



Shri Shankaracharya Technical Campus

Shri Shankaracharya Group of Institutions

Faculty of Pharmaceutical Sciences

(An Autonomous Institute affiliated to Chhattisgarh Swami Vivekanand Technical University, Bhilai)

SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108801	BIOSTATISTICS AND RESEARCH METHODOLOGY	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.	Upon completion of the course the student shall be able to CO1: Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment) CO2: Know the various statistical techniques to solve statistical problems CO3: Appreciate statistical techniques in solving the problems.

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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 - 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, Reportwriting and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

UNIT-VI :

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

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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

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Pharmaceutical statistics- Practical and clinical applications	Sanford Bolton	-	Publisher Marcel Dekker Inc. New York
2	Fundamental of Statistics	S.C.Guptha		Himalaya Publishing House

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Design and Analysis of Experiments	R.Pannervselvam	-	PHI Learning Private Limited

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108802	SOCIAL AND PREVENTIVE PHARMACY	L=3	T =1	P =4	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
<p>Upon completion of this course the student Should be able to:</p> <ul style="list-style-type: none"> Acquire high consciousness/ realization of current Issues related to health and pharmaceutical problems within the country and worldwide. Have a critical way of thinking based on current healthcare development. Evaluate alternative ways issues of solving problems related to health and pharmaceutical 	<p>On successful completion of the course, the student will be able to:</p> <p>CO1:- Explain the concepts of health, disease, hygiene and socio cultural factors related to health, concepts of prevention, control and cause of diseases. (Level 2)</p> <p>CO2:- Analyse the different national health intervention programmes, Describe the Objectives:, functioning and importance of national programmes for prevention and control of diseases (Level 4)</p> <p>CO3:- Discuss the types of community services offered in urban and rural areas. (Level 2)</p> <p>CO4:- Illustrate the general measures of prevention and control of infections and diseases. (Level 2)</p>

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Unit I:

The 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. **(10 Hours)**

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.

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Health education and community pharmacy	Ashok k. Gupta	1 st edition	CBS Publisher and distributors
2	Health education and community pharmacy	Dr. Anees Ahmad Siddiqui	5 th edition	Birla Publication
3	Social and Preventive Pharmacy	Sourabh Kosey	1 st edition	Nirali Prakashan

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Preventive and Social medicine	Rabindra Nath Roy	4 th edition	Jaypee brothers medical publishers
2	Preventive and Social medicine	K. Park	23 rd edition	Banarsidas Bhanot Publishers

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108841	PHARMA MARKETING MANAGEMENT	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management	The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

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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 :

CO3, CO4

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-VI :

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

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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 :

CO1

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.

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Marketing Management	Philip Kotler and Kevin Lane Keller	-	Prentice Hall of India
2	Marketing Strategy- Planning and Implementation	Walker, Boyd and Larreche	-	TataMC GrawHill

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Marketing Management	Arun Kumar and N Menakshi	-	Vikas Publishing

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108842	PHARMACEUTICAL REGULATORY SCIENCE	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.	Upon completion of the subject student shall be able to; CO1. Know about the process of drug discovery and development CO2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals CO3. Know the regulatory approval process and their registration in Indian and international markets.

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UNIT-I :

CO2

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

CO1

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 :

CO3, CO4

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

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UNIT-V :

CO1

Regulatory Concepts

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

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Drug Regulatory Affairs	Sachin Itkar, Dr. N.S. Vyawahare,	1 st	Nirali Prakashan.
2	The Pharmaceutical Regulatory Process,	Ira R. Berry and Robert P. Martin	2 nd	Informa health care publiser

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	New Drug Approval Process: Accelerating Global Registrations	Richard A Guarino	5 th	edition, Drugs and the Pharmaceutical Sciences

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH10843	Pharmacovigilance – Theory	L=3	T =1	P =0	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objective	Course Outcomes
The main purpose of the subject is to understand about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.	CO 1. Discuss the importance of drug safety monitoring and the development of pharmacovigilance program CO 2. Explain international standards for classification of diseases and drugs CO 3. Recognize various methods of drug safety surveillance and communication in pharmacovigilance. CO 4. Explain the methods to generate safety data during the phases of clinical trial and recognize the role of ICH and GCP guidelines, pharmacogenomics and evaluate drug safety in special population

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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 of 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

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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

Statistical methods for evaluating medication safety data

Safety data generation

Pre clinical phase

Clinical phase

Post-approval phase

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

Drug safety evaluation in special population

Paediatrics

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Pregnancy and lactation

Geriatrics

CIOMS

CIOMS Working Groups

CIOMS Form

CDSCO (India) and Pharmaovigilance

D&C Act and Schedule Y

Differences in Indian and global pharmacovigilance requirements

Text Books:

S.No.	Title	Authors	Edition	Publisher
1	Pharmacovigilance	Dr. Snehaltha, Vaishnavi S.	2 nd edition	Nirali Prakashan
2	Pharmacovigilance	Dr. D. K. Tripathi, Dr. Shiv Shankar Shukla	1 st edition	Nirali Prakashan

Reference books:

S. No.	Title	Authors	Edition	Publisher
1	Current Trends in Pharmacovigilance	Pragi Arora, Varun Arora	1 st edition	S. Vikas and Company
2	Concise Course in Pharmacovigilance	Pramod V. Burakale, Dr, Suresh G. sudke	1 st edition	S. Vikas and Company

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Subject Code PH108844	QUALITY CONTROL AND STANDARDIZATION OF HERBALS	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.	Objectives: Upon completion of the subject student shall be able to; CO1.Know WHO guidelines for quality control of herbal drugs CO2.Know Quality assurance in herbal drug industry CO3.Know the regulatory approval process and their registration in Indian and international markets CO4.Appreciate EU and ICH guidelines for quality control of herbal drugs

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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-VI :

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

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Pharmacognosy	Kokate, Purohit and Gokhale	1 st	-
2	Text book of Pharmacognosy and Phytochemistry	Rangari, V.D.	2 nd	-

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals	Mukherjee, P.W.	1 st	Business Horizons Publishers

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108845	COMPUTER AIDED DRUG DESIGN	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.	Upon completion of the course, the student shall be able to understand CO1.Design and discovery of lead molecules CO2.The role of drug design in drug discovery process CO3.The concept of QSAR and docking CO4.Variety strategies to develop new drug like molecules. CO5.The design of new drug molecules using molecular modeling software

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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-VI :

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

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UNIT-V :

CO1

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

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Drug Action at the Molecular Level	Robert GCK	1 st	University Prak Press Baltimore

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry	Delgado JN, Remers WA eds	-	Lippincott, New York

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108846	CELL AND MOLECULAR BIOLOGY	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
<p>Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.</p> <p>This is done both on a microscopic and molecular level.</p> <p>Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.</p>	<p>Upon completion of the subject student shall be able to;</p> <ol style="list-style-type: none">1. Summarize cell and molecular biology history.2. Summarize cellular functioning and composition.3. Describe the chemical foundations of cell biology.4. Summarize the DNA properties of cell biology.5. Describe protein structure and function.6. Describe cellular membrane structure and function.7. Describe basic molecular genetic mechanisms.

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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

Transcription and Translation

UNIT-III :

- 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-VI :

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

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UNIT-V :

- 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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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Industrial Microbiology	Prescott and Dunn	4 th	CBS Publishers
2	Pharmaceutical Microbiology	N.K.Jain	-	Vallabh Prakashan

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Pharmaceutical Microbiology	W.B. Hugo and A.D. Russel	-	Blackwell Scientific publications, Oxford London
2	Fundamentals of Microbiology	Probisher, Hinsdill	9th	-

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

Subject Code PH108847	COSMETIC SCIENCE	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
Upon completion of this course the student Should be able to: <ul style="list-style-type: none">• Write the skin care and hair care formulation in cosmetics.• Write the role of herbs in cosmetics .• Describe analytical cosmetics.• Describe cosmetic excipients.	On successful completion of the course, the student will be able to: CO1:- Illustrate the various skin care, oral care and hair care formulations, evaluation methods in cosmetics. CO2:- Explain various cosmetic excipients. CO3:- Explain the role of herbs in cosmetics . CO4:- Describe the importance of analytical methods used in cosmetics. CO5:- Explain cosmetic evaluation parameters.

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SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)

UNIT-I :

CO2

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

CO1

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.

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 :

CO3, CO4

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.

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UNIT-IV :

CO5

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 :

CO1

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	A handbook of cosmetics	B.M.Mithal	1 st	Vallabh Prakashan
2	Cosmetics – Formulations, Manufacturing and Quality Control	P.P. Sharma	4 th	Vandana Publications

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	A Concise book of Cosmetic	K.Sampath	5 th	Birla Publication
2	Cosmetic Technology	Sanju Nanda	1 st	Birla Publication

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Bachelor in Pharma Fourth Year (8th semester)

Subject Code PH108848	EXPERIMENTAL PHARMACOLOGY	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.	Upon completion of the subject student shall be able to; CO1: Appreciate the applications of various commonly used laboratory animals. CO2: Appreciate and demonstrate the various screening methods used in preclinical research CO3: Appreciate and demonstrate the importance of biostatistics and research methodology CO4: Design and execute a research hypothesis independently

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Bachelor in Pharma Fourth Year (8th semester)

UNIT-I :

CO2

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

CO1

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 selection of animal species and sex for the study.

b) **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 :

CO3, CO4

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytic, parasympathomimetic, parasympatholytic, 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.

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UNIT-V :

CO1

Research methodology and Bio-statistics

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

Pre-clinical data analysis and interpretation using Student's 't' test and One-way ANOVA. Graphical representation of data

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Hand book of Experimental Pharmacology	S.K.Kulakarni	1 st	-
2	Fundamentals of experimental Pharmacology	M.N.Ghosh	-	-

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Drug discovery and Evaluation	Vogel H.G.	1 st	

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Bachelor in Pharma Fourth Year (8th semester)

Subject Code PH108849	ADVANCED INSTRUMENT TECHNIQUES	L=3	T =1	P =	Credits= 4
Evaluation Scheme	ESE	CT	TA	Total	ESE Duration
	75	15	10	100	3 Hours

Course Objectives	Course Outcomes
This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.	Upon completion of the course the student shall be able to CO1: understand the advanced instruments used and its applications in drug analysis CO2: understand the chromatographic separation and analysis of drugs. CO3: understand the calibration of various analytical instruments know analysis of drugs using various analytical instruments.

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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

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UNIT-V :

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

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Text Books:

S. No.	Title	Authors	Edition	Publisher
1	Organic spectroscopy	Y.R Sharma	1 st	-
2	Instrumental Methods of Chemical Analysis	B.K Sharma	1 st	-

Reference Books:

S. No.	Title	Authors	Edition	Publisher
1	Vogel's Text book of Quantitative Chemical Analysis	A.I. Vogel	-	-

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