NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm.)
(Semester - VIII)

L	T	P	C
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Course Code	**BP801T**
Course Title	**Biostatistics and Research Methodology - Theory**

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 this course the student should be able to:

5. Know the operation of MS Excel, SPSS, R and MINITAB, DoE (Design of Experiment)
6. Know the various statistical techniques to solve statistical problems
7. Appreciate statistical techniques in solving the problems.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Remember various statistical formulas used for pharmaceutical sciences.
2. Understand the basic concepts of various statistical test for data analysis.
3. Describe fundamentals in research methodology, data presentations and interpretation of graphs.
4. Apply appropriate statistical test for pharmaceutical data treatment.
5. Illustrate the operation of various software for experimental designs.
6. Analyze scientific data using suitable experimental design.

Syllabus:

Teaching hours: **45 Hours**

UNIT I **10 Hours**

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 **10 Hours**

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.
Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.

UNIT – III **10 Hours**

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 **08 Hours**

Factors: Blocking and confounding system for Two-level factorials.
Regression modeling: Hypothesis testing in Simple and Multiple regression models.
Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, Design of Experiments, R, etc. Online Statistical Software's to Industrial and Clinical trial approach

UNIV – V **07 Hours**

Design and Analysis of experiments:
Factorial Design: Definition, 2^2 design, 2^3 design. Advantage of factorial design.
Response Surface methodology: Central composite design, Historical design, Optimization Techniques.

Tutorials Teaching hours: **15 Hours**

Tutorials will be based on above syllabus

Suggested Readings^: (Latest edition)

14. Bolton, S. *Pharmaceutical Statistics - Practical and Clinical Applications*, New York, Marcel Dekker Inc Publishers.
15. Gupta, S.C. *Fundamental of Statistics*, Mumbai, Himalaya Publishing House.
16. Panneerselvam, R. *Design and Analysis of Experiments*, New Delhi, PHI Learning Pvt. Ltd.
17. Montgomery, D.C. *Design and Analysis of Experiments,* New Jersey, Wiley Students Choice Publishers

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NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - VIII)

L	T	P	C
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Course Code	**BP802T**
Course Title	**Social and Preventive Pharmacy – Theory**

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.

Objective: At the end of the course, the student shall be able to
1. Acquire high consciousness/realization of current issues related 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

Course Learning Outcomes (CLO):
After successful completion of the course, student will be able to -
6. Explain the concept of health and disease, social and health education as well as social impact and effect of hygiene on health and disease.
7. Relate general principles of use of preventive medicines for various diseases.
8. List national health programs, its objectives, functioning and outcomes.
9. Discuss importance of national health intervention program for mother, child, family welfare, and social health improvement as well as role of WHO in Indian national programs.
10. Elaborate role of community services in rural and urban areas.

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

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 **10 Hours**

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 **10 Hours**

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 **08 Hours**

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 **07 Hours**

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.

Tutorials **Teaching hours: 15 Hours**

Tutorials will be based on above syllabus.

Suggested Readings^:(Latest edition)

27. Prabhakara GN, *Short Textbook of Preventive and Social Medicine*, JAYPEE Publications, New Delhi
28. Mahajan and Gupta. *Textbook of Preventive and Social Medicine* (Edited by Roy Rabindra Nath and Saha Indranil), JAYPEE Publications, New Delhi
29. Jain V. *Review of Preventive and Social Medicine (Including Biostatistics),* Jain Vivek, JAYPEE Publications, New Delhi
30. Hiremath Lalita D, Hiremath Dhananjaya. *Essentials of Community Medicine—A Practical Approach,* JAYPEE Publications, New Delhi
31. Park K, *Textbook of Preventive and Social Medicine*, Banarasidas Bhanot Publishers, Jabalpur.
32. Adepu R. *Community Pharmacy Practice*, BSP publishers, Hyderabad.
33. *Research in Social and Administrative Pharmacy*, Elsevier, Netherland
34. WHO Reports (https://www.who.int/)

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NIRMA UNIVERSITY
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(B. Pharm)
(Semester - VIII)

L	T	P	C
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Course Code	**BP803ET**
Course Title	**Pharma Marketing Management – Theory**

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.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Understand the concepts of marketing environment and competitive analysis with respect to pharmaceutical market
2. Describe product life cycle and product management in pharmaceutical industry
3. Discuss budget and various promotional methods for pharmaceutical product
4. Select channel for pharmaceutical marketing and distribution management
5. Manage the strategies for pricing in pharmaceutical industry and propose new concepts in marketing

Syllabus: **Teaching hours: 45 Hours**

UNIT I **10 Hours**

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 **10 Hours**

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 **10 Hours**

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 **10 Hours**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management, Product recalls and its impact.

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 **10 Hours**

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.

Tutorials **Teaching hours: 30 Hours**

Tutorials will be based on above syllabus

Suggested Readings^: (Latest Edition)

1. Philip, K. and Kevin, L.K., *Marketing Management*, New Delhi, India: Prentice Hall of India.
2. Walker, B. and Larreche, *Marketing Strategy - Planning and Implementation*, New Delhi, India: Tata MC GrawHill.
3. Dhruv, G. and Michael, L., *Marketing*, India: Tata MC Graw Hill
4. Arun, K. and Menakshi, N., *Marketing Management*, India: Vikas Publishing
5. Rajan, S., *Marketing Management,* India: Tata MC Graw-Hill

6. Ramaswamy, U.S and Nanakamari, S, *Marketing Managemnt*: *Global Perspective*, Indian Context, New Delhi, India: Macmilan
7. Shanker, R., *Service Marketing*, New Delhi, India: Excell Books
8. Subba, R.C., *Pharmaceutical Marketing in India*, Excel Publications.

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NIRMA UNIVERSITY
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(B. Pharm)
(Semester - VIII)

L	T	P	C
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Course Code	**BP804ET**
Course Title	**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 course, the 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

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Discuss about the process of drug discovery and development
2. Understand the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Discuss the regulatory approval process and their registration in Indian and international markets
4. Explain the requirement to conduct clinical trials along with safety monitoring
5. Describe basic regulations, laws and documents like orange book, Code of Federal Regulatory, Purple book

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

- **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 **10 Hours**

- **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 **10 Hours**

- **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 **08 Hours**

- **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 **07 Hours**

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

Suggested Readings^: (Latest edition)

1. Vyawahare, Ns. & Itkar, S.C. Drug regulatory affairs, Nirali Prakashan.
2. Berry, I. R., & Martin, R. P. The pharmaceutical regulatory process. CRC Press.
3. Guarino, R. A., & Guarino, R. (Eds.). New drug approval process. CRC Press.
4. Weinberg, S. Guidebook for Drug Regulatory Submissions. John Wiley & Sons.
5. Pisano, D. J., & Mantus, D. S. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. CRC Press.
6. Shargel, L., & Kanfer, I. Generic drug product development: solid oral dosage forms. CRC Press.
7. Rozovsky, F. A., & Adams, R. K. Clinical trials and human research: A practical guide to regulatory compliance. John Wiley & Sons.
8. Gallin, J. I., & Ognibene, F. P. (Eds.). Principles and practice of clinical research. Academic Press.
9. Ng, R. Drugs: from discovery to approval. John Wiley & Sons.

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NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - VIII)

L	T	P	C
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Course Code	**BP805ET**
Course Title	**Pharmacovigilance-Theory**

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.

Objective: At the end of the course, the student shall be able to

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.

Course Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

6. Explain basics of adverse drug reactions and pharmacovigilance.
7. Illustrate drug and disease classification, drug dictionaries, coding, information resources and establishment of pharmacovigilance programme.
8. Outline pharmacovigilance methods, vaccine safety surveillance and communicate with stakeholders in pharmacovigilance.
9. Summarize ICH guidelines for pharmacovigilance and safety data generation
10. Discuss about drug safety evaluation in special population, Pharmacogenomics of adverse drug reactions, CIOMS and CDSCO.

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

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 **10 Hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Nonproprietary 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
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

UNIT III **10 Hours**

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 **08 Hours**

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 **07 Hours**

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 New Drugs and clinical trials rules 2019
- Differences in Indian and global pharmacovigilance requirements

Tutorials **Teaching Hours: 15 Hours**

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Gupta, S. K. "*Textbook of Pharmacovigilance*." Jaypee Brothers medical publishers (P) Ltd., New Delhi, India
2. Cobert, B., and Pierre B. *Practical drug safety from A to Z*. Jones & Bartlett Publishers, USA.
3. Andrews, Elizabeth B., Nicholas M., eds. Mann's pharmacovigilance. John Wiley & Sons, USA.

4. Talbot, J., Patrick W. Stephens' Detection of New Adverse Drug Reactions. Wiley Publishers, USA.
5. Waller, P., Mira Harrison-Woolrych. *An introduction to pharmacovigilance*. Chichester: Wiley-Blackwell, USA.
6. Cobert, B. *Cobert's manual of drug safety and pharmacovigilance*. Jones & Bartlett Publishers, USA.
7. Strom, B.L., Kimmel S., Hennessy S., eds. *Textbook of pharmacoepidemiology*. John Wiley & Sons, USA.
8. Parthasarathi, G., Karin Nyfort-Hansen, and Milap C. Nahata, eds. A Text Book of Clinical Pharmacy Practice: Essential Concepts and Skills. Orient Blackswan, Hyderabad, India.
9. National Formulary of India, India
10. Munjal, Y.. *API Textbook of Medicine (Volume I & II)*. JP Medical Ltd, India.
11. Mohanta, G.P., Manna, P.K. *Text book of Pharmacovigilance: concept and practice*. PharmaMed Press/BSP Books, India.

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NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VIII)

L	T	P	C
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Course Code	**BP806ET**
Course Title	**Quality Control And Standardization Of Herbals –Theory**

Scope:
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;
1. Know WHO guidelines for quality control of herbal drugs
2. Know Quality assurance in herbal drug industry
3. Know the regulatory approval process and their registration in Indian and international markets
4. Appreciate EU and ICH guidelines for quality control of herbal drugs

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

7. Understand WHO, EU and ICH guidelines for quality control of herbal drugs and comparison of pharmacopoeias
8. Describe various quality assurance parameters in herbal drug industry.
9. Illustrate the guidelines for evaluating the safety monitoring and efficacy of herbal medicines
10. Relate the applications of various chromatographic techniques and stability testing for standardization of herbal extracts/formulations.
11. Develop the understanding of regulatory requirements for herbal medicines

Syllabus: **Teaching hours**: **45 Hours**

Unit I **10 hours**
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 **12 hours**
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.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Unit III **10 hours**
EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

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. **Guidelines for Phytopharmaceutical Drugs and AYUSH**

Unit V **05 hours**

Regulatory requirements for herbal medicines.
Role of chemical and biological markers in standardization of herbal products
Comparison of various Herbal Pharmacopoeias

Tutorials **Teaching hours: 15 hours**

Tutorials will be based on syllabus

Suggested Readings^: (Latest Editions)

1. Evans, W. C. (2009). Trease and Evans' Pharmacognosy E-Book. Elsevier Health Sciences.
2. Kokate, C. K., Purohit, A. P., & Gokhale, S. B. (2007). Hand Book of Pharmacognosy.
3. Agrawal, S. S., & Paridhavi, M. (2007). *Herbal drug technology*. Hyderabad: Universities Press Private Limited.
4. European Medicines Agency. (2011). Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products.
5. Pulok, K. M., & Mukherjee, K. (2002). Quality control of herbal drugs. *An approach to evaluation of botanicals. New Delhi: Business Horizons-Pharmaceutical Publishers*.
6. Shinde, V. M., Dhalwal, K., Potdar, M., & Mahadik, K. R. (2009). Application of quality control principles to herbal drugs. *International Journal of Phytomedicine*, *1*(1). pp 4-8.
7. World Health Organization. (1998). Guidelines for the appropriate use of herbal medicines.
8. World Health Organization. (1998). Quality control methods for medicinal plant materials.
9. World Health Organization. (1981). *The International Pharmacopoeia. Vol. 2. Quality specifications* (Vol. 2, No. 3rd edition). Geneva, Switzerland.
10. Bodeker, G., & Ong, C. K. (2005). *WHO global atlas of traditional, complementary and alternative medicine* (Vol. 1). World Health Organization.
11. World Health Organization. (2009). Guidelines on Good Agricultural and Collection Practices (GACP) for medicinal plants; 2003. *Available: http:/whqlibdoc. who. int/publicatio ns/2003/9241546271 (Accessed on 3 September, 2009)*.

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Course Code	**BP807ET**
Course Title	**Computer Aided Drug Design - Theory**

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

Objective: Upon completion of the course, the student shall be able to understand -

1. Design and discovery of lead molecules.
2. The role of drug design in drug discovery process.
3. The concept of QSAR and docking.
4. Various strategies to develop new drug like molecules.
5. The design of new drug molecules using molecular modeling software.

Course Learning Outcomes (CLO):
After successful completion of the course, student will be able to –

1. Understand the role of molecular mechanics and quantum mechanics in molecular modeling.
2. Describe various stages of lead design, drug discovery and development process.
3. Discuss concepts and applications of different molecular modeling techniques.
4. Explain the role of quantitative structure-activity relationship (QSAR) studies in rational drug design.
5. Use various informatics and methods in drug design.

Syllabus: **Teaching hours: 45 Hours**
Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*).

UNIT I **10 Hours**

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 **10 Hours**

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.

UNIT III **10 Hours**

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 **08 Hours**

Informatics & Methods in drug design

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

UNIT V **07 Hours**

Molecular Modeling

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

Tutorials **15 Hours**

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. Robert, G.C.K. ed. *Drug Action at the Molecular Level*. University Prak Press Baltimore.
2. Martin, Y. C. (2010). *Quantitative drug design: a critical introduction*. CRC Press.
3. Wilson, C. O., Beale, J. M., & Block, J. H. Wilson and Gisvold's textbook of organic medicinal and pharmaceutical chemistry. Lippincott Williams & Wilkins.
4. Foye, W. O. Foye's principles of medicinal chemistry. Lippincott Williams & Wilkins..
5. Koro l.A. Burckhalter J.H. *Essentials of Medicinal* Chemistry. Wiley Interscience
6. Burger, A., & Abraham, D. J. *Burger's medicinal chemistry and drug discovery* (Vol. I–IV). Wiley.
7. Patrick, G. L. (2013). *An introduction to medicinal chemistry*. Oxford university press.
8. Smith, H. J., & Williams, H. (2016). *Introduction to the principles of drug design*. Elsevier.
9. Silverman, R. B., & Holladay, M. W. (2014). *The organic chemistry of drug design and drug action*. Academic press.

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(B. Pharm)
(Semester - VIII)

L	T	P	C
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Course Code	**BP808ET**
Course Title	**Cell and Molecular Biology - Theory**

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 organisms such as humans, plants, and sponges.

Objective: At the end of the course, the student shall be able to

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.
8. Summarize the Cell Cycle

Course Learning Outcomes (CLO):

After successful completion of the course, student will be able to -

16. Recall basics of prokaryotic and eukaryotic cell structure, molecular biology and cellular reproduction.
17. Relate functioning of DNA and RNA and process of transcription and translation.
18. Illustrate amino acids and protein synthesis pathways.
19. Summarize cell division, cell cycle, its regulation and basic techniques of genomic analysis.
20. Explain receptors and cell signaling pathways.

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

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 **10 Hours**

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

UNIT III **10 Hours**

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

UNIT IV **08 Hours**

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

UNIT V **07 Hours**

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

Tutorials **Teaching hours: 15 Hours**

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

35. Cooper GM, *The Cell, A Molecular Approach.* Sinauer Associates, Sunderland (MA).
36. Licinio J & Wong M (eds). *Pharmacogenomics: The Search for Individualized Therapies*, Wiley, Weinheim Germany.
37. Bradshaw RA and Dennis EA. *Handbook of Cell Signaling*, Elsevier, Netherlands.
38. Dickenson et al., *Molecular Pharmacology: From DNA to Drug Discovery.* Wiley Blackwell, USA.
39. Ausubel et al. Current protocols in molecular biology vol I to VI. Wiley & sons, USA.

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NIRMA UNIVERSITY
Institute of Pharmacy

(B. Pharm)
(Semester - VIII)

L	T	P	C
3	1	-	4

Course Code	**BP809ET**
Course Title	**Cosmetic Science – Theory**

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Define and classify of cosmetic products and excipients
2. Understand the principles of formulation development of skin care products and discuss skin related cosmetic problems **(S, E)**
3. Discuss the principles of the instruments, BIS specification and analytical techniques for cosmetics **(S, E, Ent)**
4. Explain the principles of formulation development of hair care products and discuss hair related cosmetic problems **(S, E)**
5. Describe the formulation development of oral care products **(S, E)**
6. Apply role of herbs in skin, hair and oral care **(S, E)**

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

Classification of cosmetic and Cosmeceuticals 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 **(S, E)**

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 **10 Hours**

Principles of formulation and building blocks of skin care products: (S, E)

Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. Application of these products in formulation of Cosmeceuticals.

Anti-perspirants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products: (S, E)

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. **(S, E)**

UNIT III **10 Hours**

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, other relevant herbal drugs for hair, skin, oral care
Analytical cosmetics: BIS specification and analytical methods for shampoo, skin- cream and toothpaste**. (S, E, Ent)**

UNIT IV **08 Hours**.
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, **Techniques for evaluation of specialized cosmetics. (S, E, Ent)**

UNIT V **07 Hours**
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 **(S, E)**
Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. **(S, E)**
Antiperspirants and Deodorants- Actives and mechanism of action **(S, E)**

Tutorials **Teaching hours: 15 hours**
Tutorials will be based on syllabus

Suggested Readings^: (Latest Editions)

1. Harry, R. G. (1982). *Harry's cosmeticology*. Chemical Publishing Company.
2. Sharma, P. P. (2008). *Cosmetics: formulation, manufacturing and quality control*. Edn. 4th. Vandana.
3. Nanda, S., Nanda, A., & Khar, R. K. (2006). Cosmetic technology. Edn. 1st, *Birla Publication.,* Dehli, 7.

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(B. Pharm.)

(Semester - VIII)

L	T	P	C
3	1	-	4

Course Code	BP810ET
Course Title	Experimental Pharmacology-Theory

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 this course the student should be able to –

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

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

12. Outline basics techniques and regulatory guidelines of experimentation on animals.
13. Construct investigational design of experiments on animal.
14. Explain preclinical screening models for diuretics, anti-pyretic, anti-inflammatory and CNS activity.
15. Select preclinical screening model for ANS activity and local anaesthetics.
16. Choose preclinical screening model for CVS activity, anti-ulcer, anti-diabetic anti-asthmatics and anti-cancer.
17. Elaborate research hypothesis, study design and interpret pre-clinical data using various statistical tools.

Syllabus: **Teaching hours: 45 Hours**

UNIT I **08 Hours**

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, common routes of drug administration and euthanasia in laboratory animals.

UNIT II **10 hours**

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, Translational research aspect on animal model.

Study of preclinical screening animal models for- Diuretics, antipyretic, anti-inflammatory, CNS activity (analgesic, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, anti-parkinsonism, Alzheimer's disease/nootropics)

UNIT III **07 Hours**

Preclinical screening models for- ANS activity **(**sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye) and local anaethetics.

15 hours

UNIT IV

Preclinical screening models for- CVS activity (antihypertensive, diuretics, anti-arrhythmic, anti-dyslipidemic), anti-aggregatory, coagulants, and anticoagulants.

Preclinical screening models for other important drugs- antiulcer, anti-diabetic, anticancer and anti-asthmatics.

UNIT V **05 Hours**

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, Dose selections, factors for converting animal dose to human dose and FDA guidelines for effective human dose calculation (NOAEL)

Tutorials Teaching hours: 15 Hours

Tutorials will be based on above syllabus

Suggested Readings^: (Latest Edition)

1. Ghosh M. N., Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
2. Kulkarni S. K., Handbook of Experimental Pharmacology. Vallabh Prakashan, New Delhi.
3. Goyal R. K., Mehta A. A., Balaraman R., Burande M. D., Dearsari and Gandhi's Elements of Pharmacology. B.S. Shah Prakashan, Ahmedabad.
4. CPCSEA guidelines for laboratory animal facility.
5. Vogel H.G., Drug discovery and Evaluation. Springer, Verlag Berlin Heidelberg New York.
6. Gupta S. K., Drug Screening Methods. Jaypee Brothers Medical Publishers, New Delhi.
7. Sundar Rao P. S. S., Richard J., Introduction to biostatistics and research methods. Phi Learning Private limited, New Delhi.

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NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - VIII)

L	T	P	C
3	1	-	4

Course Code	**BP811ET**
Course Title	**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-

1. Know the advanced instruments used and its applications in drug analysis.
2. Understand the chromatographic separation and analysis of drugs.
3. Understand the calibration of various analytical instruments.
4. Describe analytical techniques used for evaluation of macromolecule

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Discuss the fundamental, principle and application of mass and NMR spectroscopy
2. Understand the techniques for solid state analysis like thermal and X-ray methods
3. Explain the calibration and validation of various instruments as per ICH and USFDA guidelines
4. Describe the importance of sample preparation for bioanalysis
5. Understand the instrumentation and application of hyphenated techniques

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **10 Hours**

- **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 **08 Hours**

- **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 **06 Hours**

- **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 **08 Hours**

- **Radio immune assay:** Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay
- **Extraction techniques:** General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT V **05 Hours**

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

UNIT VI

- **Physico chemical characterization of Biopharmaceutical Protein:** **08 Hours**
  Covalent structure determination: Peptide mapping, N-Terminal sequencing, Disulfide bond characterization, Post translation modifications
  Higher order structure and folding, Stability related structural changes determination by AUC, SEC etc
  Cell based and non-cell based functional Bioassays

Suggested Readings^: (Latest edition)

1. Sharma, B. K. Instrumental methods of chemical analysis. Krishna Prakashan Media.
2. Sharma, Y. R. Elementary organic spectroscopy. S. Chand Publishing.
3. Connors, K. A. A textbook of pharmaceutical analysis. John Wiley & Sons.
4. Vogel, A. I., & Jeffery, G. H. Vogel's textbook of quantitative chemical analysis. Wiley.
5. Beckett, A. H., & Stenlake, J. B. (Eds.). Practical Pharmaceutical Chemistry: Part I & II. A&C Black.
6. Finar, I. L. Organic Chemistry. Wiley.
7. Kemp, W. Qualitative organic analysis: spectrochemical techniques. McGraw-Hill Book Co Ltd.
8. Garratt, D. C. The quantitative analysis of drugs. Springer Science & Business Media.
9. Sethi, P. D. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers.
10. Silverstein, R. M., Bassler, G. C., & Morrill, T. C. Spectrometric Identification of Organic Compounds, John Wiley& Sons. Inc., New York.
11. Ronald E R, Peptide and Protein Drug Analysis, Marcel Dekker Inc,
12. Satinder Ahuja and Stephen Seypinski, Handbook of Modern Pharmaceutical Analysis, 2nd Edition, Academic Press

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NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - VIII)

L	T	P	C
3	1	-	4

Course Code	**BP812ET**
Course Title	**Dietary Supplements and Nutraceuticals-Theory**

Scope:

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

Objectives:

Upon completion of the course the student shall 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

Course Learning Outcomes (CLO):

At the end of the course, students will be able to -

1. Understand the concept of nutraceuticals and their significance in public health
2. Describe the role of various classes of phytochemicals as nutraceuticals and functional foods
3. Discuss the importance of dietary fibres in functional foods
4. Explain the role of antioxidants in free radicals mediated diseases
5. Develop the understanding of Pharmacopoeial specifications and regulatory aspects of food supplements

Syllabus: **Teaching hours**: **45 Hours**

UNIT I **07 Hours**

Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II **15 Hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature, medicinal benefits) of following

Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein

Sulfides: Diallyl sulfides, Allyl trisulfide.
Polyphenolics: Resveratrol
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 **07 Hours**

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 **10 Hours**

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 nonenzymatic antioxidant defense, 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 **06 Hours**

Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.
Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
Pharmacopoeial Specifications for dietary supplements and nutraceuticals and their Recommended Daily Intake (RDI).

Tutorials **Teaching hours: 15 Hours**
Tutorials will be based on above syllabus.

Suggested Readings^: (Latest Edition)

1. Srilakshmi, B. (2007). *Dietetics*. New Age International.
2. Augusti, K. T. (2009). *Role of Dietary Fibers and Nutraceuticals in Preventing Diseases*. PharmaMed Press.
3. Cooper, K. H., & Kenneth, H. (1997). *Advanced nutritional therapies*. Thomas Nelson Publishers.
4. Carper, J. (1992). *The Food Pharmacy guide to good eating*. Bantam.
5. Balch, J. F., & Balch, P. A. (1990). CNC, *Prescription for Nutritional Healing.* Garden City Park, NY: Avery Publishing Group Inc.

6. Gibson, G. C. Williams Editors 2000 *Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods.* 1994.
8. Labuza, T. P. (2000). *Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in Essentials of Functional Foods* MK Sachmidl and TP Labuza eds
9. Wildman, R. E. (2016). *Handbook of nutraceuticals and functional foods*. CRC press.
10. Shils, M. E., Olson, J. A., & Shike, M. (1994). *Modern nutrition in health and disease.* Lea and Febiger, Philadelphia.

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NIRMA UNIVERSITY
Institute of Pharmacy

B. Pharm.
(Semester - VIII)

L	T	P	C
3	1	-	4

Course Code	**BP813ET**
Course Title	**Pharmaceutical Product Development**

Scope:
Course enables the student to understand the pharmaceutical product development cycle and appreciate the influence of pharmaceutical additives, QbD concepts and packaging technology on the performance of the drug product.

Objectives:
Upon completion of the course the student shall be able to
1. Know the development cycle and optimization of various pharmaceutical dosage forms.
2. Know various excipients and their role in development of pharmaceutical dosage forms
3. Formulate pharmaceutical dosage forms using concepts of QbD

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -
1. Recognize the development cycle of a pharmaceutical product.
2. Describe various types of excipients like solubilizer, suspending agents.
3. Determine quality control testing of packaging materials for product development.
4. Apply quality by design concepts for optimization of pharmaceutical dosage forms.
5. Interpret application of excipients for formulation development.

Syllabus: **Teaching hours: 45 Hours**

UNIT I **10 Hours**
Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

UNIT II **10 Hours**

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

1. Solvents and solubilizers
2. Cyclodextrins and their applications
3. Non - ionic surfactants and their applications
4. Polyethylene glycols and sorbitols
5. Suspending and emulsifying agents
6. Semi solid excipients

UNIT III **10 Hours**

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

1. Tablet and capsule excipients
2. Directly compressible vehicles
3. Coat materials
4. Excipients in parenteral and aerosols products
5. Excipients for formulation of NDDS

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

UNIT IV **08 Hours**

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 **07 Hours**

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

Tutorials **Teaching hours: 15 Hours**

Tutorials will be based on above syllabus

Suggested Readings^: (Latest Edition)

1. Bolton, Stanford; Bon, Charles, *Pharmaceutical Statistics Practical and Clinical Applications*, USA: Marcel Dekker Inc.
2. swarbrick, James, *Encyclopedia of Pharmaceutical Technology*, USA: Informa Healthcare publishers.
3. Lieberman, Herbert; Lachman, Leon, *Pharmaceutical Dosage Forms, Tablets*, USA: Marcel Dekker Inc.
4. Khar, Roop; Vyas, S. P.; Ahmad, Farhan; Jain, Gaurav, *The Theory and Practice of Industrial Pharmacy*, India: CBS Publishers and Distributors Pvt.Ltd.
5. Sinko, Patrick, *Martin's Physical Pharmacy and Pharmaceutical Sciences*, USA: Lippincott Williams & Wilkins.

6. Vyas, S. P.; Khar, Roop, *Targeted and Controlled Drug Delivery, Novel Carrier Systems*, India: CBS Publishers and Distributors Pvt.Ltd.
7. Allen, Loyd; Popovich, Nicholas; Ansel, Howard, *Pharmaceutical Dosage Forms and Drug Delivery Systems*, USA: Lippincott Williams & Wilkins.
8. Aulton, Michael, *Aulton's Pharmaceutics – The Design and Manufacture of Medicines*, UK: Churchill Livingstone.
9. Remington, Joseph, *Remington – The Science and Practice of Pharmacy*, USA: Lippincott Williams & Wilkins.
10. Lieberman, Herbert; Martin, M; Banker, Gilbert, *Pharmaceutical Dosage Forms – Disperse Systems*, USA: Marcel Dekker Inc.
11. Avis, Kenneth; Lieberman, Herbert, *Pharmaceutical Dosage Forms – Parenteral Medication*, USA: Marcel Dekker Inc.

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