethi ,HPTLC High Performance Thin Layer Chromatography
34. Raymond P.W.Scott ,Chromatographic Detectors Design Function Function and Operation ,Marcel Dekker Inc
35. Larry T.Taylor ,Supercritical Fluid Extraction ,John Wiley and Sons
36. John A.Adam ,Chromatographic Analysis of Pharmaceuticals 2nd ed ,Marcel Dekker Inc
37. W.M.A.Niessen ,Liquid Chromatography Mass Spectrometry 2nd ed ,Marcel Dekker Inc
38. P.D.Sethi ,Dilip Charegaokar ,Identification of Drugs in Pharmaceutical Formulations by Thin Layer Chromatography, CBS Publishers and Distributors
39. Dale R Baker ,Capillary Electrophoresis ,John Wiley and Sons
40. H.E.Schwartz, R.H.Palmieri ,Introduction to Capillary Electrophoresis of Proteins and Peptides ,Beckman
41. Kelvin Altria and Manus Rogan ,Introduction of Quantitative Applications of C.E in Pharmaceutical Analysis ,Beckman
42. Margaret D.Le Compte, Wendy L.Millroy ,Judith Preissle ,The Handbook of Qualitative Research in Eductaion ,Academic Press
43. Bohdan O.Szuprouiez ,Multimedia Networking, McGraw - Hill
44. Margaret D.Le Compte ,Wendy L.Millroy,Judith Preissle ,The Handbook of Qualitative Research in Eductaion ,Academic Press
45. Richard Friary,Jobs in the Drug Industry ,Academic Press
46. Jonathan Anderson ,Millicent Poole ,Assignment and Thesis Writing ,John Wiley and Sons
47. WHO ,Specification for the Identity and Purity of some enzymes and certain other substances ,W.H.O
48. S.F.Bloomfield , R.Baird, R.E.Leak, R.Leech ,Microbial Quality Assurance in Pharmaceuticals,Cosmetics and Toiletries ,Ellis Horwood
49. William Hewitt ,Stephen Vincent ,Theory and Application of Microbiology Assay,Academic Press
50. Michael Pelczar ,E.C.G Chan, Noel R.Krieg ,Microbiology ,McGraw Hill
51. Randall C.Baselt ,Biological Monitoring Methods for Industrial Chemicals Biomedical
52. Ronald M.Atlas ,Lawrence C.Parks ,Handbook of Microbiological Media ,CRC Press
53. Lily Y.Young,Microbial Transformation and Degradation of Toxic ,Dermot Diamond ,John Wiley & Sons

54. Simon Benita ,Microencapsulation Methods and Industrial Applications ,Marcel Dekker
55. R.K.Dart ,Microbiology for the Analytical Chemist ,The Royal Soc
56. John E.Ladbury ,Babur Chowdhry ,Biocalorimetry Applications of Calorimetry in the Biological Sciences, John WileyAnd Sons
57. Dermot Diamond ,Principles of Chemical and Biological Sensors ,John Wiley &Sons
58. Aspi F.Golwalla ,Sharukh A.Golwalla ,ABC of Medicine ,A.F.Golwalla
59. Richard A.Guarino ,New Drug Approval Process ,Marcel Dekker
60. M.D.B.Stephens ,Detection of New Adverse Drug Reactions, Macmillan Publisher
61. Lisbeth Illum ,Stanley S.Davis ,Polymers in Controlled Drug Delivery,Wright IOP
62. John E.Conte ,Steven L.Barriere ,Manual of Antibiotics and Infectious Disease 6th ed ,Lea & Febiger
63. Ivan H.Stockley ,Drug Interactions -A Source Book of Adverse Interactionstheir Mechanisms Clinical Importance & Management, Blackwell ScientificPublications
64. John B. Taylor ,Peter D. Kennewell ,Modern Medicinal Chemistry, Ellis Horwood
65. Jens T. Carstensen ,Drug Stability Principles & Practices 2nd e.d.,Marcel Dekker
66. Gene S.Gilbert ,Drug Safety Assessment in Clinical Trials ,Marcel Dekker
67. F.D.King ,Medicinal Chemistry Principles and Practice,The Royal Soc.Of Chem
68. Alex Gringauz ,Introduction to Medicinal Chemistry ,Wiley VCH
69. Camille George Wermuth ,The Practice of Medicinal Chemistry 2nd ed.,Academic Press
70. James W.Robinson ,Practical Handbook of Spectroscopy,Crc Press
71. R.W.Hannah ,J.S.Swinehart ,Experiments in Techniques of Infrared Spectroscopy ,Perkin Elmer
72. Patrick Hendra ,Catherine Jones ,Gavin Warnes ,Fourier Transform Raman Spectroscopy Instrumentationand Chemical Applications, Ellis Horwood
73. G.L.Moore ,Introduction to Inductively Coupled Plasma Atomic Emission Spectrometry,Elsevier
74. Gordon M.Barrow ,Introduction to Molecular Spectroscopy ,McGraw Hill
75. Stephen G.Schulman ,Molecular Luminescence Spectroscopy Methods andApplications Part I ,John Wiley and Sons
76. George G.Guilbault ,Practical Fluorescence ,Marcel Dekker
77. B.J.Clark, T.Frost ,M.A.Russell ,UV Spectroscopy Techniques Instrumentation Data Handling.Chapman and Hall
78. W.O.George, H.A.Willis ,Computer Methods in UV Visible and IR Spectroscopy ,Royal Society of Chemistry
79. Richard D Beaty ,Concepts, Instrumentation and Techniques in AtomicAbsorption Spectrophotometry.,Pekin-Elmer
80. A-Knowles , C.Burgess ,Practical Absorption Spectrometry,Chapman & Hall
81. Takekiyo Matsoo ,Richard M.Capridi ,Michael L.Gross ,Yousuke Seyama ,Biological Mass Spectrometry Present and Future ,John Wiley and Sons

82. Barbara Stuart ,Modern Infrared Spectroscopy - ACOL ,John Wiley and Sons
83. George Turrell ,Jacques Corset ,Raman Microscopy Developments and Applications ,Academic Press
84. Irving Sunshine ,Handbook of Spectrophotometric Data of Drugs ,CRC Press
85. Codric M.Smith, Alan M.Reynard ,Textbook of Pharmacology ,W.B.Saunders Comp.
86. Umesh V.Banakar ,Pharmaceutical Dissolution Testing ,Marcel Dekker
87. Howard C.Ansel ,Introduction to Pharmaceutical Dosage Forms 4th ed., Lea & Febiger
88. H.J.Roth, A.Kleemann ,Pharmaceutical Chemistry Vol 1 ,Ellis Horwood
89. P.Johnson ,J.G.Lloyd-Jones ,Drug Delivery Systems Fundamentals and Techniques ,Ellis Horwood
90. M.H.Rubinstein ,Pharmaceutical Technology Controlled Drug Release Vol 1 ,Ellis Horwood
91. Michael G.Palfregman ,Peter McCann ,Walter Lovenberg ,Joseph G.Temple ,Albert Sjoerdsrna Enzymes as Targets for Drug Design, Academic Press
92. Milo Gibaldi, Biopharmaceutics and Clinical Pharmacokinetics 4th ed., Lea and Febiger
93. David B.Jack, Handbook of Clinical Pharmacokinetic Data, Macmillan Publisher
94. Betram G.Katzung, Basic and Clinical Pharamcology 4th ed., Prentice-Hall
95. Kenneth A.Connors, Gordon L.Amidon, Valentino J.Stella, Chemical Stability of Pharmaceuticals, John Wiley & Sons
96. Hamed M.Abdon, Dissolution Bioavailbaility and Bioequivalence, MACK Publishers
97. Varro E.Tyler, Lynn R.Brody, James E.Robbers, Pharmacognosy 9th ed., Lea and Febiger
98. James I.Wells, Pharmaceutical Preformulation the Physicochemical Properties of Drug Substances, Ellis Horwood
99. B.Widdop, Therapeutic Drug Monitoring, Churchill & Livingstone
100. Peter G.Welling, Pharmacokinetics, Marcel Dekker
101. D.R.Karsa, R.A.Stephenson, Excipients & Delivery Systems for Pharmaceutical Formulations, The Royal Society of Chemistry
102. R.S.Iyer, Schedule M and Beyond Good Manufacturing Practices, Indian Drug Manufacturers Association
103. Takeru Higuchi, Einar Brochmann, Hanffen Hanssen, Pharmaceutical Analysis, CBS Publishers & Distributors
104. H.Jackson Knight, Patent Strategy for Researchers and Research Managers 2nd ed, John Wiley and Sons
105. David Lee, Pharmaceutical analysis, CRC Press
106. A.F.Rudole Hoernle, Vaidya Bhagwan Dash, Studies in the Medicine of Ancient India, Concept Publisher Co.
107. J.F.Royle, Antiquity of Hindoo Medicine, Wm.H.Allen and Co
108. Prof.(Mrs) Asima Chatterjee, Dr.Satyesh Chandra Prakash, The Treatise on Indian Medicinal Plants Vol 1, Publications & Information Direct
109. Richard P.Steiner, Folk Medicine - The Art and the Science, American Chemical soc

110. Roberto Chiej, The Macdeonald Encyclopedia of Medicinal Plants, Macdonald and co
111. P.A.G.M.De Smet, K.Keller, R.Hansel, Chandler, Adverse Effects of Herbal Drugs-1, Springer Verlag
112. W.Tang, G.Eisenbrand, Chinese Drugs of Plant Origin, Springer Verlag
113. Alan Harvey, Drugs From Naturall Products Pharmaceuticals and Agrochemicals, Ellis Horwood
114. Dr.R.O.B.Wijesekera, The Medicinal Plant Industry
115. V.V.Sivarajan, Indira Balachandran, Ayurvedic Drugs and Their Plant Sources, Oxford and IBH
116. Dr.V.B.Athavale, Bala-Veda Pediatrics and Ayurveda
117. Dr.V.B.Athavale, Bastivijnyana Urology in Ayurveda,
118. L.D.Kapoor, Handbook of Ayurvedic Medicinal Plants, CRP Press
119. Chandra Chakraberty, An Interpretation of Ancient Hindu Medicine, Neeraj Publishing House
120. S.K.Ramcachandra Rao, Encyclopedia of Indian Medicine Vol 1, Popular Prakashan
121. H.Wagner, S.Bladt , Zgainski, Plant Drug Analysis A Thin Layer Chromatography Atlas, Springer Veriag
122. Govind Kelkar, Directory of Herbal Health Care Products, Chemexcil
123. S.T.Han, Research Guidelines For Evaluating the Safety Andefficacy of Herbal Medicines, World Health Org.
124. Govt. Of India Ministry of Health & Family Welfare National Formlary of Unani Medicine - Part I 1ed., J.M. Jaina and Bros
125. Govt.Of India Ministry of Health & Family Welfare The Ayurvedic Formulary of India Part I 1 ed., J.M.Jaina and Bros
126. Govt. Of India Ministry of Health & Family Welfare The Ayurvedic Pharmacopoeia of India Part I Vol I, J.M.Jain and Bros
127. Prof.Dr.F.C.Czygan, D.Frohne, C.Hohxel, A.Nagell, H.J., Pfainder, G.Willuhn , W.Buff, Herbal Drugs and Phytopharmaceuticals, CRC Press
128. A.Vinaya Kumar, Principles of Ayurvedic Therapeutics, Sri Satguru Publisher
129. Dr.C.R.Karnick, Pharmacopoeial Standards of Herbal Plants Vol I, Sri Satguru Publisher
130. Dr.C.R.Karnick, Pharmacopoeial Standards Of Herbal Plants Vol II, Sri Satguru Publisher
131. Dr.V.Rajpal, Standardization of Botanicals Vol I, Eastern Publishers
132. Regional Research Lab & IDMA, Indian Herbal Pharmacoepoeia Vol II, Regional Research Lab
133. World Trade Centre, Export Potential of Herbal and Ayurvedic Drugs, Quest Publications
134. P.C. Sharma, M.B. Yelne, T.J. Dennis, Database on Medicinal Plants use in Ayurveda Vol. 1 - Vol. 5, Central Council for, Research in Ayurved and Siddha
135. Edward Johnson, Robert Stevenson, Basic Liquid Chromatography, Varian Associate
136. W.M.A.Niessen, J.Van der Greef, Liquid Chromatography Mass Spectrometry, Marcel Dekker

137. Thomas M. Vickrey, Liquid Chromatography Detectors,
138. L.R.Snyder, J.J.Kirkland, Introduction to Modern Liquid Chromatography 2nd ed., John Wiley & Sons
139. W.R.Day, An Introduction to Liquid Chromatography (L.C), Water Associates
140. Willaim V.Willis, Laboratory Experiments in Liquid Chromatography, CRC Press
141. A.Zlatkis, R.E.Kaiser, HPTLC High Performance Thin Layer Chromatography, Elsevier Scientific
142. Nelu Grinberg, Modern Thin-Layer Chromatography, Marcel Dekker
143. W.Bertsch, S.S.Hama, R.E.Kaiser, A.Zlatkis, Instrumentelle HPTLC, Dr.Alfred Huthig
144. A.M.Krstulovic, Chiral Separations by HPLC,
145. Lioyd R.Snyder, Joseph L.Glajch, Joseph J.Krikland, Practical HPLC Method Development
146. Ante M.Krstulovic, Reversed-Phase High Performance Liquid Chromatography - Theory Practice and Biomedical Applications, John Wiley & Sons
147. William S.Hancock, High Performance Liquid Chromatography in Biotechnology, Joh Wiley and Sons
148. Dennis J. Runser, Maintaining and Troubleshooting HPLC Systems, John Wiley and Sons
149. I.N.Papadoyannis, HPLC in Clinical Chemistry, Marcel Dekker Inc
150. Roger M.Smith, Gas and Liquid Chromatography in Analytical Chemistry, John Wiley and Sons
151. J.B.Pattison, A Programmed Introduction to Gas Liquid Chromatography, Heyden & Sons
152. D.J.David, Gas Chromatographic Detectors, John Wiley & Sons
153. H.M.McNair, Basic Gas Chromatography,
154. John W.Dolan, Lloyd R.Snyder, Troubleshooting LC Systems, Human Press
155. Fulton G.Kitson, Barbara S.Larsen, Gas Chromatography and Mass Spectrometry A Practical Guide, Academic Press
156. George Lunn, HPLC Methods for Pharmaceutical Analysis Vol 2 (A-D), John Wiley and Sons
157. George Lunn, HPLC Methods for Pharmaceutical Analysis Vol 3 (E-O), John Wiley & Sons
158. George Lunn, HPLC Methods for Pharmaceutical Analysis Vol 4 (P-Z)
159. Eric Reid, Ian D.Wilson, Analysis for Drugs and Metabolites, Royal Society of Chemistry
160. Malcolm R.Smyth, Chemical Analysis in Complex Matrices, Ellis Horwood Ltd
161. J.P.Hart, Electroanalysis of Biologically Important Compounds, Ellis Horwood
162. Quanyun A.Xu, Lawrence A.Trissel, Stability - Indicating HPLC Methods for Drug Analysis, Pharmaceutical Press
163. A.Fajgelj, A.Ambrus, Principles and Practices of Method Validation, Royal Society of Chemistry
164. ED Metcalfe, Atomic Absorption and Emission Spectroscopy, John Wiley & Sons
165. Rey Davis, Martin Frearson, Mass Spectrometry, John Wiley & Sons
166. Brian W. Woodget, Derek Cooper, Samples and Standards, John Wiley & Sons
167. Richard Anderson, Sample Pretreatment and Separation, John Wiley & Sons

168. James W.Dodd, Kenneth H.Tonge, Thermal Methods, John Wiley & Sons
169. James F.Lawrence, Trace Analysis Vol 1, Academic Press
170. Ronald C.Denney, Ray Sinclair, Visible and Ultraviolet Spectroscopy, John Wiley & Sons
171. Clive Whiston, X-ray Methods, John Wiley & Sons
172. David Hawcroft, Diagnostic Enymology, John Wiley & Sons
173. Judith W.Zyskind, Sanford Bernstein, Recombinant DNA Laboratory Manual, Academic Press, INC
174. Mark D.Adams, Automated DNA Sequencing and Analysis, Academic Press, INC
175. A.T.Rhys Williams, luoroimmunoassay, Perkin-Elmer
176. Edouard Kurstak, Enyme Immunodiagnosis, Academic Press Inc
177. David T.Plummer, An Introduction to Practical Biochemistry 2nd ed., Tata McGraw-Hill
178. H.Robert Horton, Laurence Moran, Raymond S.Ochs, J.David Rawn, K.Gray Scrimgeour, Principles of Biochemistry, Neil Patterson
179. Martin Vanderlaan, Larry H.Stanker, Bruce Watkins, Dean, Roberts, Immunoassays for Trace Chemical Analysis, American Chemical Society
180. Rodney E.Longman, The Immune System, Academic Press Inc
181. Quentin Myrvik, Russell S.Welser, Fundamentals of Immunology 2nd ed, Lea & Febiger
182. Julia M.Polak, Susan Van Noorden, Immunocy to Chemistry 2nd ed, Wright Bristol
183. Terry M.Phillips, Analytical Techniques in Immunochemistry, Marcel Dekker Inc
184. Radiommunoassay Ria in Theory and Practice, Pakard
185. S.Lam, G.Malikin, Analytical Applications of Immobilized Enzyme Reactors, Blackie Academic and Professional
186. Richard F.Venn, Principles and Practice of Bioanalysis, CBS Publishers
187. Bruce H.Mahan, College Chemistry, Addison Wesley P.Co
188. Voltrath Hopp, Ingo Hennig, Handbook of Applied Chemistry, McGraw-Hill Book Co.
189. V.Semishin, Laboratory Exercises in General Chemistry, Peace Publishers
190. K.M.Gokhale, R.G.Limaye, D.A.Bhagwat, Y.R.Wani, A Textbook of Industrial Chemistry, Pragati Agencies