GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP801TT
SEMESTER: VIII
Subject Name: Biostatistics and Research Methodology

Scope: To understand the applications of Biostatics 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.

Objectives: Upon completion of the course the student shall be able to

1. Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
2. Know the various statistical techniques to solve statistical problems
3. Appreciate statistical techniques in solving the problems.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
1.	**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	10
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, 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	10
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, 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.	10
4.	Blocking and confounding system for Two-level factorials **Regression modeling:** Hypothesis testing in Simple and Multiple regression models	8

	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	
5.	**Design and Analysis of experiments:** **Factorial Design:** Definition, 22, 23design. Advantage of factorial design **Response Surface methodology**: Central composite design, Historical design, Optimization Techniques	7

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP802TT
SEMESTER: VIII
Subject Name: Social and Preventive Pharmacy

Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives: Upon completion of the course the student shall be able to

1. Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide
2. Have a critical way of thinking based on current healthcare development
3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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	10
2.	**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	10
3.	**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
4.	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	8
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.	7

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP803TT
SEMESTER: VIII
Subject Name: Pharma Marketing Management

Scope: 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.

Objectives: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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.	10
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.	10
3.	**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.	10
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.	10
5.	**Pricing:** Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview	10

	of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority). **Emerging concepts in marketing:** Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.	

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP804TT
SEMESTER: VIII
Subject Name: Pharmaceutical Regulatory science

Scope: 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.

Objectives: Upon completion of the subject student shall be able to:

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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	10
2.	**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)	10
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.	10
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 - safetymonitoring in clinical trials	8
5.	**Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	7

Recommended Books: (Latest Editions)

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / SandyWeinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP805TT
SEMESTER: VIII
Subject Name: PHARMACOVIGILANCE

Scope: This paper will provide an opportunity for the student to learn 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.

Objectives: *At completion of this paper it is expected that students will be able to (know, do, and appreciate):*

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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 • 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	10
2.	**Drug and disease classification** • Anatomical, therapeutic and chemical classification of drugs • International classification of diseases	10

	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	
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	10
4.	**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	8
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	7

	Differences in Indian and global pharmacovigilance requirements	

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP807TT
SEMESTER: VIII
Subject Name: Computer Aided Drug Design

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand
- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	70	30	0	0

Sr No	Topics	% weightage
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	10
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 Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.	10
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.	10
4.	**Informatics & Methods in drug design** Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.	8
5.	**Molecular Modeling:** Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.	7

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.

3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" JohnWiley& Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP808TT
SEMESTER: VIII
Subject Name: Cell and Molecular Biology

Scope:

- 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.
- This is done both on a microscopic and molecular level.
- 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 organismssuch as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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)	10
2.	a) DNA and the Flow of Molecular Information b) DNA Functioning c) DNA and RNA d) Types of RNA e) Transcription and Translation	10
3.	a) Proteins: Defined **and** Amino Acids b) Protein Structure 173 c) Regularities in Protein Pathways d) Cellular Processes e) Positive Control and significance of Protein Synthesis	10
4.	a) Science of Genetics b) Transgenics and Genomic Analysis c) Cell Cycle analysis d) Mitosis and Meiosis e) Cellular Activities and Checkpoints	8

5.	a) Cell Signals: Introduction b) Receptors for Cell Signals c) Signaling Pathways: Overview d) Misregulation of Signaling Pathways e) Protein-Kinases: Functioning	7

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP809TT
SEMESTER: VIII
Subject Name: Cosmetic Science

Scope: To understand the classification of cosmetics and cosmeceutical products as per Indian and EU regulations. This subject deals with principles of formulation and the building blocks of skin care products, classification of sunscreens and sun protection factor, the role of herbs in cosmetics with their analytical methods, principles of cosmetic evaluation. The subject also includes about oily and dry skin, causes leading to dry skin, skin miniaturization as well as a basic understanding of the terms covering cosmetics.

Objectives: Upon completion of the course the student shall be able to
1. To know and explain about cosmetics, and related sciences, cosmeceuticals (cosmetics with skin, hair and oral care benefits) and personal care and hygiene products.
2. To demonstrate practical skills in the area of biology, formulation science and analytical techniques required to scientifically design and develop various cosmetic products.
3. To describe about basic cosmetic problems associated with skin, hair and oral care etc.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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, rheologymodifiers, 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**.**	10
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 cosmecuticals. **Antiperspants & 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-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.	10
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, skincream and toothpaste**.**	10

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 benfits.	8
5.	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	7

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4thEdition, Vandana Publications Pvt. Ltd., Delhi.
3) .Drugs and Cosmetic act/rules by govt. of India Publication
4) European Union regulation for cosmetics.
5) Poucher's Perfumes, Cosmetics and Soaps, Hilda Butler, 10th Edition, Kluwer Academic Publishers
6) Handbook of Cosmetic Science and Technology, 3rd Edition, André O. Barel, Marc Paye, Howard
7) Pulok K.Mukherjee. Quality Control Herbal Drugs Business Horizons; Reprint 2012 edition
8) Trease, G.E. and Evans, W.C. "Trease and Evans' Pharmacognosy" WB Saunders Co.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP810TT
SEMESTER: VIII
Subject Name: Experimental Pharmacology

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- ☐ Appreciate the applications of various commonly used laboratory animals.
- ☐ Appreciate and demonstrate the various screening methods used in preclinical research
- ☐ Appreciate and demonstrate the importance of biostatistics and research methodology
- ☐ Design and execute a research hypothesis independently

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	Teaching Hrs
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.	7
2.	**Introduction to preclinical studies**: 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	3
3.	**Preclinical screening models** **Preclinical screening models for drugs acting on CNS** :- analgesic, antipyretic, anti-inflammatory, general anesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, nootropics anti Parkinsonism drugs, anti-Alzheimer drug **Preclinical screening models** for drugs acting on eye and local aesthetics	12
4.	**Preclinical screening models for drugs acting on ANS :** sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants	5
5.	**Preclinical screening models for drugs acting on CVS :-** antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants **Preclinical screening models** for antiulcer, antidiabetic, anticancer and antiasthmatic activities	13

6.	**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	5

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-byM.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP811TT
SEMESTER: VIII
Subject Name: Advanced Instrumentation Techniques

Scope: 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

Objectives

Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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	10
2.	**Thermal Methods of Analysis**: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) **X-Ray Diffraction Methods:** Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.	10
3.	**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	10
4.	**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	8
5.	**Hyphenated techniques**-LC-MS/MS, GC-MS/MS, HPTLC-MS.	5

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel

5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy byWilliam Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP812TT
SEMESTER: VIII
Subject Name: Dietary Supplements and Nutraceuticals

Scope: This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objectives
This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to:
1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	% weightage
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 ageing, nutrition education in community. c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds	7
2.	Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin b) Sulfides: Diallyl sulfides, Allyl trisulfide. c) Polyphenolics: Reservetrol d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans g) Tocopherols h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.	15
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, nucleic acids. b) Dietary fibres and complex carbohydrates as functional food ingredients..	7
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,	10

	Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole. c) Functional foods for chronic disease prevention	
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. c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.	6

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP813PP
SEMESTER: VIII
Subject Name: Project Work

Guidelines:

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII or Minor research project at R & D organization/ CRO/ Manufacturing organization/QA & QC Laboratory/ Public testing laboratory/ Drug regulatory body/Hospital/ Community Pharmacy/ Help Centre or at Institute. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The students can perform the activities for project work after completion of Semester VI onwards (during the vacation/ official Holidays) but the credit of project work will be transferred in Semester VIII. Those who are doing Project work during this period must complete the prescribed days or hours for Project work as per the guidelines. Institute should maintain documentation regarding project Work for each student with requisite evidence.

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP814TT
SEMESTER: VIII
Subject Name: Pharmaceutical Product Development

Scope: To understand the regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms. The subject also includes an advanced study of pharmaceutical excipients in pharmaceutical product development. It also covers optimization techniques to be used in pharmaceutical product development.

Objectives: Upon completion of the course the student shall be able to -
1. To know and explain about the basic concepts of product development and right selection of excipients for the conventional and novel formulation.
2. To describe Quality by design, Optimization technique and experimental design pharmaceutical product development for the conventional and novel formulation.
3. To explain the GRAS listing & inactive ingredient guide (IIG) limit for the excipients.
4. To discuss Regulatory requirement for Selection of packaging material and Quality control of various dosage form.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	0	4	80	20	0	0

Sr No	Topics	Teaching Hrs
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.	7
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 sorbitol's v. Suspending and emulsifying agents vi. Semi solid excipients	10
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 aerosols products v. Excipients for formulation of NDDS Selection and application of excipients in pharmaceutical formulations with specific industrial applications	10
4.	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.	8

5.	Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.	7

References:

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B.Schwartz.
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman.
3. Theory and Practice of Industrial Pharmacy by Liberman & Lachman.
4. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill livingstone, Latest edition.
5. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005.
6. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.
7. Gennaro, Alfonso R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York.
8. Bolton S. Optimization techniques. In: Pharmaceutical Statistics: Practical and Clinical Applications. 3rd ed. New York: Marcel Dekker, 1997

GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Pharmacy
Subject Code: BP815TT
Semester: VIII
Subject Name: Epidemiology

Scope: This course introduces the student to the principles and basic methods of modem epidemiology. Epidemiology is defined as the study distribution and determinants of health-related states and events in defined populations and the application of this to study to solving public health problems. Presentation of epidemiologic data and basic measures of disease frequency are covered. Descriptive, analytical and interventional study designs are discussed in context to the health system with their corresponding analysis techniques. The concept of risk and its associated measures is also covered. It also covers the estimation and interpretation of odds ratio, attributable risk and their confidence intervals.

Objectives: Upon completion of this course, it is expected that students will be able to:

- To have a clear understanding of the definition and uses of epidemiology and appreciate its role in public health.
- To be able to identify the key sources of data and have the ability to draw appropriate inferences from them.
- To understand the concept and practical application of various measures such as: measures of disease frequency (prevalence and incidence), measures of effect (e.g. rate/risk ratios and rate/risk differences), and measures of public health impact (e.g. population attributable risk / fraction)
- To know the various types of epidemiological study designs and, understand their basic principles and the main analytic methods used in each specific design
- Ascertain causality between an exposure and an outcome

Teaching Scheme and examination scheme:

Teaching Scheme				**Evaluation Scheme**				**Total Marks**
Theory	**Tutorial**	**Practical**	**Total**	**Theory**		**Practical**		
				External	**Internal**	**External**	**Internal**	
3	**1**	**0**	**4**	**80**	**20**	**0**	**0**	**100**

Sr.	**Topic**	**Teaching Hrs**
1	Definition of Epidemiology, History and evolution of epidemiology. Aims and principles of Epidemiology Basic concepts and applications.	3
2	Sources of data and various methods of data collection Important aspects of data collection: Reliability and validity Sensitivity, specificity and predictive values.	10
3	Natural history of a disease and its application in disease control. Levels of prevention and modes of intervention. Bias, Confounding, & Effect Modification Causation & Risk	8
4	Epidemiological methods – Descriptive, Analytical & Experimental. Surveillance	4

5	Epidemiological study designs Overview of study designs Descriptive studies Ecological studies. Case control studies, cohort studies, randomized control trials.	6
6	Hybrid designs in epidemiology. Community based epidemiological studies.	3
7	Measuring disease occurrence. Measurement tools in Epidemiology – Rate, Ratio & Proportion Risk – frequency measures, morbidity frequency measures, mortality frequency measures, birth measures, measures of association, measures of public health impact.	8
8	Ethical and Professional Issues in Epidemiology.	3

Textbooks:

1. Epidemiology: Gordis, Leon Elsevier Saunders, latest edition.
2. Foundations of Epidemiology: Marit L. Bovbjerg, Kelly Johnson, Oregon State University

   Download for free at https://open.oregonstate.education/epidemiology/

3. Principles of Epidemiology in Public Health Practice, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Third Edition.
4. Basic Epidemiology: R. Bonita, R. Beaglehole, TKjellstrom, WHO, 2nd Edition.
5. Park's text book of Preventive and Social medicine: K. Park, M/s Banarasidas Bhanot publication, latest edition