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# UNIVERSITY OF MUMBAI

## Revised Syllabus for the
## M.Sc. SemI/II/III/IV
## Program: M.Sc.
## Course : Bioanalytical Sciences

(Credit Based Semester and Grading System with effect from the academic year 2014–2015)

**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

## M.Sc. Bioanalytical Sciences: SYLLABUS IN BRIEF

### M.Sc. Semester - I

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

### M.Sc. Semester - II

| Paper | Code | Lectures | Credits | Code | Practical | Credits |
|---|---|---|---|---|---|---|
| Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques | PSBN101 | 60 | 4 | PSBNP101 | 60 | 2 |
| IPR and Patenting, Stability Studies and Packaging | PSBN102 | 60 | 4 | PSBNP102 | 60 | 2 |
| Chromatography and Spectroscopy-I | PSBN103 | 60 | 4 | PSBNP103 | 60 | 2 |
| New Drug Development, Immunoassays, Pharmacokinetics, Laboratory Safety Measures | PSBN104 | 60 | 4 | PSBNP104 | 60 | 2 |
| TOTAL | | **240** | **16** | | **240** | **8** |
| TOTAL CREDITS | | | **24** | | | |

### M.Sc. 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 | | | | | | |

## M.Sc. 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 AGenomics, CE and Toxicolognalysis 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** | | | |

## Distribution of Topics

## M.Sc. Semester I

### PSBN101-Different Medicinal Systems, Pharmacognosy & Extraction Techniques

| | |
|---|---|
| **101.1** | Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani (15) |
| **101.2** | Modern Medicine (15) |

| | | |
|---|---|---|
| **101.3** | Pharmacognosy | (15) |
| **101.4** | Principle of extraction and Isolation of analytes | (15) |

**PSBN102- GLP, Drug Act and Quality Management**

| | | |
|---|---|---|
| **102.1** | Good Laboratory Practice (GLP) | (15) |
| **102.2** | Pharmacopeial standards and Testing Procedure | (15) |
| **102.3** | Drug Act & Regulations | (15) |
| **102.4** | Quality Control (QC) and Quality Assurance (QA) | (15) |

**PSBN103-Chromatography & Spectroscopy-I**

| | | |
|---|---|---|
| **103.1** | Theory of Chromatographic separation and TLC | (15) |
| **103.2** | HPLC – 1 | (15) |
| **103.3** | GC – I | (15) |
| **103.4** | Spectroscopy – I | (15) |

**PSBN104-Proteomics, Bioinformatics & Environmental Issues**

| | | |
|---|---|---|
| **104.1** | OMICS | (15) |
| **104.2** | Electrophoresis | (15) |
| **104.3** | Bioinformatics | (15) |
| **104.4** | Environmental Issues of Bioanalytical laboratory | (15) |

## Distribution of Topics

## M.Sc. Semester II

**PSBN201-Indian Pharmaceutical Industry, Phytochemistry & Extraction Techniques**

| | | |
|---|---|---|
| **201.1** | R and D in Pharma industry and Recent trends in Indian Pharmaceutical industry | (15) |

| | | |
|---|---|---|
| **201.2** | Solid Phase Extraction (SPE) | (15) |
| **201.3** | Phytochemistry | (15) |
| **201.4** | Super Critical Fluid Extraction (SCFE) and SCFC (Super Critical Fluid Chromatography) | (15) |

**PSBN202- IPR and Patenting, Stability Studies and Packaging**

| | | |
|---|---|---|
| **202.1** | IPR and Patenting- I | (15) |
| **202.2** | Stability Studies | (15) |
| **202.3** | IPR and Patenting -2 | (15) |
| **202.4** | Packaging in Pharma industry | (15) |

**PSBN203- Chromatography & Spectroscopy-II**

| | | |
|---|---|---|
| **203.1** | HPTLC | (15) |
| **203.2** | HPLC – 2 | (15) |
| **203.3** | GC – II | (15) |
| **203.4** | Spectroscopy – II | (15) |

**PSBN204- New Drug Development, Immunoassays, Pharmacokinetics, Laboratory Safety Measures**

| | | |
|---|---|---|
| **204.1** | NCE and its development into a New Drug and Enzymes | (15) |
| **204.2** | Immunoassay & ELISA | (15) |
| **204.3** | Basic Pharmacokinetics, pharmacodynamics and Drug properties | (15) |
| **204.4** | Laboratory Safety measures w.r.t handling of chemicals and biological materials | (15) |

Distribution of Topics

M.Sc. Semester III

**PSBN 301- Basic Microbiology, Genomics, CE and Toxicology-I**

| | | |
|---|---|---|
| **301.1** | Basic Microbiology and Its application in Pharmaceuticals | (15) |
| **301.2** | Genomics | (15) |
| **301.3** | Basic and Regulatory Toxicology | (15) |
| **301.4** | Regulatory Microbiology and its application in Pharmaceutical and food industry | (15) |

**PSBN302- MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-I**

| | | |
|---|---|---|
| **302.1** | MS basics | (15) |
| **302.2** | Hyphenation | (15) |
| **302.3** | Thermal Analysis | (15) |
| **302.4** | Analytical Methods | (15) |

**PSBN303- Standardization of ASU drugs, Statistics & GMP-I**

| | | |
|---|---|---|
| **303.1** | Standardization of ASU drugs | (15) |
| **303.2** | General Statistical Methods | (15) |
| **303.3** | Concepts of Biostatistics | (15) |
| **303.4** | Good Manufacturing Practice | (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 (BE) studies – 1 | (15) |
| **304.4** | Analytical Method Validation | (15) |

## Distribution of Topics

## M.Sc. Semester IV

**PSBN401- Basic Microbiology, Genomics, CE and Toxicology-II**

| | | |
|---|---|---|
| **401.1** | Bioassays in Pharmaceutical Evaluation | (15) |
| **401.2** | Polymerase Chain Reaction(PCR) & DNA fingerprinting | (15) |
| **401.3** | Automation and Analysis | (15) |
| **401.4** | Capillary Electrophoresis | (15) |

**PSBN402 MS applications, Metabolite studies, Thermal Analysis and Tracer Techniques-II**

| | | |
|---|---|---|
| **402.1** | Applications of Quantitative Analysis | (15) |
| **402.2** | Applications of Qualitative Analysis | (15) |
| **402.3** | LC/MS/MS | (15) |
| **402.4** | Tracer Techniques in Bioanalytical assays | (15) |

**PSBN403- Standardization of ASU drugs, Statistics & GMP-II**

| | | |
|---|---|---|
| **403.1** | Regulatory Aspects of ASU drugs | (15) |
| **403.2** | Environmental Safety in Bioanalytical laboratory | (15) |
| **403.3** | Electronic Data Management | (15) |
| **403.4** | Regulatory Issues | (15) |

**PSBN404- BA/ BE Studies, GCP and Method Validation-II**

| | | |
|---|---|---|
| **404.1** | Therapeutic drug monitoring and Pharmacovigilance | (15) |
| **404.2** | Good Clinical Practice (GCP) – 2 | (15) |
| **404.3** | Bioavailability (BA) & Bioequivalence (BE) studies – 2 | (15) |
| **404.4** | QC and QA of ASU drugs | (15) |

## DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES

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

| Module No. | Topics |
|---|---|
| 101.1 | Title: Indian systems of Medicine (ASU) – Ayurveda, Siddha & Unani (15)<br><br>Subtopics: |

| DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES | |
|---|---|
| **SEMESTER II-theory**<br>**PSBN202- IPR and Patenting, Stability Studies and Packaging**<br>**(Lecture allotment includes periods for Seminars and Discussions)** | |
| 202.1 | Title: IPR and Patenting- I (15)<br><br>Subtopics:<br><br>1. Concept of IPR - Understanding the meaning of IPR & its significance in knowledge based economy.<br>2. Types of IPR - Patents, Trade Marks & Service Marks, Design Registration, Trade Secrets, Geographical indications, Protection of New Plant Varieties, Copyright.<br>3. Global Harmonization - Impact of IPR on global trade and the need for harmonization, WTO and its role in a global harmonization, TRIPS and introduction to the articles in TRIPs document as well as the flexibilities provided by TRIPS.<br>4. International Agreements related to IPR & patents - Paris Convention, PCT. |
| 202.2 | Title: Stability Studies (15)<br><br>Subtopics:<br><br>1. Factors that influence stability of drug formulations<br>2. Types of Stability chambers and their design considerations<br>3. Stability issues of ASU raw materials and finished products<br>4. Guidelines on Stability evaluations<br>5. Approaches to stability studies of ASU formulations |
| 202.3 | Title: IPR and Patenting -2 (15)<br><br>Subtopics:<br><br>1. Indian Patent Act -<br>a. Criteria to be fulfilled for Patentability - new/novel, non-obvious/inventive step, useful/capable of industrial application.<br>b. Non-patentable subject matter - what is not patentable.<br>c. Concept of Mailbox and EMR and how it has helped India in its transition to full TRIPS compliance.<br>d. Role of patentee and patent offices in patent management including lab documentation, confidentiality agreements, pre- and post-grant opposition, servicing of patents.<br>e. Provisional Patents, Divisional Patents & Patents of Addition.<br>2. IPR as a strategic tool -<br>a. Concepts of piracy, reverse engineering and knowledge worker.<br>b. Benefits of creating and/or owning patents and other IPR.<br>c. How India has leveraged the flexibilities provided by TRIPS to safeguard the industry and prevent ever-greening of patents.<br>3. IP clearance – Precautions before launching of product anywhere in the world -<br>a. Concepts of Freedom to operate (FTO) search and analysis for patents, Exclusivity and SPC status check<br>b. Other IPR checks like trademarks, copyrights (for printed data on leaflets, packages etc.), Putting IPR related disclaimers while advertising product list or selling products. |
| 202.4 | Title: Packaging in Pharma industry (15) |

| DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES | |
|---|---|
| **SEMESTER II-theory**<br>**PSBN204- New Drug Development, Immunoassays, Pharmacokinetics, Laboratory Safety Measures**<br>**(Lecture allotment includes periods for Seminars and Discussions)** | |
| 204.1 | Title: NCE and its development into a New Drug and Enzymes (15)<br><br>1. What is NCE?<br>2. Stages in the development of NCE<br>3. Preclinical studies on NCE<br>4. Enzyme as Therapeutics agents, as diagnostics, as catalyst in processes as drug target |
| 204.2 | Title: Immunoassay & ELISA (15)<br><br>Subtopics:<br><br>1. Introduction<br>2. Definitions<br>3. Theory<br>4. Requirements for immunoassay<br>5. Practical aspects<br>6. Data handling<br>7. Advantages of immunoassay<br>8. Principles and instrumentation in ELISA<br>9. Applications of ELISA<br>10. Types of Detection systems |
| 204.3 | Title: Basic Pharmacokinetics, pharmacodynamics and Drug properties (15)<br><br>Subtopics:<br><br>1. Basic concepts of Pharmacokinetcs & pharmacodynamics<br>2. Different pharmacokinetic & pharmacodynamics parameters and their meanings<br>3. Basic techniques of evaluating Pharmacokinetic & pharmacodynamics parameters<br>4. Basic types of models in pharmacokinetics & pharmacodynamics<br>5. General classification of Drugs and their formulations<br>6. Drug – Route of entry, Absorption and Distribution with examples<br>7. Concepts of Drug Metabolism & elimination with examples<br>8. Adverse Drug reactions( ADRs)<br>9. Serious Adverse Events( SAEs) |
| 204.4 | Title: Laboratory Safety Measures w.r.t handling of chemicals and biological materials (15)<br><br>Subtopics: |

| DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES<br>SEMESTER III-theory<br>PSBN301- Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology – I<br><br>(Lecture allotment includes periods for Seminars and Discussions) | |
|---|---|
| 301.1 | Title: Basic Microbiology and its application in pharmaceuticals (15)<br><br>Subtopics:<br><br>1. Microbes & Their environment, Significance and scope of Microbiology, Biodiversity and types of Microorganisms, Visualization of Microorganisms : staining and Simple and compound microscopy, Electron Microscopy<br>2. Growth of Microorganisms, methods to study growth of microorganisms, preservation of microorganisms, maintenance media, etc<br>3. Sources of antimicrobial agents: plants and microorganisms, therapeutic Antimicrobial Agents e.g. Erythromycin, Amphotericin B, Cephalosporins and their commercial production, Antimicrobial Drug Resistance and Drug Discovery |
| 301.2 | Title: Genomics (15)<br><br>Subtopics:<br><br>1. Nucleic Acid chemistry<br>2. Principles of DNA sequencing<br>3. DNA & RNA probes<br>4. Concepts of Gene manipulation (introduction only)<br>5. Restriction enzymes & their uses<br>6. Vectors & their uses<br>7. Producing Transgenic organisms<br>8. Hybridoma technology<br>9. cDNA production & applications<br>10. . Gene libraries & applications |
| 301.3 | Title: Basic and Regulatory Toxicology (15)<br><br>Subtopics:<br><br>1. Introduction, scope and types of toxicological studies.<br>2. Toxicants, their route of entry, distribution<br>3. Metabolism & elimination of toxicants<br>4. Concept of LD50, ED50 Title: Regulatory Toxicology<br>5. Types of toxicity studies<br>6. Design considerations.<br>7. Evaluation of results<br>8. Extrapolation to man.<br>9. OECD Guidelines on Toxicological studies<br>10. Schedule Y and its interpretation. |

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| 301.4 | Title: Regulatory Microbiology and its application in pharmaceutical and food industry (15)<br><br>Subtopics: (New Addition)<br><br>1. Asepsis, Sterilization and Disinfection, concept of Death curve of microbial population, Aseptic filling in pharmaceutical industry, Classification Clean rooms / Clean areas, QA and QC in Microbiology Laboratory<br>2. Important Microbes for Food & Drug Industry, Pathogenic Organisms in Food & Pharma Industry<br>3. Sources of contamination, Microbial Contamination in ASU preparations<br>4. Regulatory Microbiological testing in pharmaceuticals<br>5. Microbiological Assays for pharmaceutical products |

DETAILED SYLLABUS FOR M. SC. BIOANALYTICAL SCIENCES

SEMESTER III-theory
PSBN302- MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques - I
(Lecture allotment includes periods for Seminars and Discussions)

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|---|---|
| 302.1 | Title: MS basics (15)<br><br>Subtopics:<br><br>1.MS<br>2. MS/MS, TQ/Ion Trap<br>3. Components: Inlets, Ion sources, Analyzers, Detectors, Vacuum System, etc Introduction |
| 302.2 | Title: Hyphenation (15)<br><br>Subtopics:<br><br>1. LC/MS and LC/MS/MS<br>2. GC/MS and GC/MS/MS<br>3. Scan events in TQ and other tandem systems and hybrid systems<br>4. ICP/MS and its applications in pharmaceuticals and food<br>5. Recent advances in the field of mass spectrometry |
| 302.3 | Title: Thermal analysis (15)<br><br>Subtopics:<br><br>1. Principles of Thermal Analysis<br>2. Instrumentation Requirements<br>3. Applications of Thermal Analysis<br>4. Thermal analysis of Bhasma preparations<br>5.Thermal Analysis Techniques |
| 302.4 | Title: Analytical Methods (15)<br><br>Subtopics:<br><br>1. Method development and applications<br>2. Sample preparation<br>3. Headspace GC and GC-MS |

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| **DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**<br><br>**SEMESTER III-theory**<br>**PSBN303- Standardization of ASU Drugs, Statistics and GMP - I**<br>**(Lecture allotment includes periods for Seminars and Discussions)** | |
| 303.1 | Title: Standardization of ASU drugs (15)<br>Subtopics:<br>1. Need of standardization of Ayurvedic drugs<br>2. What does standardization involve?<br>3. Bioanalytical tools for standardization<br>4. Clinical studies in Standardization<br>5. Approaches to standardization;<br>6. Raw materials<br>7. In-process materials<br>8. Finished products<br>9. Developing standardized QC methods<br>10. Shelf life studies on finished products |
| 303.2 | Title: General Statistical Methods (15)<br>Subtopics:<br>1. Basic concepts of sample statistics<br>2. Concept of sample size and power<br>3. Concept of ramdomisation and sampling techniques<br>4. Concept of significance and confidence limits<br>5. Introduction to Various statistical tests - parametric and non parametric<br>6. Use of Statistical Packages for Data evaluation<br>7.Concept of random sampling and sampling techniques<br>8. Concept of level of significance, power of test and confidence limits<br>9.Concept of sample size<br>10.Application of normal distribution |
| 303.3 | Title: Concepts of Biostatistics (15)<br>Subtopics:<br>1. Statistical approach to biological samples<br>2. Variations in biological samples & their statistical treatment<br>3. Introduction to Data collection techniques<br>4. Design of experiments with eg. Block designs, Latin square<br>5. COV and ANOVA<br>6. Student's t test and F test<br>7. Regression analysis with application to Std Graph<br>8. Non parametric tests with examples<br>9. Statistical Guidance from regulatory agencies<br>10. . Student's T test, chi square test, Z test and F test<br>11.Single sample and two sample Non parametric tests with examples<br>12.Use of statistical packages for data analysis (SPSS software) |
| 303.4 | Title: Good Manufacturing Practice (15)<br>Subtopics:<br>1. What is GMP?<br>2. Requirements of GMP implementation<br>3. Documentation of GMP practices |

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| | 4. Regulatory certification of GMP<br>5. GMP in production of ASU drugs<br>6. Harmonization of SOP of manufacture<br>7. Audit for GMP compliances |
| **DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**<br><br>**SEMESTER III-theory**<br>**PSBN304- BA/BE Studies, GCP and Method Validation - I**<br>**(Lecture allotment includes periods for Seminars and Discussions)** | |
| 304.1 | Title: Ethical Issues in Clinical Trials (15)<br><br>Subtopics:<br><br>1. Origin of Ethical Issues<br>2. Dealing with Ethical issues<br>3. Ensuring compliance to ethical issues<br>4. Ethical Committees & their set up<br>5. Regulatory powers of ethical committees<br>6. Ethical issues in animal studies<br>7.Compliance to ethical guidelines<br>8.Dealing with Ethical issues<br>(subject compensation and subject rights)<br>9. Compliance to current ethical guidelines |
| 304.2 | Title: Good Clinical Practice (GCP) – 1 (15)<br><br>Subtopics:<br><br>1. What is GCP?<br>2. Origin of GCP<br>3. Earlier Guidelines for GCP<br>4. Requirements of GCP compliance |
| 304.3 | Title: Bioavailability (BA) & Bioequivalence (BE) studies – 1 (15)<br><br>Subtopics:<br><br>1. What is BA?<br>2. Parameters to evaluate BA of a drug<br>3. Factors that influence BA of a drug<br>4. Evaluating BA of a drug<br>5. Estimating BA parameters of a drug<br>6. What is BE?<br>7. Parameters to evaluate BE of a drug<br>8. Factors that influence BE of a drug<br>9. Evaluating BE of a drug<br>10. Estimating BE parameters of a drug |

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| 304.4 | Title: Analytical Method Validation (15)<br><br>Subtopics:<br><br>1. Strategies for Method development<br>2. What and Why of method validation<br>3. Regulatory requirements of validation<br>4. IQ, OQ and PQ of analytical instruments<br>5. Use of Reference standards<br>6. Issues of Method transfer<br>7. Intra and inter lab – Validation<br>8. Sampling<br>9. Calibration of glassware and instruments, concepts of Good weighing Practice<br>10. Use of Reference standards and working standards<br>11. format of Certificate of Analysis |
| **DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**<br><br>**SEMESTER IV-theory**<br>**PSBN401- Basic Microbiology, Genomics, Capillary Electrophoresis and Toxicology – I**<br>**(Lecture allotment includes periods for Seminars and Discussions)** | |
| 401.1 | Title: Bio assays in Pharmaceutical evaluation (15)<br><br>Subtopics:<br><br>1. General idea about bio assay systems used in pharmaceutical evaluations<br>2. In vitro assays and in vivo assays<br>3. Ethical issues of using animal assay systems<br>4. Alternatives to animal assays – one or two examples |
| 401.2 | Title: Polymerase Chain Reaction (PCR) & DNA Fingerprinting (15)<br><br>Subtopics:<br><br>1. Types of PCR & its applications<br>2. DNA amplification w.r.t its applications<br>3. DNA fingerprinting and applications<br>4. Use of genomic techniques in diagnostics |
| 401.3 | Title: Automation and analysis (15)<br><br>Subtopics:<br><br>1. Automation and its advantages in sample preparation<br>2. Automation in bioanalysis<br>3. Advanced automated liquid handling systems<br>4. Robotic Workstations<br>5. High throughput Screening |
| 401.4 | Title: Capillary Electrophoresis (15) |

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| | Subtopics:<br>1. Introduction<br>2. How capillary electrophoresis works<br>3. Why capillary electrophoresis works<br>4. CE hardware<br>Use in bioanalysis |

**DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**

**SEMESTER IV-theory**

**PSBN402- MS Applications, Metabolite Studies, Thermal Analysis and Tracer Techniques - I**

**(Lecture allotment includes periods for Seminars and Discussions)**

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| 402.1 | Title: Applications of Quantitative Analysis (15)<br><br>1.SM quantitation for e.g.<br>2. Macromolecule quantitation for e.g |
| 402.2 | Title: Applications of Qualitative Analysis (15)<br><br>Subtopics:<br><br>1. Technique of generating drug metabolites<br>2. Metabolite Identification<br>3. Impurity profiling |
| 402.3 | Title: LC/MS/MS (15)<br><br>Subtopics:<br><br>1. Impurity profile in drugs and drug products<br>2. Proteomics<br>3. Pesticides, pesticide residues in food |
| 402.4 | Title: Tracer techniques in Bioanalytical assays (15)<br><br>Subtopics:<br><br>1. Concept of Radioactivity & Half life<br>2. ∝, β, γ emitters and their biological applications<br>3. Using tracers in assays<br>4. Detectors and counters<br>5. Concept of autoradiography<br>6. Radio labeled probes and their uses |

**DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**

**SEMESTER IV-theory**

**PSBN403- Standardization of ASU Drugs, Statistics and GMP - I**

**(Lecture allotment includes periods for Seminars and Discussions)**

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| 403.1 | Title: Regulatory Aspects of ASU drugs (15)<br><br>Subtopics:<br>1. National initiatives for regulation of ASU drugs<br>2. Schedule T and Schedule Y of Drugs and Cosmetics Act<br>3. International initiatives for regulation of ASU drugs with special reference to<br>- WHO guidelines on traditional medicine<br>- Approaches of US and EU to ASU drug regulation<br>4. Provisions of Drugs and Cosmetics Act applied to ASU (e.g. Schedule T and Y) |
| 403.2 | Title: Environmental Safety in Bioanalytical laboratory (15)<br><br>Subtopics:<br>• Strategies to reduce environmental impact of Bioanalytical laboratory<br>• Standards of Laboratory Safety (Including Biosafety Levels)<br>• Overview of guidelines for laboratories handing Radioactive substances<br>• Introduction to ISO 14001 and OSHAS 18001.<br>• Introduction to Environment Impact Assessment & Reporting<br>• Biodiversity: Red Data Book, Endemic and endangered Medicinal Plant Species, Conservation and sustainable use of medicinal raw materials, Introduction to Wildlife Act of India & CITES<br>• Carbon footprints and Carbon credits. |
| 403.3 | Title: Electronic Data Management (15)<br><br>Subtopics:<br><br>1. Electronic Acquisition of data<br>2. Management of data in Computers<br>3. Electronic Data Validation and regulatory requirements<br>4. Electronic signatures & its regulation<br>5. Generating reports using computers<br>6. Regulatory requirements of Data evaluation |
| 403.4 | Title: Regulatory Issues (15)<br><br>Subtopics:<br>1. OTC drugs<br>2. Cosmetics<br>3. Food supplements<br>4. Nutraceuticals w.r.t. FSSI regulations |
| **DETAILED SYLLABUS FOR M. Sc. BIOANALYTICAL SCIENCES**<br><br>**SEMESTER IV-theory**<br>**PSBN404- BA/BE Studies, GCP and Method Validation - I**<br>**(Lecture allotment includes periods for Seminars and Discussions)** | |
| 404.1 | Title: Therapeutic drug monitoring and Pharmacovigilance (15) |

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| | Subtopics:<br><br>1. Purpose of therapeutic Drug Monitoring<br>2. Bioanalytical techniques in TDM<br>3. Analytical and practical issues of TDM<br>4. Pharmacoeconomics of TDM<br>5. Significance and need for Pharmacovigilance<br>6. Indian scenario and the role of regulatory in Pharmacovigilance<br>7. Pharmacovigilance and safe use of medicines (with case studies) |
| 404.2 | Title: Good Clinical Practice (GCP) – 2 (15)<br><br>Subtopics:<br><br>1. GCP guidelines of ICH<br>2. GCP guidelines of ICMR<br>3. Ensuring GCP<br>4. Documentation of GCP practice<br>5. Audit of GCP compliance |
| 404.3 | Title: Bioavailability (BA) & Bioequivalence (BE) studies – 2 (15)<br><br>Subtopics:<br><br>1. Design of a BA study<br>2. Conduct of a BA study<br>3. Data collection and evaluation<br>4. Reporting a BA study<br>5. Regulatory requirements of BA<br>6. Design of a BE study<br>7. Conduct of a BE study<br>8. Regulatory requirements of BA and BE<br>9. Data record and evaluation<br>10. Estimating Pharmacokinetic parameters<br>11. Assessment of Bioequivalence<br>12. Regulatory requirements and their compliance in pharmacokinetics |
| 404.4 | Title: QC and QA of ASU drugs (15)<br><br>Subtopics:<br><br>1. Herbal pharmacopoeia and Ayurvedic Formulary of India<br>2. Approaches to Quality control of ASU formulations<br>3. Govt initiatives<br>4. Some Initiatives from manufacturers<br>5. QC of RM and In-process materials (some examples)<br>6. QC / OA for finished products (some examples)<br>7. Applications of Herbal pharmacopoeia and Ayurvedic Formulary of India<br>8. Recent advances in Quality control of ASU formulations<br>9. QC / OA for finished products (some examples like Taila, Vati, Churna, Sufoof, Jawarish, Majoon,etc.) ) |

## M.Sc. Semester I PRACTICAL PSBNP 101

- Liquid – liquid extraction of a modern drug from plasma and formulations (e.g. Diclofenac sodium, Glimiperide, Aceclofenac, Metformin etc.)

- Microscopic evaluation of sections and powders with adulteration and formulation comparision of the following medicinal plants;

1) Emblica officinalis – (Amla - dried fruit)
2) Vitex nigundo - Leaves
3) Asteracantha Longifolia – Whole plant
4) Calotropis gigantea – Leaves
5) 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

- Determination of sugars by descending paper chromatography.

## M.Sc. Semester I PRACTICAL

## PSBNP 102

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

- Research Paper Review

- Carry out dissolution test, disintegration, hardness and friability on any one tablet preparation

- Modification by using Sodium dodecyl sulphate buffer and other buffer system (for water soluble and water insoluble drug). And With one modification that student should carry out tablet preparation with the help of IR Punch and then study all the test w.r.t. different parameters.

## M.Sc. Semester I PRACTICAL

## PSBNP 103

- 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

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

- Derivatisation in GC

## M.Sc. Semester I PRACTICAL PSBNP 104

- Separation of human serum / plasma proteins / egg white using PAGE((Protein molecular weight determination kit may be used)

- 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.

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

- Separation of proteins using 2D gel electrophoresis

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

- Protein profiling of plant seed by SDS-PAGE

# M.Sc. Semester II PRACTICAL PSBNP 201

- 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.)
- 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).
- Preparation of Herbarium of following medicinal plants;
  *1) Asteracanthalongifolia*
  *2) Trigonellafoenum*
  *3) Clitoriaternatea*
  *4) Coriandrumsativum*
  *5) Achyranthusaspera*
  *6) Scopariadulcis*
  *7) Amaranthusspinosa*
  *8) Phyllanthusamarus*
  *9) Calotroprisgigantea*
  *10) Vitexnigundo*

  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.
- 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
- Comparison of classical and modern method of extraction of phytoconstituent of medicinal plants
- Effect of drying on phytoconstituents.(Terpenes, alkaloids, tannins
- Phytochemical variation within a species using HPLC/HPTLC

# M.Sc. Semester II PRACTICAL PSBNP 202

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

- Accelerated stability studies of various formulations or drugs with respect to Temperature (b) Effect of buffers / pH dependent (2 – 4 Expts.)
- Test for degradation of compounds using TLC for any two drugs.
- Stability testing of solution and solid dosage forms for photo degradation.(2 experiments).
- Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
- Stability studies of drugs in dosage forms at 25oC, 60% RH and 40oC, 75% RH and at different Pressure

## M.Sc. Semester II PRACTICAL PSBNP 203

- 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. Asteracanthalongifolia, Ricinus cummunis, Calotropisgigantia)
- HPTLC detection of herbal raw material from its formulations (e.g. Asteracantha longifolia from LUKOL / SPEMAN, Vitexnigundo from PANCHGUN TAILA, Glycerrizhaglabra 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

  ii) HPLC

  iii) UV

## M.Sc. Semester II PRACTICAL PSBNP 204

- Immunoassay of HEPALISA in serum.
- Immunoassay for HCG in urine
- Immunoassay of T3 and T4 by RIA/IRMA

- Calculation of different Pharmacokinetic parameters like Ka, Ke, t½, C max, Tmax and AUC from the given blood data.

## M.Sc. Semester III PRACTICAL PSBNP 301

- 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)
- Gram staining of bacteria and mounting of filamentous and non-filamentous fungi *(Staphylococcus aureus, E. coli, Candida albicans, Penicilliumsps, Lactobacillus sps etc.)*
- Sterility testing (Microbial load) of drug formulations (According to IP 2013)
- CCl4 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)
- LD 50 evaluation using a suitable model (e.g. *Daphnia* / rice weevil)
- Isolation & screening of industrially important microorganisms
- Sterility testing of laminar airflow bench top.
- Strain improvement by mutation (by UV radiation & Chemical mutagens)
- Central streak with Bacillus species isolated from soil

## M.Sc. Semester III PRACTICAL PSBNP 302

- LC/MS quantitation of a modern drug (e.g. Diclofenac Sodium, Ezetimibe etc.)
- GC/MS separation of plant essential oil (Demonstration)
- 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 Mycophenolatemofitil)
- Mass Fingerprinting of peptides using a suitable sample.

## M.Sc. Semester III PRACTICAL PSBNP 303

- The project should involve industrial training of 8 to 12 weeks period. Data evaluation must involve application of biostatistics
- Problem based on Biostatistics

## M.Sc. Semester III PRACTICAL PSBNP 304

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

- Study of matrix effect on IR spectra using solution IR technique and quantitate the solutefrom a given sample. Identify solute from a given solution using IR library and carry out quantitative assay.

## M.Sc. Semester IV PRACTICAL PSBNP 401

- CE separation of a modern drug from plasma and its formulation (e.g. DFS)
- CE separation of peptides (e.g. erythropoietin as per E.P.)
- CE separation of N. Acids
- 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)
- Blue white screening of mutated organism
- Serum levels of drug attained by agar cup method
- Zone of inhibition assay for penicillin (using spiked plasma and formulation)
- Zone of exhibition assay for Vitamin B12

## M.Sc. Semester IV PRACTICAL PSBNP 402

- The project should involve preparation of herbal formulations and standardization Student can work on one of the following formulation

1. Any oil based preparation or ayurvedictaila preparation
2. Any vatti(Ayurvedic) or Guliga(Siddha)
3. Awahela (semi-solid,jiggery/sugar syrup based formulation)
4. Any preparation from unani e.g. Saffoof, Jawarish, Majoon.

Students should involve any modern chromatographic techniques,microscopic evaluation, chemical and physical tests for QC of formulation prepared.

## M.Sc. Semester IV PRACTICAL PSBNP 403

- IR patterns of an Ayurvedic Bhasma preparation (e.g. calcium containing shanka bhasma – comparison with pure $CaCO_3$ and formulations like Calcium supplement tablets)
- AAS of a suitable Ayurvedic metal bhasma preparation (e.g Tamara bhasma ) / Paracetamol
- Environment audit report
- Problem based on calculation of carbon credit and carbon footprint

## M.Sc. Semester IV PRACTICAL PSBNP 404

- BA & BE of a modern drug (Demonstration – witnessing an actual trial)
- Calculation of AUC and bioequivalence from the given data (2 expts.)
- Total viable count of herbal formulations/raw material
- Screening of pathogens from herbal formulation/raw material (*E.coli, S. aureus, Candida albicans*)