

## SEMESTER- VIII

### BP 801T BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

#### 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 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, 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-V

**Design and Analysis of experiments:**

**Factorial Design:** Definition,  $2^2$ ,  $2^3$  design. Advantage of factorial design

**Response Surface methodology:** Central composite design, Historical design, Optimization Techniques

### BP- 802T SOCIAL AND PREVENTIVE PHARMACY(Theory)

#### 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, chicken guinea, 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 program

**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.

**BP-803T (A) PHARMACEUTICAL MARKETING MANAGEMENT (Theory)**

**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.

**BP-803T(B) QUALITY CONTROL AND STANDARDIZATION OF HERBALS  
(Theory)****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

**BP-803T(C) 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 cosmetics.

**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-phenylene diamine 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

## **BP-803T(D) PHARMACOLOGICAL SCREENING METHODS**

### **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, antidiabetic, anti aggregatory, coagulants, and anticoagulants

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

### **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

## **BP- 803T (E) ADVANCED INSTRUMENTATION TECHNIQUES (Theory)**

### **UNIT-I**

#### **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**

**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 Radio immuno 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.**

## **BP-804T (A): PHARMACEUTICAL REGULATORY SCIENCE (Theory)**

### **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 Regulatory, Purple book

## **BP- 804T(B): PHARMACOVIGILANCE (Theory)**

### **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 defined 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 Pharma covigilance 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 studie

## **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

## BP- 804T(C) COMPUTER AIDED DRUG DESIGN (Theory)

### 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, cheminformatics. 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.

## BP- 804T( E). DIETARY SUPPLEMENTS AND NUTRACEUTICALS(Theory)

### 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, Ginkgo, 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, Lacto bacillum

Phyto estrogens : Isoflavones, daidzein, Geobustin, 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.

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

## **UNIT IV**

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 radicalstheory of ageing.

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. Functional foods for chronic disease prevention

## **UNIT V**

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.

Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

## **BP-804T (F) PHARMACEUTICAL PRODUCT DEVELOPMENT (Theory)**

### **Unit-I**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

### **Unit-II**

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**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

Tablet and capsule excipients Directly compressible vehicles Coat materials

Excipients in parenteral and aerosols products Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

### **Unit-IV**

Optimization techniques in pharmaceutical product development. A study of various optimization techniques for pharmaceutical product development with specific examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

### **Unit-V**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

## **BP-805(P) PRACTICE SCHOOL (Practical)**

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school .

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

## CAMPUS FACILITIES

Hostel	:	Separate Hostel for Girls.
Computer Centre	:	with more than 30 nodes are internet facility.
Library	:	Central Library with about 90,000/- books & 150 Journals with book bank and other facilities.
Department Library	:	Text books related to course.
Communication Facilities:	:	STD/ISD/Photocopy Internet etc.
Health Centre	:	Free primary health check up facility within the campus.
SC/ST Cell	:	Special cell for SC/ST students.
Sports	:	Sports Ground and All Indoor, Outdoor Games.
Canteen Facility	:	Canteen is available for snacks & working lunch etc.
NSS	:	Studies have option of joining NSS.
Cultural Society	:	Promotes & Organizes various cultural activities among the campus students.

# Institute Telephone Directory

Authority	Department	Contact No.
Dr. Akash Dubey	Admission Cell	7987796396
Dr. Anshul Gangele AIST Principal	Engineering	9009694290
Dr. Vivek Jain AIPS Principal	Pharmacy	8770790989
Dr. Prateek Jain ACP Principal	Pharmacy	7987010486
Er. Rajkumar Yadav Head of the Deptt.	Humanities and Science	8982160106
Er. Animesh Awasthi Head of the Deptt.	Civil Engineering	9713318171
Er. Rajneesh Pachouri Head of the Deptt.	Computer Science And Engineering	7869104217
Er. Vivek Bhargava Head of the Deptt.	Electrical And Electronics Engineering	9406519528
Er. Amar Mishra Head of the Deptt.	Mechanical Engineering	8602732365
TPO	Training & Placement Cell	6268621222
IT Manager	System	9827075734
Sports and Music In-charge	Sports	9827075734
Engineering Librarian	Library	7987909255
Mrs. Sapna Mishra AIPS Librarian	Library	9806682800
Ms. Riya Jain ACP Librarian	Library	9589886326
Mr. Neeraj Soni	Fee In-charge (Engineering College)	9329207780
Dr. Akash Dubey	Scholarship In-charge	9981305781
Mr. Ashok Sen	Office In-charge (Pharmacy College)	7583804850