EVALUATION SCHEME & SYLLABUS

BACHELOR OF PHARMACY
## EIGHTH SEMESTER

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Name of the Course</th>
<th>No. of Hours/Week</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP801T</td>
<td>Biostatistics and Research Methodology</td>
<td>4</td>
<td>Continuous Mode</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP802T</td>
<td>Social and Preventive Pharmacy</td>
<td>4</td>
<td>Internal Assessment</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP803ET</td>
<td>Pharma Marketing Management*</td>
<td>4</td>
<td>Sessional Exams</td>
<td>15</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP804ET</td>
<td>Pharmaceutical Regulatory Science*</td>
<td>4</td>
<td>Duration</td>
<td>1</td>
<td>2 Hrs</td>
<td>50</td>
</tr>
<tr>
<td>BP805ET</td>
<td>Pharmacovigilance*</td>
<td>4</td>
<td>Total Marks</td>
<td>100</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>BP806ET</td>
<td>Quality Control and Standardization of Herbal*</td>
<td>4</td>
<td>Continuous Mode</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP807ET</td>
<td>Computer Aided Drug</td>
<td>4</td>
<td>Internal Assessment</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP808ET</td>
<td>Cell and Molecular</td>
<td>4</td>
<td>Sessional Exams</td>
<td>15</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP809ET</td>
<td>Cosmetic Science*</td>
<td>4</td>
<td>Duration</td>
<td>1</td>
<td>2 Hrs</td>
<td>50</td>
</tr>
<tr>
<td>BP810ET</td>
<td>Experimental</td>
<td>4</td>
<td>Total Marks</td>
<td>100</td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>BP811ET</td>
<td>Advanced Instrumentation Techniques*</td>
<td>4</td>
<td>Continuous Mode</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP812ET</td>
<td>Dietary Supplements and Nutraceuticals*</td>
<td>4</td>
<td>Internal Assessment</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP813ET</td>
<td>Pharmaceutical Product Development*</td>
<td>4</td>
<td>Sessional Exams</td>
<td>15</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP814ET</td>
<td>LSSSDC Elective*</td>
<td>4</td>
<td>Duration</td>
<td>1</td>
<td>2 Hrs</td>
<td>50</td>
</tr>
<tr>
<td>BP815PW</td>
<td>Project Work (On Elective)</td>
<td>12</td>
<td>Continuous Mode</td>
<td>10</td>
<td>25</td>
<td>75</td>
</tr>
<tr>
<td>BP816P</td>
<td>Report on Industrial Tour</td>
<td>-</td>
<td>Internal Assessment</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*ET: Elective subject* Every candidate has to **opt for two** of the elective subjects, and has to carry out **project on any one** of them. The student has the choice to choose both the elective subjects from the already prescribed list of elective subjects by the PCI or choose one elective subject from the existing prescribed list of elective subjects of B. Pharm. programme by the PCI and the other (second subject) elective from list of skill pack/modules available with the LSSSDC from time to time.

---

Evaluation Scheme Bachelor of Pharmacy I, II, III & IV Year syllabus 2019-2020
BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

Course content:

Unit-I
Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples.
Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems.
Correlation: Definition, Karl Pearson’s coefficient of correlation, multiple correlation- Pharmaceuticals examples.

Unit-II
Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical examples. Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson’s distribution, properties– problems.
Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples.
Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference.

Unit-III
Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.
Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, Plagiarism.
Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph
Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV
Blocking and confounding system for Two-level factorials.
Regression modeling: Hypothesis testing in Simple and Multiple regression models
Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, Design of experiment, R- Online Statistical Software’s to Industrial and Clinical trial approach.
Unit-V
Design and Analysis of experiments: 7 Hours

Factorial Design: Definition, $2^2$, $2^3$ design. Advantages of factorial design.
Response Surface methodology: Central composite design, Historical design, Optimization Techniques.

Recommended Books (Latest edition):

- Design and Analysis of Experiments by R. Pannerselvam, PHI Learning Private Limited.
BP802T. SOCIAL AND PREVENTIVE PHARMACY (Theory)  45 Hours

Course content:

Unit-I  10 Hours
Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.
Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.
Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health.
Hygiene and health: personal hygiene and health care; avoidable habits.

Unit-II  10 Hours
Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.

Unit-III  10 Hours
National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit-IV  08 Hours
National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program.

Unit-V  07 Hours
Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.
**Recommended Books (Latest edition):**

- Short Textbook of Preventive and Social Medicine, G.N. Prabhakara, 2\(^{nd}\) Edition, Jaypee Publications.
- Community Pharmacy Practice by Ramesh Adepu, BSP publishers, Hyderabad.
- Sociology for Pharmacist by Kevin Taylor, Sarah Nettleton and Geoffrey Harding.

**Recommended Journals:**

- Research in Social and Administrative Pharmacy, Elsevier, Ireland.
BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

Course content: 45 Hours

Unit-I 10 Hours
Marketing:

Pharmaceutical market:
Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patient's choice of physician and retail pharmacist. Analysing the Market; Role of market research.

Unit-II 10 Hours
Product decision:
Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit-III 10 Hours
Promotion:
Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit-IV 08 Hours
Pharmaceutical marketing channels:
Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):
Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit-V 07 Hours
Pricing:
Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:
Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.
**Recommended Books: (Latest Editions)**

- Marketing Management by Philip Kotler and Kevin Lane Keller, Prentice Hall of India, New Delhi.
- Textbook of Forensic Pharmacy by B.M. Mittal, Vallabh Prakashan, Delhi.
- A textbook of Forensic Pharmacy by N.K. Jain, Vallabh Prakashan, Delhi.
- Pharmaceutical Industrial Management by Vidya Sagar, PharmaMed Press, Hyderabad.
- Drugs and Cosmetics Act 1940 by Vijay Malik, EBC Publishing House Pvt. Ltd. Lucknow.
BP804ET. PHARMACEUTICAL REGULATORY SCIENCE (Theory)  

Course content:

Unit-I  
New Drug Discovery and development  
10 Hours  
Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit-II  
Regulatory Approval Process  
10 Hours  
Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.  
Regulatory authorities and agencies  
Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).

Unit-III 
Registration of Indian drug product in overseas market  
10 Hours  

Unit-IV 
Clinical trials  
08 Hours  
Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.

Unit-V 
Regulatory Concepts  
07 Hours  
Recommended books (Latest edition):

- Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
- Drugs: From Discovery to Approval by Rick Ng., 2nd Edition, Wiley-Blackwell.
- Validation of Active Pharmaceuticals Ingredients by Ira R. Bony & Daniel Harpaz, CRC Press, US.
BP805ET. PHARMACOVIGILANCE (Theory)  45 hours

Course Content

Unit-I  10 Hours
Introduction to Pharmacovigilance
History and development of Pharmacovigilance, Importance of safety monitoring of Medicine, WHO international drug monitoring programme, Pharmacovigilance Program of India (PvPI).

Introduction to adverse drug reactions
Definitions and classification of ADRs, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions.

Basic terminologies used in pharmacovigilance
Terminologies of adverse medication related events, Regulatory terminologies.

Unit-II  10 hours
Drug and disease classification
Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses, International Non-proprietary names for drugs.

Drug dictionaries and coding in pharmacovigilance

Information resources in pharmacovigilance
Basic drug information resources, Specialized resources for ADRs.

Establishing pharmacovigilance programme
Establishing in a hospital, Establishment & operation of drug safety department in industry, Contract Research Organizations (CROs), Establishing a national program.

Unit-III  10 Hours
Vaccine safety surveillance
Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization.

Pharmacovigilance methods
Passive surveillance – Spontaneous reports and case series, Stimulated reporting, Active surveillance– Sentinel sites, drug event monitoring and registries. Comparative observational studies– Cross sectional study, case control study and cohort study. Targeted clinical investigations.

Communication in pharmacovigilance
Unit-IV 8 Hours
Safety data generation: Pre clinical phase, Clinical phase, Post approval phase (PMS).
ICH Guidelines for Pharmacovigilance: Organization and objectives of ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies

Unit-V 7 Hours
Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK parameters.
Drug safety evaluation in special population: Paediatrics, Pregnancy and lactation, Geriatrics.
CIOMS: CIOMS Working Groups, CIOMS Form.
CDSCO (India) and Pharmacovigilance: D & C Act and Schedule Y, Differences in Indian and global pharmacovigilance requirements.

Recommended Books (Latest edition):
- Quintessence of Pharmacovigilance by Tapan Kumar Chatterjee, PharmaMed Press.
- Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
- An Introduction to Pharmacovigilance by Patrick Waller, Wiley Publishers.
- National Formulary of India.
- Textbook of Medicine by Yashpal Munjal.
- http://www.cioms.ch/
- http://cdsco.nic.in/
- http://www.who.int/vaccine_safety/en/
- http://www.ipc.gov.in/PvPI/pv_home.html
BP806ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS
(Theory) 45 Hours

Course Content

Unit-I 10 hours
Basic tests for drugs—Pharmaceutical substances, Medicinal plants materials and dosage forms.
WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use.

Unit-II 10 hours
Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.
WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants.

Unit-III 10 hours
EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines.

Unit-IV 08 hours
Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.
Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.

Unit-V 07 Hours
Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems
Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products.
Recommended Books: (Latest Editions)


- EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products.
BP807ET. COMPUTER AIDED DRUG DESIGN (Theory)

Course Content:

UNIT-I  10 Hours
Introduction to Drug Discovery and Development: Stages of drug discovery and development.
Lead discovery and Analogue Based Drug Design: Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.
Analogue Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies.

UNIT-II  10 Hours
Quantitative Structure Activity Relationship (QSAR)
SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet’s substituent constant and Taft’s steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III  10 Hours
Molecular Modeling and virtual screening techniques:
Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening.
Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. De novo drug design.

UNIT-IV  08 Hours
Informatics & Methods in drug design:
Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V  07 Hours
Recommended Books (Latest Editions)

- An Introduction to Medicinal Chemistry by Patrick Graham, L., Oxford University Press.
- Molecular Modelling and Design by Vinter J.V. and G. Mark, CRC Press, NY.
BP808ET. CELL AND MOLECULAR BIOLOGY (Theory)

Course content:

Unit-I
Properties of cells and cell membrane.
Prokaryotic versus Eukaryotic.
Cellular Reproduction.
Chemical Foundations – an Introduction and Reactions (Types).

Unit-II
DNA and the Flow of Molecular Information. DNA Functioning.
DNA and RNA. Types of RNA. Transcription and Translation.

Unit-III
Regularities in Protein Pathways.
Cellular Processes.
Positive Control and significance of Protein Synthesis.

Unit-IV
Science of Genetics.
Transgenics and genomic analysis. Cell cycle analysis.
Mitosis and Meiosis.
Cellular Activities and checkpoints.

Unit-V
Signaling Pathways: Overview.
Misregulation of Signaling Pathways.
Protein-Kinases: Functioning.
Recommended Books (latest edition):
- Pharmaceutical Microbiology by Malcolm Harris, Balliere Tindall and Cox.
- Industrial Microbiology by Rose, Butterworths, USA.
- Cooper and Gunn’s Tutorial Pharmacy by Carter S.J., CBS Publications, New Delhi.
- Microbial Technology by Peppler, Academic Press.
- Fundamentals of Microbiology by Edward, Benjamin Cummings, USA.
- Pharmaceutical Microbiology by N.K. Jain, Vallabh Prakashan, Delhi.
- Bergey’s Manual of Systematic Bacteriology by Williams and Wilkins, A Waverly company.
- Kuby Immunology by R.A. Goldsby et. al., W.H. Freeman and Company, NY.
BP809ET. COSMETIC SCIENCE (Theory)  

Unit-I  
Classification of cosmetic and cosmeceutical products.  
Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs.  
**Cosmetic excipients:** Surfactants, rheology modifiers, humectants, emollients, preservatives.  
Classification and application  
**Skin:** Basic structure and function of skin.  
**Hair:** Basic structure of hair. Hair growth cycle.  
**Oral Cavity:** Common problem associated with teeth and gums.  

Unit-II  
**Principles of formulation and building blocks of skin care products:** Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of cosmeceuticals.  
**Antiperspirants & deodorants**- Actives & mechanism of action.  

Unit-III  
Sun protection, Classification of Sunscreens and SPF.  
**Role of herbs in cosmetics:**  
**Skin Care:** Aloe and turmeric.  
**Hair care:** Henna and amla.  
**Oral care:** Neem and clove.  
**Analytical cosmetics:** BIS specification and analytical methods for shampoo, skin-cream and toothpaste.  

Unit-IV  
Soaps and syndet bars. Evolution and skin benefits.  

Unit-V  
Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.  
Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odour. Antiperspirants and Deodorants- Actives and mechanism of action.
Recommended Books (latest edition):
- Poucher’s Perfumes, Cosmetics and Soaps edited by Hilda Bulter, Springer (India) Pvt. Ltd., New Delhi.
- Cosmeceuticals by Madhusudan Rao, PharmaMed Press, Hyderabad.
- Cosmeceuticals by Rao Y.N., Shayeda, PharmaMed Press, Hyderabad.
- Drugs and Cosmetics Act/Rules, Govt. of India Publications.
- Drugs and Cosmetics Act 1940 by Vijay Malik, EBC Publishing House Pvt. Ltd. Lucknow.
BP810ET. PHARMACOLOGICAL SCREENING METHODS (Theory)

45 Hours

Course content:

Unit-I 10 Hours
Laboratory Animals:
Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

Unit-II 10 Hours
Preclinical screening models
Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.
Study of screening animal models for:
Diuretics, nootropics, anti-Parkinson’s, anti-asthmatics.

Unit-III 10 Hours
Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics.

Unit-IV 08 Hours
Preclinical screening models: for CVS activity – anti-hypertensives, diuretics, antiarrhythmic, anti-dyslipidemic, anti-aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, anti-diabetic, anticancer and anti-asthmatics.

Unit-V 07 Hours
Research methodology and Bio-statistics:
Selection of research topic, review of literature, research hypothesis and study design. Preclinical data analysis and interpretation using Students ‘t’ test and One-way ANOVA. Graphical representation of data.
Recommended Books (latest edition):
- CPCSEA Guidelines for Laboratory Animal Facility.
- Screening Methods in Pharmacology by Tumer, Elsevier a Division of Reed India Pvt. Ltd. Noida.
BP811ET. ADVANCED INSTRUMENTATION TECHNIQUES (Theory)

45 Hours

Course Content:

Unit-I 10 Hours

**Nuclear Magnetic Resonance spectroscopy**
Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications.

**Mass Spectrometry** - Principles, Fragmentation, Ionization techniques- Electron impact, chemical ionization, MALDI, FAB, Analyzers -Time of flight and Quadrupole, instrumentation, applications.

Unit-II 10 Hours

**Thermal Methods of Analysis**: Principles, instrumentation and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC).

**X-Ray Diffraction Methods**: Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

Unit-III 10 Hours

**Calibration and validation**- as per ICH and USFDA guidelines.

**Calibration of following Instruments**: Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC.

Unit-IV 08 Hours

**Radio immune assay**: Importance, various components, Principle, different methods, Limitation and Applications of Radio immunoassay.

**Extraction techniques**: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction.

Unit-V 07 Hours

**Hyphenated techniques**: LC-MS/MS, GC-MS/MS, HPTLC-MS.
Recommended Books (Latest Editions)

- Instrumental Methods of Chemical Analysis by B.K. Sharma, Krishna Prakasan Media (P) Ltd., Meerut, India.
- Pharmaceutical Chemistry Instrumental Technique by Leslie G. Chatten, CBS Publisher and Distributer Pvt. Ltd., New Delhi.
- Vogel’s Textbook of Quantitative Chemical Analysis by A.I. Vogel, Addison Wesley Logman, Singapore.
- Organic Spectroscopy by William Kemp, Palgrave, NY.
BP812ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS (Theory)  
45 Hours

Course Content:

Unit-I  
Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. 
Public health nutrition, maternal and child nutrition. Nutrition and ageing, nutrition education in community. 
Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soybean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds.

Unit-II  
Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following: 
Carotenoids: α and β-Carotene, Lycopene, Xanthophylls, leutin. 
Sulfides: Diallyl sulfides, Allyl trisulfide. 
Polyphenolics: Reservetrol. 
Flavonoids: Rutin, Naringin, Quercitin, Anthocyanidins, catechins, Flavones. 
Prebiotics/Probiotics: Fructo-oligosaccharides, Lacto bacillum. 
Phyto estrogens: Isoflavones, daidzein, Geebustin, lignans. 
Tocopherols. 
Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

Unit-III  
Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. Dietary fibres and complex carbohydrates as functional food ingredients.

Unit-IV  
Functional foods for chronic disease prevention.
Unit-V
07 Hours
Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
Regulatory Aspects: FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Pharmacopeial Specifications for dietary supplements and nutraceuticals.

Recommended Books (Latest editions)
- Role of Dietary Fibers and Nutraceuticals in Preventing Diseases by K.T. Agusti and P. Faizal: BS Publication.
- Essentials of Food Process Engineering by Chandra Gopala Rao, BS Publications, Hyderabad.
BP813ET. PHARMACEUTICAL PRODUCT DEVELOPMENT (Theory)

Course Content:

Unit-I 10 Hours
Introduction to pharmaceutical product development, objectives, and regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms.

Unit-II 10 Hours
An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories:
Solvents and solubilizers. Cyclodextrins and their applications.
Non-ionic surfactants and their applications. Polyethylene glycols and sorbitols.
Suspending and emulsifying agents. Semi solid excipients.

Unit-III 10 Hours
An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories:
Excipients in parenteral and aerosols products. Excipients for formulation of NDDS.
Selection and application of excipients for pharmaceutical formulations, with specific industrial applications.

Unit-IV 08 Hours

Unit-V 07 Hours
Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.
Recommended Books (Latest editions)

- Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, Charles Bon; Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, by A. Lieberman, Leon Lachman and Joseph B. Schwartz, Marcel Dekker Inc., USA.
- Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, by H.A. Liberman, Martin, M.R and Gilbert S. Banker, Marcel Dekker Inc., USA.
- Martin’s Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, Lippincott Williams & Wilkins, USA.
- Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems by Loyd V. Allen, Jr., N.G. Popovich and H. C. Ansel, Lippincott Williams & Wilkins, USA.
- Advanced Review Articles related to the topics.
BP803ET to BP814ET (Elective Subjects)

The student has the choice to choose both the elective subjects from the already prescribed list of elective subjects by the PCI or choose one elective subject from the existing prescribed list of elective subjects of B. Pharm. programme by the PCI and the other (second subject) elective from list of skill pack/modules available with the LSSSDC from time to time.
BP815PW. PROJECT WORK (On Elective)

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subjects opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).
BP816P. REPORT ON INDUSTRIAL TOUR

Visit of students to an industrial establishment or an approved research laboratory. The industrial visit shall include: in case of industry- visit to different sections and subsections of the industry, an idea about the functioning of the industry, product range of the industry and various approvals of the industry; in case of research laboratory-visit to different departments of the laboratory, an idea about the interdisciplinary coordination, contribution of the laboratory to the society and various approvals of the laboratory. A proper report of the same shall be submitted by the students, which shall be subsequently evaluated to assess the impact of the visit.

May be performed at the end of the 7th semester.