B.Pharm Syllabus

Semester 08

Subjects

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BP801T - 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, 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: Factorial Design: Definition, 22, 23design. Advantages of factorial design.
- Response Surface methodology: Central composite design, Historical design, Optimization Techniques.

BP802T - 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.

BP803ET - Pharma Marketing Management

Elective Theory

Unit I

- Marketing: Definition, general concepts and scope of marketing, distinction between marketing & selling.
- Marketing environment. Industry and competitive analysis. Analyzing consumer buying behaviour and industrial buying behaviour.
- 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

- 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.

BP804ET - Pharmaceutical Regulatory Science

Elective 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.

BP805ET - Pharmacovigilance

Elective 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 Standardized 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 Organizations (CROs), Establishing a national program.

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.

BP806ET - Quality Control and Standardization of Herbal Drugs

Elective 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.

BP807ET - Computer Aided Drug Design

Elective Theory

Unit I

- 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

- 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

- 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.

BP808ET - Cell and Molecular Biology

Elective Theory

Unit I

- Cell and Molecular Biology: Definitions theory and basics and Applications. Cell and Molecular Biology: History and Summation.
- 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

- Proteins: Defined and Amino Acids. Protein Structure.
- 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

- Cell Signals: Introduction. Receptors for Cell Signals.
- Signaling Pathways: Overview.
- Misregulation of Signaling Pathways.
- Protein-Kinases: Functioning.

BP809ET - Cosmetic Science

Elective 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.
- 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 Colour, 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 odour. Antiperspirants and Deodorants-Actives and mechanism of action.

BP810ET - Pharmacological Screening Methods

Elective Theory

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, anti-asthmatics.
- 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 - 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

- 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.

BP811ET - Advanced Instrumentation Techniques

Elective 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 immunoassay.
- 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.

BP812ET - Dietary Supplements and Nutraceuticals

Elective 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 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

- 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.
- Antioxidants: Endogenous antioxidants-enzymatic and non-enzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione, Vitamin C, Vitamin E, α-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.
- Pharmacopeial Specifications for dietary supplements and nutraceuticals.

BP813ET - Pharmaceutical Product Development

Elective Theory

Unit I

- 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

- 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 for 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.

BP815PW - Project Work on an Elective

Project

- A supervised project directly related to one of the elective subjects selected in Semester VIII.

BP816P - Industrial Tour

Activity

- Sections and subsections of a pharmaceutical industry and their functions.
- Product range and industry approvals.
- Departments of an approved research laboratory.
- Interdisciplinary coordination in a research laboratory.
- Contribution of the laboratory to society and laboratory approvals.

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