PHARMACEUTICALS & COSMETIC SCIENCE

Programme Structure

Course Code	Course Title	Lectures (L) Hours per week	Tutorial (T) Hours per week	Practical (P) Hours per week	Total Credits (18)
CHY2351	Cosmetic Formulation	2	1	-	3
CHY2451	Industrial management & safety process	2	1	-	3
CHY2551	Drug Design	2	1	-	3
CHY2651	Application of Nanotechnology in Medicine	2	1	-	3
CHY2751	Intellectual Property Rights & Quality Assurance (THEORY)	2	1	-	3
CHY2851	Pharmaceutical & Cosmetic Sciences lab	-	-	6	3
	TOTAL				**18**

PHARMACEUTICALS & COSMETIC SCIENCE

Syllabus

COSMETIC FORMULATION

Course Code: CHY2351 **Credit Units: 03**

Course Objective:
This course is intended to provide a comprehensive survey of ingredients fundamental to the cosmetic industry. The course will emphasize current trends in the selection of cosmetic ingredients. The chemistry and technology of cosmetic raw materials will be related to their behavioral properties as utilized in the construction of stable functional systems. In this way, it is intended to generate a better understanding of the contributions of ingredients to the performance of finished product formulations. Emphasis will be placed on recognizing and dealing with problem areas associated with the use of various ingredients. Safety considerations and other pertinent matters which can influence ingredient selection will be included in these discussions.

Course Content:
Module I:
Classification of raw materials and raw materials used in the cosmetic industry for the manufacture of finished products. Method of sampling, Indian Standard specification laid down for sampling and testing of various cosmetics in finished form by the bureau of Indian standards. Factors affecting stability of a formulation, ICH guidelines, Methods of stabilizations and Methods of stability testing.Concept of development of stability indicating analytical methods.

Module II:
Determination of Physical and chemical constants such as extractive values, moisture content, alcohol content, volatile oil content, ash values, bitterness values, foreign matters, and physical constants applicable to the lipid containing drugs. Microbial counts, bioburden and Pharmacopoeial microbial assays.

Module III:
Brief introduction of the following cosmetic preparation and a detailed study on their quality control: Shampoo, Tooth paste, skin powder, skin creams, hair creams, nail polish, after shave lotion, bath and toiletries, lipstick and hair dyes, perfumes, depilatories.

Module IV:
Packaging of cosmetics –Filling of solids, semisolids & liquids. Materials used for cosmetic packaging Rules & regulations and legal provisions for packaging & labeling.

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	10	7	8	5	70

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Text & References:

1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson – 2004.
2. Applied Biopharmaceutics and Pharmacokinetics, 4th Edition by Leon Shargel / Andrew B.C., Yu – 1999.
3. A. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition.
4. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
5. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II - 1996.
6. J. B. Wilkinson and R. J. Moore :Herry'sCosmeticology; Longman Scientific and Technical Publishers, Singapore.
7. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition - 1997,
8. ICH guideline for impurity determination and stability studies.
9. Practical HPLC method development by Lloyd R. Snyder, Joseph J. Kirkland, Joseph I. Glajch, John Wiley and Sons 2nd Edition – 1997.

INDUSTRIAL MANAGEMENT AND SAFETY PROCESSES

Course Code: CHY2451 **Credit Units: 03**

Course Objective:
The curriculum is developed to help the students understand the basic functions & responsibilities of a manager, provide him tools and techniques of managing different activities of the business concerned and to understand & interpret the provisions of some of the important provisions related to patent, trademark etc. It also aims at minimizing the chances of risks, injuries and accidents by implementing risk management techniques and safety management operations, monitoring the operating systems and bolstering the safety measures of an industry in general. With the rise of natural disasters in and around our world, the importance of the safety of human capital, protection of the environment and conservation of existing assets of an industry is increasing, leading to growing relevance of these skills.

Course Contents:
Module I:
Basic Concepts of Management Function of Management
Planning, Organizing, Directing, Control, Decision-making, Budgeting, Inventory Management (IM) & Quality Control (QC), Meaning & Importance of Inventory management, Inventory models, Cost consideration, Economic order quantity model.
Quality Management
Meaning & definition of Quality-Quality control systems-quality assurance-planning for quality- total quality management (TQM) philosophy-implementation of TQM in service and manufacturing industries-national & international standards.

Module II:
Manufacturing Management
Production planning & control, dynamics of material flow-inventory-bottlenecks and process variability, planning levels and time scales, forecasting-aggregate planning, synchronized manufacturing and theory of constraints-just in time production-shop floor performance monitoring.

Module III:
Safety in Chemical Process Industries
Safety in industries; need for development; importance safety consciousness in Indian chemical industry; safety programmes, elements of safety programme; effective realization, economic and social benefits.Industrial safety- Chemical process industries; potential hazard; chemical and physical job safety analysis; high presssure; high temperature operation; dangerous and toxic chemicals; highly radioactive materials; safe handling and operation of materials and machineries; planning and layout.

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	10	7	8	5	70

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Text & References:

1. William Handley, “Industrial Safety ", Hand Book McGraw-Hill Book Company 2nd Edition, 1969.
2. Fawatt, H.H. and Wood, W.S., “Safety and Accident Prevention in Chemical Operation", Interscience, 1965.
3. Heinrich, H.W. Dan Peterson, P.E. and Nester Rood, “Industrial Accident Prevention ", McGraw-Hill Book Co., 1980.
4. Blake, R.P., “Industrial Safety ", Prentice Hall Inc., New Jersy - III Edition, 1963.
5. Subbaram N.R. “Handbook of Indian Patent Law and Practice", S. Viswanathan (Printers and Publishers) Pvt. Ltd., 1998.
6. Eli Whitney, United States Patent Number: 72X, Cotton Gin, March 14, 1794.
7. Intellectual Property Today: Volume 8, No. 5, May 2001, [www.iptoday.com].

DRUG DESIGN

Course Code: CHY2551 **Credit Units: 03**

Course Objective

The Principles of Drug Design course aims to provide students with an understanding of the process of drug discovery and development from the identification of novel drug targets to the introduction of new drugs into clinical practice. It covers the basic principles of how new drugs are discovered with emphasis on lead identification, lead optimization, classification and kinetics of molecules targeting enzymes and receptors, prodrug design and applications, as well as structure-based drug design methods. Recent advances in the use of computational and combinatorial chemistry in drug design will also be presented. The course is further enhanced with invited lectures on recent developments and applications of drug design principles in the pharmaceutical industry.

Course Content:

Module I:

Introduction- Definition of drug (WHO), classification of drugs, nomenclature of drugs, stereochemical aspects of drugs, definitions of terms commonly used in the chemistry of drugs, routes of drug administration and different dosage forms and applications

Module II:

Structure Activity Relationships in drug design-Structure based drug design, ligand based drug design. Some case studies e.g. development of penicillin and ciprofloxacin. Target selection and lead identification, Natural product sources, Fermentation / Microbial sources, Synthetic, Introduction to Pharmacogenomics. Methods of conformational search used in pharmacophore mapping; catalyst/HipHop, DiscoTech, GASP, etc. with practical examples, ADME databases

Module III:

Molecular Modeling- Energy minimization, geometry optimization, conformational analysis, Approaches and problems; Bioactive vs. global minimum conformations; Mechanism based Drug Design including SEX, MM, Molecular graphics.

Module IV:

QSAR-Electronic effects; Hammett equation, Lipophilicity effects; Hansch equation, Steric Effects; Taft Equation; Experimental and theoretical approaches for the determination of physico-chemical parameters, parameter inter-dependence; Regression analysis, extrapolation versus interpolation, linearity versus non-linearity of different examples Free Wilson Analysis; The importance of biological data in the correct form; 2D – QSAR; 3D-QSAR-examples CoMFA and CoMSIA (any one).

Module V:

Molecular docking and dynamics-Rigid docking, flexible docking, manual docking; Advantages and disadvantages of flex-X, flex-S, autodock and dock softwares with successful examples; Monte Carlo simulations and molecular dynamics in performing conformational search, docking etc. De novo drug design techniques.

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	10	7	8	5	70

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Text & References:

1. The Organic Chemistry of Drug Synthesis, Vol. 1,2,3,4 by Lednicer Daniel, 1st edition, John Wiley & Sons INC.
2. Exploring QSAR Vol; I Fundamentals and Applications in Chemistry and Biology by C Hansh and A Leo Vol. II: hydrophobic, Electronic and Steric Constants by C Hansh, A Leo and D Hockman ACS Book Catalog.
3. Foye' s Principles of Medicinal Chemistry by Foye, 6th edition, Lippincott William Wilkins.
4. Comprehensive Medicinal Chemistry by Hansh C, Vol IV, Elsevier Pergamon.
5. Quantitative Drug Design- A Critical Introduction by Martin YC, Marcel Dekker Inc. New York.
6. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
7. Computer Aided Drug Design, by Pops and Perruns, Academic Press, NY
8. Burger' s Medicinal Chemistry by Wolff ME, John Wiley & Sons, New York.
9. Introduction to Medicinal Chemistry' – How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
10. Drug Design by Bothara KG &Kulkarni VM, 3rd edition, NiraliPrakashan.
11. An Introduction to Drug Design by SN Pandeya& IR Dimmock, 1st edition, New Age International Publishers.
12. Structure based Drug Design by Veerapandian, 1st edition, Taylor & Francis New York, London.
13. GuarinoRechard A. – New Drug Approval Process, 3rd Edition, Marcel Decker.;2004
14. Deshpande S. W. – Drug & Magic Remedies Act, 1954.;2008
15. Ariens, Drug Design, Academic press, NY,1975.
16. Foye, Principals of Med. Chem.
17. Martin, Y., QSAR, 1978
18. Hansch, Principles of Med. Chem.
19. Kubiny's, QSAR
20. Holtje. Sippl.,Rognan and Folkers, Molecular Modeling.
21. P.K. Larsen, Tommy and U.Madsen, textbook of Drug Design and Discovery.

APPLICATION OF NANOTECHNOLOGY IN MEDICINE

Course Code: CHY2651 **Credit Units: 03**

Course Objective:
This course will focus on developing students' understanding of the fundamental properties, as well as synthesis and characterization of nanomaterials, coupled with their applications in nanomedicine. This course also provides a realistic approach and covers the basic concepts of chemistry, physics and biology in the behavior of molecules and molecular interaction. It also includes various experimental techniques used to characterize bio-nano systems, the nano scientific principle involved in the processing, fabrication and manipulation of nanostructures and nanoparticles .

Course Content:
Module I:
Introduction to nanomedicine-Overview of nanotechnology from medical perceptive, different types of nanobiomaterials and their biomedical applications, and cell nanostructure interactions, Synthesis, characterization, and properties of smart nanomaterials, Surface modification/bio functionalization of nanomaterials
Module II:
Nanocarriers (e.g. liposomes, polymer capsules, polymer nanoparticles, porous materials, nanogels, dendrimers, microemulsions, inorganic nanoparticles, carbon nanotubes, lipoproteins, solid lipid nanoparticles) for drug delivery applications, Stimuli-responsive smart nanomaterials, Nanomaterials in different imaging (e.g.fluorescence and MRI) applications

Module III:
BioMEMS, Lab-on-a-Chip, nano/microfluidics, biosensors, Regenerative medicine, including tissue engineering, cell and gene therapy, DNA-based nanostructures, Cellular nanomachines, Toxicology of nanomaterials

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	10	7	8	5	70

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Text & References:

- Nano Medicines Edited by Dr.ParagDiwan and AshishBharadwaj, Pentagon press(2006) ISBN 81-8274-139-4.
- Christof M. Niemeyer, Chad A. Mirkin, Nanobiotechnology:Concepts, applications and perpectives, Wiley-Interscience 2004).
- Geoffery A. Ozin, Andre C. Arsenault, Nanochemistry: A chemical approach to nanomaterials, RSC publishing (2005)
- Challa Kumar, Biofunctionalization of nanomaterials, Wiley-Interscience (2006).

INTELLECTUAL PROPERTY RIGHTS AND QUALITY ASSURANCE

Course Code: CHY2751 **Credit Units: 03**

Course Objective:
This course will focus on intellectual property rights and patenting & Indian patent law for pharmaceutical industry.

Course Content:
Module I:
Requirements of GMP, cGMP, GLP, USFDA, WHO Guidelines and ISO 9000 Series, Drugs and Cosmetics Acts and rules, Drug Regulatory Affairs, Documentation- Protocols, Forms and Maintenance of records in Pharmaceutical industry, Preparation of documents for New Drug Approval and Export Registration, Processing and its application, Intellectual Property Rights (Patent, Copyright and Trademarks), Standard Operating Procedure (SOP) for different dosage forms.

Module II:
Concepts in Validation, Validation of manufacturing, Analytical and Process Validation and its Application, Basic concepts of Quality Control and Quality Assurance Systems, Source and Control of Quality Variation of Raw Materials: Containers, Closures, Personnel, Environmental, Etc., In-process quality tests, IPQC problems in Pharmaceutical industries. ICH Guidelines, Sampling Plans, Sampling and Characteristic Curves, Master Formula generation and Maintenance.

Module III:
Patenting, Indian patent law and pharmaceutical industry
Introduction of (IPR) Intellectual Property Rights, Patents, Design, Trademarks, Copyrights, Geographical Indications etc
Patent System: Definition of Patent, Criteria for obtaining patent (Novel, Non-obvious Applications) Filing and Processing of Patents: General procedure for securing patents in India. Case studies Opposition to Grant of Patent, Patent infringement: Silent features of Indian Patents Act 1970 with latest amendments with special reference to- Product & Process Patents, Provision of compulsory license, Exclusive Marketing Right, The Term of Patent, Patent offices in India; International convention relating to Intellectual Property - Establishment of WIPO - Mission and Activities -History - General Agreement on Trade and Tariff (GATT).
Case Studies on - Patents (Basmati rice, turmeric, neem, etc.) - Copyright and related rights - Trade Marks.

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	10	7	8	5	70

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Text & References:

1. Willing, S.H., "Good Manufacturing Practices for Pharmaceuticals" Marcel Dekker, Inc., New York
2. Drugs and Cosmetics Acts and rules
3. Patel, A.H., "Industrial Microbiology" Macmillon India Ltd., Delhi.
4. Nash, R.A. and Wachter A.H., "Pharmaceutical Process Validation" Marcel Dekker, Inc., New York
5. Bolton, S.H. "Pharmaceutical Statistics"
6. Banker, G.S. and Rhodes, C.T. "Modern Phaarmaceutics" Marcel Dekker, Inc., New York.
7. Careleton, F.J. and Agallow, J.P. "Validation of Aseptic Pharmaceutical Processes" Marcel Dekker, Inc.,
New York.
8. Garfeild "Quality Assurance Principles of Analytical Laboratories"
9. Latest Editions of I.P., U.S.P and B.P.
10. Bubharam N. R. - Whatever one should know about patents, 2nd Edition, Pharmabook Syndicate.
11. P. Narayan – Intellectual Property Law, Edition 3rd; Eastern Law House; 2001.

PHARMACEUTICAL & COSMETICS SCIENCES LAB

Course Code: CHY2851 **Credit Units: 03**

List of Experiments (Any 15 Experiments are to be performed)

Polymers

- Caprolactum from cyclcohexanone .
- Synthesis of Nylon-6,10
- Preparation of Polystyrene.
- Study the morphology of polymers through optical microscopy.
- Preparation of Epoxy resin using Bisphenol-A and Epichlorohydrin.
- Determination of molecular weight of high polymer using viscosity method.
- Determination of melt flow index of polymers and Compare their Melt Flow Characteristics

Dyes

- Preparation of Methyl Orange- An azodye.
- Preparation of Indigo

Food Industry

- Separation of artificial colorants in confectionary using TLC.
- Determination of protein content of wheat flour.

Cosmetic Products

- Shampoo
- Detergent
- Talc
- Lipstick
- Perfumes

Drugs Analysis

- Preparation of Paracetamol and Aspirin
- Analysis of Drugs:
    - Novalgin
    - Sulfa-drugs
    - Paracetamol

Examination Scheme:

Components	TA	LR	V	ATTD	EE
Weightage(%)	8	7	10	5	70

Note: TA-Teacher's Assessment, LR-Lab Record, V-Viva

Text & References:

- A Textbook of quantitative chemical analysis, VIth Edition Vogel, Pearson Education Limited.
- Practical Organic Chemistry, Mann and Saunders, IV Edition, ELBS and Longman Publication
- Comprehensive Experimental Chemistry, V. K. Ahluwalia, New Age Publication, Delhi
- Practical Manual of Organic Chemistry, R. K. Bansal
- A Textbook of quantitative inorganic analysis including elementary instrumental analysis, IVth Edition Vogel, ELBS and Longman Publication
- Advanced Practical Inorganic Chemistry, Gurdeep Raj, Goel Publishing House, Meerut