



**B.PHARM SYLLABUS**

**SEMESTER VIII**

**Biostatistics and research methodology –Theory (TIU-UBP-801T)**

**Credit points-4**

**Course Outcomes**

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Explain</b> the measures of central tendency and measures of dispersion, correlation	K2
<b>CO2</b>	<b>Identify</b> and solve various statistical problems based on regression, probability and parametric test	K3
<b>CO3</b>	<b>Design</b> methodology and <b>draw</b> graphs and understand concept of non parametric test and research	K5
<b>CO4</b>	<b>Solve</b> industrial and clinical trial problems and learn regression modelling	K3
<b>CO5</b>	<b>Design</b> experiments and analyze through response surface methodology	K5

**Course Content**

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**Unit-I**

- **Introduction:** Statistics, Biostatistics, Frequency distribution
- **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 Pharmaceutical 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, Experimental 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 EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

### 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 EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

### Unit-V

- **Design and Analysis of experiments:** Factorial Design: Definition, 2<sup>2</sup>, 2<sup>3</sup> design. Advantage of factorial design
- **Response Surface methodology:** Central composite design, Historical design, Optimization Techniques

### Social and preventive pharmacy- Theory (TIU-UBP-802T)

#### Credit points-4

#### Course Outcomes

Upon completion of the course, the student shall be able

CO1	<b>Summarize</b> the concept of health and disease.	K2
CO2	<b>Demonstrate</b> the relationship between food and health.	K2
CO3	<b>Explain</b> Socio cultural factors related to health and disease.	K2
CO4	<b>Discuss</b> the impact of personal hygiene on health.	K2
CO5	<b>Identify</b> the general principles of prevention and control of diseases.	K3

## **Course Content**

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### **UNIT-I**

#### **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**

#### **Preventive medicine:**

General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chikungunya, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.

### **UNIT-III**

#### **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**

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 programme.

### **UNIT V**

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.

**Pharma Marketing Management- Theory (TIU-UBP-803ET)**  
**Credit points-4**

**Course Outcomes**

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Illustrate</b> marketing concept and Pharmaceutical market.	K2
<b>CO2</b>	<b>Identify</b> product decision and product management in pharma industry	K3
<b>CO3</b>	<b>Examine</b> the concept of promotion for marketing.	K4
<b>CO4</b>	<b>Describe</b> the importance of role of marketing channels and distribution strategy	K2
<b>CO5</b>	<b>Describe</b> pricing strategy of firms.	K2

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**Course content-**

**Unit-I Marketing:**

Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

**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; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

**Unit- II**

**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**

**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- 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 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.

**Pharmaceutical Regulatory Science –Theory (TIU-UBP-804ET)**

**Credit points-4**

**Course Outcomes**

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Demonstrate</b> the stages of drug discovery, drug development process.	K2
<b>CO2</b>	<b>Compare</b> the various regulatory authorities in different countries and their drug approval processes.	K4
<b>CO3</b>	<b>Identify</b> process of registration of Indian drug product in overseas market.	K3
<b>CO4</b>	<b>Summarize</b> the clinical trials protocols and the concept of pharmacovigilance.	K2
<b>CO5</b>	<b>Demonstrate</b> the various regulatory concepts relating to drug manufacturing and sale.	K2

**Course Content**

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**Unit I****New Drug Discovery and development**

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**

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**

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

### **Unit IV**

#### **Clinical trials**

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**

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulations, Purple book

### **Pharmacovigilance- Theory (TIU-UBP-805ET)**

**Credit points-4**

#### **Course Outcomes**

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Identify</b> new adverse drug reactions and their assessment and <b>Describe</b> the importance of drug safe monitoring.	K3
<b>CO2</b>	<b>Classify</b> drug and disease and <b>Demonstrate</b> dictionaries, coding and resources used in pharmacovigilance.	K2
<b>CO3</b>	<b>Summarize</b> pharmacovigilance methods in vaccine safety and <b>illustrate</b> methods and communication in pharmacovigilance	K2
<b>CO4</b>	<b>Demonstrate</b> ICH guidelines for pharmacovigilance	K2
<b>CO5</b>	<b>Evaluate</b> drug safety in special population and pharmacogenomics of adverse reactions	K4

## **Course Content**

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### **UNIT-I**

#### **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**

#### **Drug and disease classification**

Anatomical, therapeutic and chemical classification of drugs  
International classification of diseases  
Daily Demonstrated doses  
International Non proprietary Names for drugs

#### **Drug dictionaries and coding in pharmacovigilance**

WHO adverse reaction terminologies  
MedDRA and Standardised MedDRA queries  
WHO drug dictionary  
Eudravigilance medicinal product dictionary

## **Information resources in pharmacovigilance**

Basic drug information resources

Specialised resources for ADRs

## **Establishing pharmacovigilance programme**

Establishing in a hospital

Establishment & operation of drug safety department in industry

Contract Research Organisations (CROs)

Establishing a national programme

## **UNIT-III**

### **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**

Effective communication in Pharmacovigilance

Communication in Drug Safety Crisis management

Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

## **UNIT IV**

### **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

### 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

## Quality Control and Standardization of Herbals- Theory (TIU-UBP-806ET)

### Credit points-4

### Course Outcomes

Upon completion of the course, the student shall be able

CO1	<b>Evaluate</b> commercial crude drugs and <b>Describe</b> the basic tests and WHO guidelines governing the quality control of herbal drugs.	K4
CO2	<b>Classify</b> the various aspects of quality assurance in herbal drug industry such as cGMP, GAP, GMP, GLP and WHO guidelines on cGMP and GACP for medicinal plants.	K2
CO3	<b>Demonstrate</b> the EU and ICH guidelines related to quality control and research guidelines for assessing the safety and efficacy of herbals.	K2
CO4	<b>Apply</b> the GMP requirements, methods of stability testing and the documentation for new drug application and export registration of herbal products in the industry.	K3
CO5	<b>Summarize</b> the regulatory requirements of herbal medicines and <b>evaluate</b> the use of chemical and biological markers in herbal drug standardization.	K2

## Course Content

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### UNIT-I

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

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

EU and ICH guidelines for quality control of herbal drugs.  
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

### UNIT IV

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

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

## Computer Aided Drug Design- Theory (TIU-UBP-807ET) Credit points-4

### Course Outcomes

Upon completion of the course, the student shall be able

CO1	<b>Summarize</b> different stages of drug discovery with special focus on in silico drug designing	K2
CO2	<b>Compare</b> different techniques, advantage and disadvantages of ligand based and structure based drug design (QSAR).	K4
CO3	<b>Identify</b> and <b>implement</b> the uses of different database and tools for screening and in silico drug design through molecular docking	K3
CO4	<b>Compute</b> and <b>interpret</b> different databases and bioinformatics as molecular	K4

	prediction tools	
<b>CO5</b>	<b>Demonstrate</b> molecular modelling techniques	K2

## Course Content

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### UNIT-I

#### **Introduction to Drug Discovery and Development**

Stages of drug discovery and development

#### **Lead discovery and Analog 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. Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies.

### UNIT-II

#### **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, Hammett's substituent constant and Taft's steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

### UNIT-III

#### **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

Informatics & Methods in drug design Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

### UNIT-V

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

**Cell and molecular biology- Theory (TIU-UBP-808ET)**  
**Credit points-4**

**Course Outcomes**

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Classify</b> types of cells and demonstrate cellular functions	K2
<b>CO2</b>	<b>Identify</b> types of DNA, RNA and related functions	K3
<b>CO3</b>	<b>Classify</b> types of proteins and <b>Compare</b> different protein structures and their synthesis.	K2
<b>CO4</b>	<b>Summarize</b> the science of genetics and cellular activities	K2
<b>CO5</b>	<b>Examine</b> cell signaling pathways	K4

**Course Content**

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**Unit I**

- a) Cell and Molecular Biology: Definitions theory and basics and Applications.
- b) Cell and Molecular Biology: History and Summation.
- c) Properties of cells and cell membrane.
- d) Prokaryotic versus Eukaryotic
- e) Cellular Reproduction
- f) Chemical Foundations – an Introduction and Reactions (Types)

**Unit II**

- a) DNA and the Flow of Molecular Information
- b) DNA Functioning
- c) DNA and RNA
- d) Types of RNA
- e) Transcription and Translation

**Unit III**

- a) Proteins: Demonstrated and Amino Acids
- b) Protein Structure
- c) Regularities in Protein Pathways
- d) Cellular Processes
- e) Positive Control and significance of Protein Synthesis

**Unit IV**

- a) Science of Genetics
- b) Transgenics and Genomic Analysis
- c) Cell Cycle analysis
- d) Mitosis and Meiosis
- e) Cellular Activities and Checkpoints

## Unit V

- a) Cell Signals: Introduction
- b) Receptors for Cell Signals
- c) Signaling Pathways: Overview
- d) Misregulation of Signaling Pathways
- e) Protein-Kinases: Functioning

## Cosmetic science – Theory (TIU-UBP-809ET)

Credit points-4

### Course Outcomes

Upon completion of the course, the student shall be able

CO1	<b>Explain</b> the concept of cosmetics, anatomy of the skin, hair and oral cavity, as well as general excipients used in cosmetics.	K2
CO2	<b>Identify</b> the methods for formulation of cosmetics for skin and hair along with their manufacturing and evaluation.	K3
CO3	<b>Recognize</b> the role of herbs in cosmetics, <b>summarize</b> cosmetics for sun protection	K2
CO4	<b>Evaluate</b> the cosmetic formulations	K4
CO5	<b>Identify</b> the various cosmetic problems relating to skin, hair and oral cavity.	K3

### Course Content

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#### 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.

**Principles of formulation and building blocks of Hair care products:**

Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils.

Chemistry and formulation of Para-phenylenediamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

### 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

Principles of Cosmetic Evaluation: Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties. 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 odor.

Antiperspirants and Deodorants- Actives and mechanism of action

## Experimental Pharmacology- Theory (TIU-UBP-810ET)

**Credit points-4**

### Course Outcomes

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Describe</b> the regulatory guidelines for proper animal care and handling.	K2
<b>CO2</b>	<b>Summarize</b> the preparation before preclinical research and explain the preclinical screening methods for pharmacological activities.	K2
<b>CO3</b>	<b>Analyze</b> preclinical screening models for ANS and other activities	K4
<b>CO4</b>	<b>Evaluate</b> preclinical screening models for CVS activity, anticancer activity, etc	K4
<b>CO5</b>	<b>Explain</b> the application of research methodology and biostatistics in preclinical studies	K2

## **Course Content**

### **UNIT-I**

#### **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**

#### **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, antiasthmatics

**Preclinical screening models:** for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

### **UNIT-III**

**Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics

### **UNIT IV**

**Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants

Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.

### **UNIT V**

#### **Research methodology and Bio-statistics**

Selection of research topic, review of literature, research hypothesis and study design

Pre-clinical data analysis and interpretation using Students't' test and One-way ANOVA.

Graphical representation of data

**Advanced instrumentation techniques- Theory (TIU-UBP-811ET)**

**Credit points-4**

## **Course Outcomes**

On completion of this course, the students will be able to

<b>CO1</b>	<b>Summarize</b> the advanced instruments used and its applications in drug analysis including NMR and Mass spectroscopy	K2
<b>CO2</b>	<b>Demonstrate</b> XRD and thermal methods of drug analysis	K2
<b>CO3</b>	<b>Examine</b> the calibration of various analytical instruments as per ICH and USFDA guidelines	K4
<b>CO4</b>	<b>Evaluate</b> radio immune assay of drugs and demonstrate extraction techniques	K4
<b>CO5</b>	<b>Apply</b> hyphenated techniques in drug analysis	K3

## Course Content

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### UNIT-I

#### **Nuclear Magnetic Resonance spectroscopy**

Principles of  $^1\text{H}$ -NMR and  $^{13}\text{C}$ -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

**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

**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

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

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



## UNIT-V

**Hyphenated techniques:** LC-MS/MS, GC-MS/MS, HPTLC-MS

### **Dietary Supplements and Nutraceuticals- Theory (TIU-UBP-812ET)** **Credit points-4**

#### **Course Outcomes**

Upon completion of the course, the student shall be able

<b>CO1</b>	<b>Classify</b> the various nutraceuticals and their use in the treatment of various diseases.	K2
<b>CO2</b>	<b>Classify</b> various phytochemicals as nutraceuticals	K2
<b>CO3</b>	<b>Recognize</b> the basic concept of free radicals and their damaging effects on the human body	K2
<b>CO4</b>	<b>Describe</b> the role of free radicals in various diseases and the different endogenous and synthetic antioxidants.	K2
<b>CO5</b>	<b>Apply</b> the regulatory aspects for pharmacopoeial specifications of dietary supplements and nutraceuticals.	K3

#### **Course Content**

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#### **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, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

#### **UNIT-II**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

- Carotenoids-  $\alpha$  and  $\beta$ -Carotene, Lycopene, Xanthophylls, leutin
- Sulfides: Diallyl sulfides, Allyl trisulfide
- Polyphenolics: Resveratrol
- Flavonoids- Rutin, Naringin, Quercetin, Anthocyanidins, catechins, Flavones
- Prebiotics / Probiotics.: Fructo oligosaccharides, Lactobacillum
- Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans
- Tocopherols

- h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

### **UNIT-III**

- a) 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.
- b) Dietary fibres and complex carbohydrates as functional food ingredients

### **UNIT IV**

- a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
- b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E,  $\alpha$ - Lipoic acid, melatonin  
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.
- c) Functional foods for chronic disease prevention

### **UNIT V**

- a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
- b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
- c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.