Proposed Certificate Courses

Following four courses are proposed:

1. Nutraceuticals In Health Care
2. Drug Discovery and Computer-Aided Drug Design
3. Analytical And Bioanalytical Techniques: Method Development & Validation
4. Cosmetics and FMCG Products: Formulation, safety and regulations

We have proposed the courses for BSc. Microbiology & BSc. Biotechnology students. However, if any of the proposed courses are suitable for any other course students like M.Sc. or any other Bachelor branch, please let us know. The detailed outline of all four courses is given in the next part of this document.

NUTRACEUTICALS IN HEALTH CARE

- **Theory course of 30 Hrs - 2 Credits**

- **Course Objectives**
  1. To make the learner understand the concept of nutraceuticals and dietary supplements along with the classification with respect to health benefits, chemical nature and mechanism of action
  2. To expose the learner to the health benefits of various classes of phytochemicals along with their salient chemical features, pharmacokinetics, doses and marketed preparations
  3. To introduce to the learner the formulation challenges of nutraceuticals and health supplements and the importance of the safety and stability of nutraceutical formulations
  4. To make the learner aware of the regulatory aspects of nutraceuticals in India and major countries

- **Course Outcomes**

Upon completion of the course student will be able to –
  1. Explain concept of nutraceuticals and dietary supplements, classify these based on chemical nature, health benefits and mechanism of action
  2. Discuss the chemistry of phytochemicals, their health benefits, pharmacokinetics, interactions with food and recommended doses along with the marketed preparations
  3. Explain the challenges in formulating nutraceuticals
  4. Understand the significance of safety and stability studies of nutraceuticals
  5. Describe the labeling and regulatory aspects for manufacture and sale of nutraceutical products.

- **Course Outline**

S No.	Details	Hours
1	**Introduction to Nutraceuticals** Definitions of Nutraceuticals, Functional foods, and Dietary supplements, Nutrigenomics, Nutricosmetics. Link between Food and Medicine. Food and No- food sources of nutraceutical factors, Nutraceutical factors in specific foods. Classification of Nutraceutical. Factors based on chemical nature and mechanism of action. Nutraceuticals used in some specific diseases (including nutraceuticals for pregnant women, lactating females and kids). Safety, Scientific evidence and market trends: Local and Global. Limitations of Nutraceuticals	5
2	**Phytochemicals as Nutraceuticals:**	14

	Occurrence, Structure, Properties, Metabolism and Pharmacokinetics, Therapeutic uses, Recommended Doses and Marketed Preparations of following a) **Carotenoids**- Lycopene, Lutein, Zeaxanthene, Astaxanthene b) **Phenolics and Polyphenolics as Antioxidants** - - Reservetrol , Grapeseed extract, Tea, Pycnogenol, Avenanthramides from Oats, Rutin, Soy Isoflavones, Curcumin	
	c) **Sulphur Compounds- Glucosinates** d) **Prebiotics / Probiotics**-Fructo-oligosaccharides, Lactobacillum. e) **Dietary fibres** – Soluble and insoluble any two examples each. f) **Lignans** – Flax Lignans g) **Essential Fatty acids**- Fish oils, α- Linolenic acid from Flax. h) **Quinones**- Tocopherol. i) **Proteins and Minerals**- Melatonin, Glutathione, Shilajit, Carnitine. j) **Marine nutraceuticals** – Collagen from fish skin	
3	**Formulations and Challenges** Challenges involved in processing, extraction and concentration of nutraceutical constituents, formulations and delivery systems, safety, storage and stability evaluation of formulations. Labeling of Nutraceuticals, Marketing of Nutraceuticals	4
4	**Safety and Toxicity of Nutraceuticals** Adverse Effects, Interactions, Adulteration- Intentional, counterfeiting, undeclared labeling, toxic contaminants	3
5	**Regulatory issues of Nutraceuticals and Dietary Supplements** a) EU, US and Indian guidelines. b) Regulatory Aspects; FSSAI. HACCP and GMPs on Food Safety. Adulteration of foods. c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals	4
	TOTAL	**30**

ANALYTICAL AND BIOANALYTICAL TECHNIQUES: METHOD DEVELOPMENT & VALIDATION

- **Theory course of 30 Hrs - 2 Credits**

- **Course Objectives:**
  1. Introduce fundamentals of analytical and bioanalytical method development.
  2. Familiarize students with regulatory expectations and validation practices.
  3. Gain exposure to analytical techniques and their bioanalytical applications through demonstrations
  4. Enable students to understand sample preparation, biomolecule quantification, and data analysis.

- **Course Outcomes**

  After completing this course, students will be able to:
  1. Explain the method development and validation steps as per ICH and USFDA guidelines for analytical and bioanalytical methods.
  2. Apply analytical tools for quantifying drugs and biomolecules in biological matrices. iii. Perform basic calculations and interpret results from analytical and bioanalytical methods
  3. Prepare validation protocols and SOPs for analytical and bioanalytical methods.

- **Proposed Topics:**

Sr. No.	Topics	Hours
1	Unit I: Fundamentals of Analytical Techniques	4
	• Introduction to Analytical & Bioanalytical Techniques Overview and historical development; Role in pharmaceutical and biomedical sciences. • Basics of HPLC Instrumentation Components: pumps, detectors, columns, autosamplers; Types of detectors; Mobile/stationary phases.	
2	Unit II: Method Development and Regulatory Framework	13
	• Method Development (Analytical & Bioanalytical) Parameters; matrix effects; sample preparation; selection of internal standards, method optimization • Regulatory Guidelines ICH Q2(R1), ICH M10, USFDA Guidance. • Validation Parameters Accuracy, precision, linearity, LOD, LOQ, specificity, recovery, stability; system suitability testing	
3	Unit III: Applications and Documentation	13

	• Applications of Bioanalytical Methods
	  • Case study on 'Method development using Analytical Quality by Design approach'
	  • Case Study on 'Extractables and Leachables: Analytical Method Development and Validation' HPLC with UV and MS detection and quantification
	• Applications of Bioanalytical Methods
	  • Case studies on quantification of drugs from biological fluids by RP-HPLC with UV and MS detection and quantification
	• Validation Exercise and Calculations
	Mock data: accuracy, linearity, LOD/LOQ; result interpretation
	• SOP Writing and Protocol Development:
	Quality Assurance Oversight in the Format and Drafting of Validation Protocols and SOPs.	

	Total No. of hours	30

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1. Skoog, D. A.; Holler, F. J.; Crouch, S. R. Principles of Instrumental Analysis, 7th ed.; Cengage Learning: Boston, MA, 2018.
2. Snyder, L. R.; Kirkland, J. J.; Dolan, J. W. Introduction to Modern Liquid Chromatography, 3rd ed.; Wiley: Hoboken, NJ, 2010.
3. Shrivastava, A.; Gupta, V. B. Methods for the Determination of Limit of Detection and Limit of Quantitation of the Analytical Methods. Chron. Young Sci. 2011, 2 (1), 21–25.
4. U.S. Food and Drug Administration (FDA). Bioanalytical Method Validation Guidance for Industry.2018. https://www.fda.gov/media/70858/download
5. International Council for Harmonisation (ICH). Validation of Analytical Procedures: Text and Methodology Q2(R1). 2005.https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-2r1-validation-analytical-procedures-text-methodology-step-5_en.pdf
6. International Council for Harmonisation (ICH). M10: Bioanalytical Method Validation.2022. https://database.ich.org/sites/default/files/M10_Guideline_Step4_2022_0719.p df
7. U.S. Pharmacopeia (USP). <1225> Validation of Compendial Procedures. In United States Pharmacopeia and National Formulary (USP–NF), USP Convention: Rockville, MD, 2023.
8. Evans, G. O. A Handbook of Bioanalysis and Drug Metabolism; CRC Press: Boca Raton, FL, 2004.

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10. United States Pharmacopeia. <1664> Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems; USP 43–NF 38; United States Pharmacopeial Convention: Rockville, MD, 2020.
11. International Council for Harmonisation. (2022). ICH Q14: Analytical Procedure Development. Geneva, Switzerland: ICH. Retrieved from https://www.ich.org

DRUG DISCOVERY AND COMPUTER-AIDED DRUG DESIGN

- **Theory course of 30 Hrs - 2 Credits**
- **Course Objectives:**

1. To introduce Drug discovery, process, definitions, targets, NCEs, and Techniques
2. To make students aware of the Role of Computer-Aided Drug Design (CADD) in drug discovery
3. Different CADD techniques and their applications
4. Various strategies to design and develop new lead-like/drug-like molecules
5. Providing Knowledge, application of modern methods in the field

- **Course Outcomes**

After completing this course, students will be able to:

1. Recall and relate the different processes, methods, and techniques in drug discovery
2. Classify and explain the different techniques to calculate the potential and kinetic energies of the system
3. Relate the use of scientific principles to construct and develop models based on desired techniques like molecular docking, 3D-QSAR, pharmacophore modelling, homology modelling, molecular dynamics, etc.
4. Evaluate the results obtained based on the characteristics of different interactions (docking), equation (QSAR), binding energy (dynamics), and interpret the molecular mechanism of how a drug acts in a particular manner to be either inhibiting or stimulating the enzyme/receptor

COURSE OUTLINE: **Theory (30 Hours)**

Sr. No.	Topics	Hours
1	Drug discovery, process, definitions, targets, NCEs, Techniques	2
2	History of CADD, different scenarios, techniques, and applications, Sources of structure and file formats	1
3	Molecular and Quantum Mechanics in Drug Design. forcefield, optimization, Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation. (systemic search, MD, and Monte Carlo, Genetic algorithm)	4
4	Software, hardware, and languages used in molecular modelling and visualization	1
5	Quantitative Structure-Activity Relationships: Basics. Hansch analysis, Free Wilson analysis, and the relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.	4

	Statistical methods used in QSAR analysis and the importance of statistical parameters.	
6	Molecular docking and drug-receptor interactions: Rigid docking, flexible docking, docking methods, and scoring functions.	4
7	*De novo* Drug Design, concept, Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment-based drug design.	2
8	Homology modelling and generation of the 3D structure of a protein.	2
9	Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modelling; Conformational search used in pharmacophore mapping.	2
10	Advanced Methods in CADD 1. Molecular dynamics and free energy of binding 2. Application of AI and Machine learning	 4 4
	TOTAL	**30**

References

A. Books:**

a. The Organic Chemistry of Drug Design and Drug Action by Richard B. Silverman, Elsevier Publishers.
b. Medicinal Chemistry by Burger, Wiley Publishing Co.
c. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott Williams & Wilkins.
d. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
e. Andrew R Leach - Molecular Modelling - Principles and Applications
f. Guidebook on Molecular Modelling in Drug Design by N. Claude Cohen. Academic Press

COSMETICS AND FMCG PRODUCTS: FORMULATION, SAFETY AND REGULATION

- **Theory course of 30 Hrs - 2 Credits**

- **Course Objectives:**

1. To **introduce the classification and scope** of cosmetics and FMCG products with insights into Indian and global markets.
2. To **familiarize students with formulation components** used in cosmetics and FMCG products.
3. To explore the **integration of herbal ingredients** in cosmetic and FMCG product development.
4. To **impart knowledge of safety, toxicity, and regulatory aspects** concerning product claims, labelling, and standards.

- **Course Outcomes:**

Upon successful completion of the course, students will be able to:

1. **Classify cosmetic and FMCG products** based on their application (skin, hair, oral care) and describe market trends and key players.
2. **Identify and describe key formulation ingredients** used in creams, soaps, deodorants, lipsticks, and other cosmetic/FMCG products.
3. **Evaluate the role of herbal ingredients** in enhancing the efficacy and appeal of cosmetic and personal care products.
4. **Demonstrate awareness of safety evaluation parameters** and **interpret regulatory guidelines** for manufacturing, labeling, and marketing.

- **Course Outline:**

Sr. No.	Topics	Hrs
1	**Introduction to Cosmetics and FMCG** • **Definitions and Classifications of Cosmetics and FMCG** (Fast Moving Consumer Goods). • **Key Segments in Cosmetics and FMCG** including Personal care, Oral Care, Colored Cosmetics, Health & Hygiene • **Trends and Challenges in the Industry** • Innovations in Packaging: devices and applicators	4
2	**Product Formulation Components** **Building blocks** such as surfactants, emollients, humectants, occlusives, surfactants, abrasives, film formers, waxes used in formulations. A. **FMCG: Personal Care Formulations---**Creams, Soaps and Cleansers, Toothpastes, Deodorants and Antiperspirants	12

	B. **Cosmetics: Coloured Formulations----**Foundation Creams, Lipsticks, Nail Lacquers • Advancement in cosmeceuticals: Nano-particulate systems	
3	**Herbs in Cosmetics and FMCG** • **Overview of herbal sources and extraction process.** • **Applications** in Skincare, Haircare, Oral Care • **Herbs in FMCG Food Products**: Nutraceutical and functional food uses.	**4**
4	**Safety and Toxicity** • **Dermal Safety---**Primary irritation, sensitization, patch tests, phototoxicity and comedogenicity testing • **Microbial Safety---**Challenge tests for preservative efficacy (PET test), Common contaminants and detection methods • **Allergen Labelling and Preservative Considerations----**List of EU/India regulated allergens in fragrance, Parabens, formaldehyde donors.	**4**
5	**Regulatory Aspects** • **Cosmetic Rules Under D&C Act (India)---**Classification of cosmetic vs drug-cosmetic, Licensing requirements and Schedule M-II. • **GMP in Cosmetics and FMCG**---Facility, personnel, and documentation requirements • **Indian and International Regulatory Bodies**--- CDSCO, BIS: IS standards, US FDA, EU (CPNP), ASEAN harmonization • **Labelling and Claims**---INCI nomenclature, ingredient listing order, Cosmetic claims substantiation: evidence types, Green claims, "cruelty-free," vegan, etc.	**6**
	Total	**30**

REFERENCES:

1. "Harry's Cosmeticology" (9th Edition), Editor: Meyer R. Rosen, Chemical Publishing Co.
2. "Handbook of Cosmetic Science and Technology" Editors: André O. Barel, Marc Paye, Howard I. Maibach CRC Press
3. **"***Cosmetics: Formulation, Manufacturing & Quality Control" (6th Edition),* P. P. Sharma, Vandana Publications, Delhi.
4. **"**Handbook of Cosmetics" (1st Edition), B. M. Mithal & R. N. Saha, Vallabh Prakashan (Delhi).

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