Bpharm 8th Semester Syllabus

BIOSTATISITCS AND RESEARCH METHODOLOGY

UNIT 1

Introduction: Statistics, Biostatistics, and Frequency distribution.
Measures of Central Tendency: Mean, Median, and Mode—Pharmaceutical examples.
Measures of Dispersion: Dispersion, Range, Standard deviation—Pharmaceutical problems.
Correlation: Definition, Karl Pearson's coefficient of correlation, and Multiple correlation—Pharmaceutical examples.

UNIT 2

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 and 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: ttt-test (Sample, Pooled or Unpaired, and Paired), ANOVA (One-way and Two-way), Least Significance Difference.

UNIT 3

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, Contour Plot Graph.
Designing the Methodology: Sample size determination and power of a study, report writing and presentation of data, protocol, cohort studies, observational studies, experimental studies, designing clinical trials, various phases.

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UNIT 4

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 for industrial and clinical trial approaches.

UNIT 5

Design and Analysis of Experiments:
Factorial Design: Definition, 2^2, 2^3 design, Advantages of factorial design.
Response Surface Methodology: Central composite design, historical design, and optimization techniques.

SOCIAL AND PREVENTIVE PHARMACY

UNIT 1

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 2

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, and substance abuse.

UNIT 3

National Health Programs: Its objectives, functioning, and outcome of the following: HIV and AIDS control program, TB control program, Integrated Disease Surveillance

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Program (IDSP), National Leprosy Control Program, National Mental Health Program, National Program for Prevention and Control of Deafness, Universal Immunization Program, National Program for Control of Blindness, Pulse Polio Programme.

UNIT 4

National Health Intervention Programs for Mother and Child, National Family Welfare Program, National Tobacco Control Program, National Malaria Prevention Program, National Program for the Health Care of the Elderly, Social Health Program; Role of WHO in Indian National Programs.

UNIT 5

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

UNIT 1

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 2

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 3

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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 4

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 5

Pricing:
Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in the 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

UNIT 1

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 2

Regulatory Approval Process
Approval processes and timelines involved in Investigational New Drug (IND), New Drug

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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 3

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 4

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 5

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

PHARMACOVIGILANCE

UNIT 1

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

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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 2

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
Specialized 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

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UNIT 3

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 4

Safety Data Generation
Preclinical phase
Clinical phase
Postapproval phase (PMS)

ICH Guidelines for Pharmacovigilance
Organization and objectives of ICH
Expedited reporting
Individual case safety reports
Periodic safety update reports
Postapproval expedited reporting
Pharmacovigilance planning
Good clinical practice in pharmacovigilance studies

UNIT 5

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

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QUALITY CONTROL AND STANDARDIZATION OF HERBALS

UNIT 1

Basic Tests for Drugs
Pharmaceutical substances, Medicinal plant materials, and dosage forms.
WHO Guidelines for Quality Control of Herbal Drugs
Evaluation of Commercial Crude Drugs Intended for use.

UNIT 2

Quality Assurance in Herbal Drug Industry
cGMP, GAP, GMP, and GLP in the traditional system of medicine.

WHO Guidelines on Current Good Manufacturing Practices (cGMP)
For herbal medicines.
WHO Guidelines on GACP For medicinal plants.

UNIT 3

EU and ICH guidelines for quality control of herbal drugs.
Research guidelines for evaluating the safety and efficacy of herbal medicines.

UNIT 4

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 5

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

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UNIT 1

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 2

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 3

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 4

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

UNIT 5

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

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CELL AND MOLECULAR BIOLOGY

UNIT 1

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 2

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

UNIT 3

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

UNIT 4

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

UNIT 5

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

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COSMETIC SCIENCE

UNIT 1

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 2

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 and 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.

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UNIT 3

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 4

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 5

Oily and dry skin, Causes leading to dry skin, skin moisturization. Basic understanding of the terms comedogenic and 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.

PHARMACOLOGICAL SCREENING METHODS

UNIT 1

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.

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UNIT 2

Preclinical Screening Models

a. 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 the selection of animal species and sex for the study.

b. Study of Screening Animal Models:

- Diuretics, nootropics, anti-Parkinson’s, antiasthmatics

- **Preclinical screening models:** for CNS activity -Analgesic, antipyretic, anti-inflammatory, general anesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti-Parkinsonism, and Alzheimer's disease.

UNIT 3

Preclinical Screening Models: for ANS Activity, Sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on the eye, and local anesthetics.

UNIT 4

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.

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

UNIT 1

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 2

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

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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 3

Calibration and validation as per ICH and USFDA guidelines.
Calibration of the following instruments: Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC, and GC.

UNIT 4

Radioimmune assay: Importance, various components, principle, different methods, limitation, and applications of radioimmune assay.
Extraction techniques: General principle and procedure involved in the solid-phase extraction and liquid-liquid extraction.

UNIT 5

Hyphenated techniques- LC-MS/MS, GC-MS/MS, HPTLC-MS.

DIETARY SUPPLEMENTS AND NUTRACEUTICALS

UNIT 1

a. 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.

b. Public health nutrition, maternal and child nutrition, nutrition and aging, nutrition education in the community.

c. Source, name of marker compounds, and their chemical nature, medicinal uses, and health benefits of the following used as nutraceuticals/functional foods: Spirulina, Soybean, Ginseng, Garlic, Broccoli, Ginkgo, Flaxseeds.

UNIT 2

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Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature, medicinal benefits) of the following:
a) Carotenoids – α and β-Carotene, Lycopene, Xanthophylls, Lutein
b) Sulfides: Diallyl sulfides, Allyl trisulfide
c) Polyphenolics: Resveratrol
d) Flavonoids – Rutin, Naringin, Quercetin, Anthocyanidins, Catechins, Flavones
e) Prebiotics / Probiotics: Fructo oligosaccharides, Lactobacillus
f) Phytoestrogens: Isoflavones, Daidzein, Geebustin, Lignans
g) Tocopherols
h) Proteins, vitamins, minerals, cereals, vegetables, and beverages as functional foods: Oats, wheat bran, rice bran, seafood, coffee, tea, and the like.

UNIT 3

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, and nucleic acids.

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

UNIT 4

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, α- Lipoic acid, melatonin.
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention.

UNIT 5

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.

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c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

ELECTIVE COURSE ON PHARMACEUTICAL PRODUCT DEVELOPMENT

UNIT 1

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 2

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories:
i. Solvents and solubilizers
ii. Cyclodextrins and their applications
iii. Non-ionic surfactants and their applications
iv. Polyethylene glycols and sorbitols
v. Suspending and emulsifying agents
vi. Semi-solid excipients

UNIT 3

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories:
i. Tablet and capsule excipients
ii. Directly compressible vehicles
iii. Coat materials
iv. Excipients in parenteral and aerosol products
v. Excipients for formulation of NDDS

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

UNIT 4

Optimization techniques in pharmaceutical product development: A study of various optimization techniques for pharmaceutical product development with specific

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examples. Optimization by factorial designs and their applications. A study of QbD and its application in pharmaceutical product development.

UNIT 5

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

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