Faculty of Pharmacy

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH
(DEEMED TO BE UNIVERSITY) MYSURU

JSS Academy of Higher Education & Research
(Deemed to be University)
Accredited "A" Grade by NAAC
Sri Shivarathreeshwara Nagar, Mysuru – 570 015

Regulation & Syllabus

PG DIPLOMA IN PHARMACY
2018

PG Diploma

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POST GRADUATE DIPLOMA COURSES

SHORT TITLE AND COMMENCEMENT

These regulations shall be called **"THE REGULATIONS FOR THE POST GRADUATE DIPLOMA COURSES IN THE FACULTY OF PHARMACY OF THE JSS ACADEMY OF HIGHER EDUCATION & RESEARCH, MYSURU"**. They shall come into force from the academic year 2018-19 session. The regulation and syllabi are subject to modifications by the Academic Council from time to time.

SECTION I - REGULATION

1. ELIGIBILITY

A candidate who has passed B.Pharm degree examination of any recognized University and has secured not less than 50% of the maximum marks (aggregate of four years) prescribed for the qualification examination shall be eligible for the admission to the following PG Diploma courses;

1. Pharmaceutical Quality Assurance
2. Pharmaceutical Regulatory Affairs
3. Pharmaceutical Nanotechnology
4. Bioinformatics
5. Food and Drug Analysis
6. Computer Aided Drug Design

A candidate who has passed B.Pharm, MBBS, BDS, BAMS and BSc (with Biology as one of the subjects) degree examination of any recognized University and has secured not less than 50% of the maximum marks prescribed for the qualification examination shall be eligible for the admission to the following PG Diploma courses;

1. Pharmacovigilance
2. Clinical Research
3. Medicine and Poison Information
4. Herbal Products and their standardization
5. Intellectual Property Rights
6. Medical Devices
7. Cosmeceutics
8. Regulatory Toxicology
9. Phytopharmaceuticals and Industrial Applications

2. REGISTRATION

A candidate admitted to the postgraduate diploma course in any one of the constituent colleges of the JSS AHER, Mysuru, shall submit the duly filled application form for registration along with prescribed fee and declaration in the format, to this Deemed to be University through the constituent colleges within 60 days from the cut-off date prescribed for PG Diploma admission.

3. DURATION OF THE COURSE

The course of study shall be of 12 months (one year) duration from the commencement of academic term. The study of PG Diploma courses shall be of annual system. No exemption shall be given from this period of study and training for any other experience gained prior to the admission to the course.

4. MEDIUM OF INSTRUCTION

English shall be the medium of instruction for all the subjects of study for examinations.

5. WORKING DAYS IN AN ACADEMIC YEAR

Each academic year shall consist of not less than 200 working days.

6. COURSES OF STUDY

Table-I Branches in Postgraduate diploma courses.

Sl. No.	Specialization
1	Bio informatics
2	Pharmacovigilance
3	Pharmaceutical quality assurance
4	Herbal product & their standardization
5	Pharmaceutical regulatory affairs
6	Nanotechnology
7	Clinical research
8	Medicine and Poison Information
9	Cosmeceutics
10	Regulatory Toxicology
11	Computer aided drug design
12	Food & Drug Analysis
13	Intellectual Property Rights
14	Medical Devices
15	Phytopharmaceuticals & Industrial application

Table-II: Subjects to be studied in different branches of PG Diploma courses

Sl. No.	Specialization	Paper	Name of the Subject
1	Bio informatics	I	Basic cellular and Molecular Biology
		II	Bioinformatics and *In Silico* Biology
2	Pharmacovigilance	I	Principles of Pharmacovigilance
		II	Regulatory Perspectives of Pharmacovigilance
3	Pharmaceutical quality assurance	I	Quality Assurance and Quality Control
		II	Pharmaceutical Validation

4	Herbal products & their standardization	I	Herbal Drug Technology
		II	Quality control of Herbal products
5	Pharmaceutical Regulatory Affairs	I	Pharmaceutical cGMP and Validation
		II	International Regulatory Requirments
6	Pharmaceutical Nanotechnology	I	Nanocarriers for Drug Delivery
		II	Characterization and Applications of Nanocarriers
7	Clinical Research	I	Clinical Development and Regulations
		II	Clinical Research
8	Medicine and Poison Information	I	Medicine Information
		II	Poison Information
9	Cosmeceutics	I	Cosmeceutics Biology and Formulation Sciences
		II	Cosmecutical Evaluation & Regulations
10	Regulatory Toxicology	I	Principles and Methods in Regulatory Toxicology
		II	Principles, documentation and implementation of Good Laboratory Practice
11	Computer Aided Drug Design	I	Quantitative Structure Activity Relationships
		II	Molecular Modelling and Virtual Screening Techniques
12	Food & Drug Analysis	I	Food analysis
		II	Drug analysis
13	Intellectual Property Rights	I	Introduction to Law & Law of patents
		II	Law of copy rights, designs, trademarks & geographical indication
14	Medical Devices	I	Regulated Markets
		II	Rest of the World Markets
15	Phytopharmaceuticals & Industrial application	I	Regulatory considerations for herbal products
		II	Phytochemistry

7. ATTENDANCE AND MONITORING PROGRESS OF STUDIES

i. Candidate pursuing PG Diploma Courses shall study in the concerned department of the institution for the entire period.
ii. Entire year shall be taken as a unit for the purpose of calculating attendance.
iii. Candidate who has put in a minimum of 80% of attendance in the theory and practical component separately shall be permitted to appear for examination.
iv. Any student who fails to complete the course in the manner stated above shall not be permitted to appear for the Deemed to be University examinations.
v. There shall be no condonation of lack of attendance in PG Diploma courses.

8. EXAMINATION

There shall be an examination at the end of one academic year.

9. SCHEME OF EXAMINATION

A. Internal (Sessional) Examination

Theory: Two sessional examinations evenly spread during the academic year shall be conducted by the constituent colleges. The average marks shall be computed out of a maximum of 50 marks and shall constitute the sessional marks awared in theory.

Practical: Students are expected to perform the number of experiments/ assignments listed in the respective syllabus. Two practical sessional examinations evenly spread during each academic year shall be conducted. The average marks shall be computed out of a maximum of 50 marks.

The candidates are required to score a minimum of 50% marks in each of the subjects (Theory and practicals separately) in the sessional examination to be eligible to appear for annual Deemed to be University examination in the respective subject.

Note: If the candidate is absent for any sessional examination for valid reasons, he/she may be permitted to appear for the re examination within 15 days.

B. Deemed to be University Examination

There shall be two examinations (annual and supplementary) conducted by the Deemed to be University. The scheme of the examination is given in Table-III.

C. Criteria for Pass

A candidate who secures 50% of marks in each subject in theory and practical separately including Sessional marks and Deemed to be University examination marks together shall be declared to have passed in PG Diploma examination. Candidate, who fails in theory or practical examination, shall reappear in the subsequent examination in that subject.

D. Class shall be declared on the basis of the aggregate of marks scored in PG Diploma as follows:

(1) 75% and above -- Distinction.
(2) 60% & above but less than 75% -- First class.
(3) 50% & above but less than 60% -- Second class.

10. Revaluation / Retotaling of answer paper

There shall be no revaluation of the answer papers of failed candidates in any Post-Graduate Diploma examination. However, the failed candidate can apply for re-totaling through the College.

11. DURATION FOR COMPLETION OF THE COURSE OF STUDY

The duration for the completion of the course shall be fixed as double the time of the course and the students have to pass within the said period otherwise they have to get fresh admission.

PG DIPLOMA EXAMINATION

Table – III: Scheme of Examination for all Branches

	Examination				
	Sessional		Annual		Total Marks
	Duration (Hrs)	Marks	Duration (Hrs)	Marks	
Paper – I	02	50	02	50	**100**
Paper – II	02	50	02	50	**100**
Practical examination	03	50	03	50	**100**
Total					**300**

Scheme of examination:

1. Long Essay: 1 X 15 = 15 Marks (1 out of 2 questions)
2. Short Essay : 2 X 10 = 20 Marks (2 out of 3 questions)
3. Short Answer: 3 X 5 = 15 Marks (3 out of 4 questions)

PG DIPLOMA IN BIOINFORMATICS

Program outcomes

Bioinformatics is an interdisciplinary program offering substantial training in both the biological sciences and computer sciences.PG Diploma in Bioinformatics emphasizes the integration of computer science with genomics, proteomics and molecular biology. Students attracted to this program have dual interests

in computer science and biology and find it an excellent choice for their broad interests. Students who complete this program enter the top graduate programs in bioinformatics and computational biology in the world, enter leading professional institutes or find employment in biotechnology, pharmaceutical, or drug designing and drug development companies.

Paper I – Basic Cellular and Molecular Biology

Scope

This course – Basic Cellular and Molecular Biology is designed to provide the knowledge to the PG diploma Bioinformatics students in invaluable areas of advanced microbiology and biotechnology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Objectives

At the completion of this course it is expected that the students will get an understanding about the following aspects;

- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Identify appropriate sources of enzymes
- Understand and perform genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.
- Understand the overview of pharmacogenomics

Course outcomes

- Students will understand the various techniques used in microbiology and biotechnology
- Students can be able to provide examples of current applications of bio-technology and advances in the different areas like medical, microbial and forensic sciences
- Students can able to explain cell-cell interaction, cell cycle and regulation and mutation process
- Students can explain the concept and application of Genomics

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Biology of cells:** Cells as a unit of life, structure of prokaryotic and eukaryotic cells, function of cell organelles. **Cellular membrane:** structure, transport, channels, Carriers, receptors, endocytosis, membrane potentials **Molecules of Life:** Introduction to carbohydrates, proteins and lipids Nucleic acids-Purines, pyrimidines, Nucleosides and Nucleotides, structure of DNA, denaturation and renaturation of DNA	**10**
II	**DNA replication:** Protien synthesis-Eukaryotic and Prokaryotic, Transcription and Translation Cell-Cell interactions and signal transductions: Intercellular junctions, signaling by hormones and neurotransmitters: receptors, G-protiens, protein kinases and Second messengers. Cell Cycle and regulation-Mitosis,Meiosis	**10**

III	**Mutation-** Types of mutations, types of mutagenic agents and their molecular mechanism; DNA repair, Chromosomal types and structure Enzymes: coenzymes and metal cofactors, temperature and Ph effects, Michaelis-Menten kinetics, inhibitors and activators, active site and mechanism of enzyme Action, Isoenzyme, allosteric enzymes	**10**
IV	**Genomics:** Definition of genome, Genome sequencing, Genome map: Types of Genome maps And their uses. Map repositories: NCBI-Entrez Human genome map viewer, OMIM- Online Mendelian Inheritence in Man. Linkage map resources. Practical uses of genome maps: Locating genomic regions, target identification, arran gement of genes, SNP diagnosis, positional specific cloning.	**10**
V	**Annotation of the Genome:** Structural Annotation. Various approaches in gene Prediction: ORF prediction, Gene prediction in prokaryotes and eukaryotes, Hidden Markov Model, pattern discrimination, Evaluation of gene prediction methods, prediction of promoter sequences, Functional annotation: Employing the similarity in the sequence, gene family and metabolic pathway. Employing the Conserved domain, profile and motif comparision, EST Comparision, Analysis of Human Genome.	**10**

Recommended Books/Sources:

1. Lehninger, A. L. 1984. Principles of Biochemistry. CBS publishers and distributors, New Delhi, India.
2. David. E. Cell Biology: Organelle structure and Function jones & Barlett publishers.
3. Structural Genomics and its importance for Gene Function Analysis. Jeffrey et al. 2000. Nature Biotechnology. 18:283-287.

Paper II – Bioinformatic and In Silico Biology

Scope

Graduation in bioinformatics can engage in any combination of research, teaching, clinical service, and consultation. There is a growing need for bioinformatics researchers who can analyze new sources of high-throughput experimental data in biology, medicine, and bioengineering. Biotechnology and pharmaceutical companies also seek bioinformatics graduates for applied research on disease and drug discovery. Medical centers are also increasingly hiring bioinformatics graduates as genomics data become important in medical research and clinical applications.

Objectives

- The basic objective is to give students an introduction to the basic theory knowledge on techniques of Biology and bioinformatics.
- Emphasis will be given to the application of bioinformatics and biological databases to problem solving in real research problems.
- The students will become familiar with the use of a wide variety of internet applications, biological database and will be able to apply these methods to research problems.

Course outcomes

- Students will be able to identify strengths and weaknesses in a variety of systems biology.
- Entire course will instruct a range of bioinformatics and modeling software to develop predictive and mechanistic models.
- Students can access, query and retrieve models from public repositories for systems biology, and structural biology.
- Students will be able to Identify an appropriate modeling approach for a given biological question and dataset

Lecture wise program

Unit No.	Chapter	No. of Hours
I	Introduction to bioinformatics, classification of biological databases, Biological data formats, Application of bioinformatics in various field. Introduction to single letter code of amino acids, symbols used in nucleotides, data retrieval- Entrez.	**10**

II	Introduction to sequence alignment. Substitution matrices, scoring matrices-PAM and BLOSUM. Local and Global alignment concept, Dot plot. Dynamic programming methodology: Needleman and Wunsch algorithm. Smith Waterman algorithm. Statistics of alignment score. Multiple sequence alignment. Progressive alignment. Database search for similar sequences using FASTA and BLAST programs. Evolutionary analysis: distances, Cladistic and phenetic method. Clustering method. Rooted and uprooted tree representation. Use of cluster and PHYLIP.	**10**
III	Protein Prediction method: Concepts of secondary structure prediction of RNA and protein. Probabilistic model: Markov chain, Hidden Markov Models-other applications. Gene prediction: Analysis and prediction of regulatory regions. Fragment assembly. Genome sequence assembly, Restriction Mapping, Repeat sequence finder.	**10**
IV	Comparative Genomics: purpose and Method of comparison, Tools for genomic comparison: Application of comparative Genomics, Reconstruction of metabolic pathway, predicting regulatory elements, Identifying targets, examination of domain function, analysis of conserved regions. Genome projects and Model Organism research –Yeast; C. Elegans; and Mouse – a comparative analysis.	**10**
V	Functional Genomics: Gene expression analysis by cDNA micro arrays, SAGE, strategies for generating ESTs and full length inserts; EST clustering and assembly. EST databases (DBEST, UNIGENE).	**10**

Recommended Books/Sources:

1. Bioinformatics Sequence and Genome Analysis. 2001. David W. Mount. Cold spring Harbour, Laboratory Press.
2. Comparative genetics. Ann Gibbons, 1998. Science. 281: 1432-1434.
3. The Molecular Biology Database Collection: Updated Compilations of Biological
4. Database Resources. Baxevanis A.D. 2001. Nucleic acids Research. 29 p 1-10.
5. Genomes. T. A Brown, 2001. Taylor and Francis Group.

Practicals – 100 Hrs

Course outcomes

- The students will be able to describe the contents and properties of the most important bioinformatics databases, perform text and sequence based searches, and analyze and discuss the results in light of molecular biological knowledge
- The students will be able to explain the major steps in pair wise and multiple sequence alignment, explain the principle for, and execute pair wise sequence alignment by dynamic programming
- The students will be able to predict the secondary and tertiary structures of protein sequences.

15 experiments/assignments

1. Data retrieval tools and methods
2. Protein sequence analysis(ExPASy proteomics tools)
3. Sequence similarity searching (NCBI BLAST)
4. Multiple sequence alignment(Clustal W)
5. Molecular phylogeny(PHYLIP)
6. Sub cellular localization prediction
7. Analysis of protein and nucleic acids sequences
8. Protein structure prediction
9. Gene structure and function prediction
10. DNA, Protein, drug binding studies using docking tools
11. Staining technique – Simple, Gram's and Negative
12. Isolation of plasmid DNA, protein
13. Estimation of DNA and protein
14. Agarose Gel Electrophoresis
15. SDS PAGE system

PG DIPLOMA IN PHARMACOVIGILANCE

Program outcomes

This program aims to impart knowledge regarding best practices in Pharmacovigilance, reporting culture, regulatory aspects, signal detection and tools used in Pharmacovigilance. Students will also gain knowledge regarding application of Pharmacovigilance in Public Health.

PAPER I- Principles of 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, national & global scenario of Pharmacovigilance. This paper will train students on

establishing Pharmacovigilance program 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 course it is expected that students will be able to (know, do, appreciate):

- Why drug safety monitoring is important?
- History and development of Pharmacovigilance
- National and international scenario of Pharmacovigilance
- Dictionaries, coding and terminologies used in Pharmacovigilance
- Detection of new adverse drug reactions and their assessment
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in Pharmacovigilance

Course outcomes

This course aims to provide the students the detailed information on safety assessment of medications though different Pharmacovigilance activities.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Introduction to adverse drug reactions** • Definition and classification of adverse drug reactions • Detection and reporting of adverse drug reactions • Management of adverse drug reactions • Causality assessment • Severity and seriousness assessment • Predictability and preventability assessment **Introduction to Pharmacovigilance** • History and development of Pharmacovigilance • Importance of safety monitoring / Why Pharmacovigilance? **National and international scenario** • Pharmacovigilance in India • Pharmacovigilance - global perspective • WHO international drug monitoring programme **Basic terminologies used in Pharmacovigilance** • Terminologies of adverse medication related events • Regulatory terminologies	**10**

II	**Information resources in Pharmacovigilance**
	• Basic drug information resources
	• Specialised resources for adverse drug reactions
	• Critical evaluation of medication safety literature
	
	Establishing Pharmacovigilance program
	• Establishment of Pharmacovigilance centre in a hospital
	• Establishment & operation of drug safety department in industry
	• Establishing a national Pharmacovigilance programme
	• SOPs – Types, designing, maintenance and training
	• Roles and responsibilities in Pharmacovigilance
	  ○ Licence Partners
	  ○ Contract Research Organisations (CROs) and
	  ○ Market Authorisation Holders (MAH)
		10

III	**Pharmacovigilance methods** • Passive surveillance – Spontaneous reports and case series • Intensified reporting • Active surveillance – Targeted reporting, cohort event monitoring and electronic health record mining • Comparative observational studies – Cross sectional study, case control study and cohort study • Targeted clinical investigations • Vaccine safety surveillance **Adverse drug reaction reporting** • Introduction to reporting systems • Spontaneous reporting system • Reporting to regulatory authorities • Guidelines for reporting adverse drug reactions **Signal detection, Risk assessment and management** • Identification of new adverse drug reactions • Signal detection in pre and post marketing period • Prioritization and risk assessment • Risk management **Drug and disease classification** • International classification of diseases • Anatomical, therapeutic and chemical classification of drugs • Defined Daily dose • International Non-proprietary Names for drugs	**10**

IV	**Drug dictionaries and coding in Pharmacovigilance** • WHO adverse reaction terminologies • MedDRA and Standardised MedDRA queries • WHO drug dictionary • Eudravigilance medicinal product dictionary **Communication in Pharmacovigilance** • Effective communication in Pharmacovigilance • Communication in Drug Safety Crisis management • Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media • Dear Doctor Letters to Healthcare Professionals **Tools used in Pharmacovigilance** • Introduction to Argus • Introduction to Aris G Pharmacovigilance and safety	**10**
V	**Drug Informatics** • Basic Prescribing Information (BPI) Labelling • EMEA labelling • Investigator's Brochure (IB) Labelling **Seriousness Assessment Criteria** • Event verbatim • CTCAE guidelines **Statistical methods for evaluating medication safety data** **Pharmacogenomics of adverse drug reactions**	**10**

Recommended Books/Sources

1. Textbook of Pharmacovigilance by S K Gupta, Jaypee Brothers, Medical Publishers
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones & Bartlett Publishers
3. Mann's Pharmacovigilance by Elizabeth B. Andrews, Nicholas, Wiley Publishers
4. Stephens' Detection of New Adverse Drug Reactions by John Talbot, Patrick Walle, Wiley Publishers
5. An Introduction to Pharmacovigilance by Patrick Waller, Wiley Publishers
6. Cobert's Manual of Drug Safety and Pharmacovigilance by Barton Cobert, Jones & Bartlett Publishers
7. Textbook of Pharmacoepidemiology by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers
8. A Textbook of Clinical Pharmacy Practice-Essential Concepts and Skills by G. Parthasarathi, Karin NyfortHansen, Milap C. Nahata, Universities Press

PAPER II- Regulatory Perspectives of Pharmacovigilance

Scope

This paper is designed to impart the knowledge of regulatory requirements of drug safety monitoring. This paper will train the students on developing drug safety data during both pre-clinical and clinical phases of drug development and also during post approval period. This paper will also impart the skills of drug safety evaluation in special population. It will familiarize students with the Pharmacovigilance guidelines of ICH and other important countries. Students will also get trained on managing the Pharmacovigilance projects in an organization including regulatory inspections.

Objectives

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

- Methods to generate safety data during pre-clinical, clinical and post approval phases of drugs' life cycle
- Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- ICH guidelines for ICSR, PSUR, expedited reporting, Pharmacovigilance planning and bridging studies
- CIOMS requirements for ADR reporting
- US FDA – CFR requirements and guidance documents
- Good Pharmacovigilance practice
- India, Japan, EMEA and Canadian regulatory requirements of drug safety monitoring
- In-house and out sourced Pharmacovigilance project management
- Writing case narratives of adverse events and their quality assessment
- How to prepare for Pharmacovigilance inspections

Course outcomes: This course aims to provide the students the detained information on regulatory requirements for different Pharmacovigilance activities.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Safety data generation** • Pre-clinical phase • Clinical phase • Post approval phase **Safety monitoring during clinical trials** • Need for safety monitoring and terminologies • Monitoring of safety • Key players and their responsibilities **Drug safety evaluation in special population** • Paediatrics • Pregnancy and lactation • Geriatrics	**10**

II	**ICH Guidelines for Pharmacovigilance** • Expedited reporting • Individual case safety reports • Periodic safety update reports • Post approval expedited reporting • Pharmacovigilance planning • Safety reporting in clinical study reports • Foreign data acceptability and safety bridging studies • Good clinical practice in Pharmacovigilance studies	**10**
III	**Organizations and Pharmacovigilance** • CIOMS • US FDA and Pharmacovigilance o CFR requirements o Guidance for pre-approval Pharmacovigilance of prescription drugs o Guidance for post-approval Pharmacovigilance of prescription drugs o Guidance for Pharmacovigilance of non-prescription drugs o Good Pharmacovigilance practice o Risk Evaluation and Mitigation Strategy • EMEA (Europe) and Pharmacovigilance o Part I – Marketing authorization holders o Part II – Competent authorities and the agency o Part III – Electronic exchange of Pharmacovigilance information in EU o Part IV – Pharmacovigilance communication • MHLW (Japan) and Pharmacovigilance • Health Canada and Pharmacovigilance o Introduction o F&D and NHP Regulations o Guidance documents for Pharmacovigilance • CDSCO (India) and Pharmacovigilance o D&C Act and Schedule Y o Differences in Indian and global Pharmacovigilance requirements	**10**

IV	**Case Narratives** • Regulatory perspectives of narrative writing • Case narratives from clinical trial data • Case narratives from spontaneous reporting • Case narratives from literature reporting • Quality assessment of case narratives	**10**

V	**Quality Assurance (QA) aspects of Pharmacovigilance activities**
	• Critical Errors
	• Handling delays in regulatory submissions
	  ○ Reasons for delays
	  ○ Impact of delayed regulatory submissions
	  ○ Measures for minimizing delays
	• PV data handling in product quality complaints
	Pharmacovigilance compliance and inspections
	• Conduct of Pharmacovigilance inspections
	• Preparation for Pharmacovigilance inspection
	  ○ Importance of Regulatory Audit
	  ○ Types of Regulatory Audits
	• Planned Audits
	• Random Visits
	  ○ Dos and Don'ts
	• Inspection reports and corrective actions
	Legal case processing, assessment and regulatory requirements
	• Introduction to legal cases
	• Source(s) for the legal cases
	• Legal case processing and assessment
	• Adverse event form completion /Data entry in to the AEM form
	• Legal case narrative writing and convention used for narrative writing
	• Regulatory reporting requirement
	Recent advances/changes in regulatory requirements
		10

Recommended Books/Sources

1. Pharmacovigilance Insight & Global Perspective by Neeru Agarwal, CreateSpace Independent Publishing Platform
2. https://www.who-umc.org/
3. http://www.ich.org/home.html
4. https://cioms.ch/
5. http://www.ema.europa.eu/ema/
6. https://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf
7. http://cdsco.nic.in/forms/Default.aspx
8. http://www.ipc.gov.in/PvPI/pv_home.html
9. http://www.who.int/vaccine_safety/en/

Practicals: Experiential Training **100 Hrs**

Course outcomes

The experiential training provides the students an opportunity to develop skills to identify, assess, management and reporting of Adverse Drug Reactions and other safety issues of medications.

15 experiments/assignments

Students are expected to perform the following activities for 100 hours over a period of ten month as a part of experiential training.

- Designing of Pharmacovigilance centre (2 Numbers)
- Signal detection and risk assessment (4 Numbers)
- Causality assessment of adverse drug reactions (4 Numbers)
- Case narratives (3 Numbers)
- Safety reporting (2 Numbers)

PG DIPLOMA IN PHARMACEUTICAL QUALITY ASSURANCE

Program outcomes

Graduates will

- Acquire adequate scientific knowledge regarding principles of Good Manufacturing Practices, GLP etc.
- Have hands on training of practical aspects of preparation of documents such as Preparation of SOP's, Protocols etc.
- Able to understand the importance of training, think logically and solve the problems, which will develop an ability to conduct, analyze and interpret data of pharmaceutical documents in various departments (Eg: Formulation & Development, Production, Quality control & Quality assurance etc) as per the needs of pharmaceutical industries
- Demonstrate the impact of documentation, data Integrity and training.
- Have basic knowledge of regulatory perspective and master the key concepts in the discipline of their interest in pharmaceutical quality assurance.

PAPER I – Quality Assurance and Quality Centre Control

Scope

- To learn the concept of TQM, GMP, ICH and ISO 9000.
- To train the students about the importance and requirement of good
- documentation practices.
- To impart training in good manufacturing practices and its conduct in manufacturing process.
- To understand the documentation procedures and their implementation.
- To introduce the basic concepts of GLP and its implementation.

Objectives

Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)

- Concepts of quality control and quality assurance and its implementation
- Regulatory guidance's and guidelines like ICH, WHO and other relevant documents
- Good Laboratory Practices, SOPs, handling of deviation
- Documentation of BMR, MFR, DMF and relevant process related documents

Course outcomes

- The students understand the importance of quality in pharmaceutical products.
- The students are explored into importance of Good practices such as

GMP,GLP etc.

- The factors affecting the quality of pharmaceutical.
- The students should understand the regulatory aspects of pharmaceuticals.
- The process involved in manufacturing of pharmaceuticals different section/department and activity is learnt.
- The various documentation processes is highlighted to the student.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	Definition - Quality control and Quality assurance, concept and philosophy of TQM, GMP, ICH and ISO 9000. Quality control test for containers, closers, caps, secondary packing materials	**10**
II	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination andGood WarehousingPractice	**10**
III	Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, complaints and evaluation of complaints, Handling of return good, recalling and waste disposal	**10**
IV	In process quality control and finished products quality control for following formulation in pharma industry: tablets, capsules, ointments, suppositories, creams, modified release products (controlled release, sustained release products, etc.), parenterals, ophthalmic and surgical products.	**10**
V	GLP: Scope of GLP, Quality assurance unit, SOP, protocols for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation.	**10**

Recommended Books/Sources:

- Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
- Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
- Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
- How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
- The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepi-

ents and Dosage forms, 3rd edition, WHO, Geneva, 2005.
- Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
- ICH guidelines
- ISO 9000 and total quality management
- The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
- QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
- Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

PAPER II - Pharmaceutical Validation

Scope

- To learn the concept of validation and process of validation.
- To train the students about the importance and requirement of validation.
- To impart training in carrying out of validation in facilities
- To understand the documentation procedures in validation
- To introduce the basic concepts of validation and their implementation in APIs and products

Objectives

Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)

- Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)
- Concepts of validation and its implementation
- Validation of process, equipment and products

Course outcomes

- The students understand the basic concept and importance of validation.
- The students should understand the validation of equipment and manufacturing facilities.
- The process involved in validation activity is learnt.
- The various documentation processes involved in validation are highlighted to the student.

Lecture wise program:

Unit No.	Chapter	No. of Hours
I	An Introduction to the Basic Concepts of Process Validation & How it Differs from Qualification (Installation Qualification (IQ), Operational Qualification (OQ) & Performance Qualification (PQ) Procedures, Validation master plan (VMP)	**10**
II	A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC) Validation of Water (Demineralised, Distilled and Water for Injection) & Thermal Systems, including Heat Ventilation and Air conditioning (HVAC), Facilities & Cleaning Validation	**10**
III	Process Validation of Active Pharmaceutical Ingredients (APIs) and finished products	**10**

IV	Validation of Sterile and Non-Sterile Facility	**10**
V	Validation of Analytical Methods, Automated Systems, Validation of process: mixing, granulation, drying, compression, filtration, filling, Validation of sterilization methods and equipments: dry heat sterilization, autoclaving, membrane filtration. Validation of analytical procedures, Validation of air handling equipments and facilities in sterile and non-sterile areas.	**10**

Recommended Books/Sources:

- Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition
- Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
- Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
- Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rdEdn, Lea &Febriger, Philadelphia.
- Pharmaceutical process validation (Drugs and Pharmaceuticals Series), Ira R. Berry and Robert A. Nash, 2nd Edn.(1993), Marcel Dekker Inc., New York.
- Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
- Remingtons Pharmaceutical Sciences, by Alfonso &Gennaro, 19th Edn. (1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
- Indian Pharmacopoeia, 2008, The Controller of Publications, Govt. of India.
- Drug Formulation Manual- by D.P.S Kohli and D.H Shah, 1st Edn.(1998), Eastern publishers, New Delhi
- The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt Ltd.
- Pharmaceutical Quality Assurance by Manohar A. Potddar, 2nd edition 2007, NiraliPrakashan, Mumbai

Practicals **100 Hrs**

Course outcomes:

- The students understand the basic concept and importance of GMP, GLPand validation.
- The students should be capable of preparation of Protocols, SOP's etc.
- The students should understand the process of validation of equipment and manufacturing facilities.
- The various documentation processes involved in pharmaceutical industries.

15 experiments/assignments:

Students are expected to perform the following activities for 100 hours over a period of 10 months as a part of experiential training

1. Documentation for in process and finished products Quality control tests for Solid, Semisolid, ophthalmic, modified release and Sterile preparations.
2. Protocol preparation for documentation of various types of records (BFR,

MFR, DR, etc.)
3. Report preparation of GLP for non-clinical testing
4. Analytical methods Validation
5. Accelerated and Photostability studies on dosage forms as per ICH Guidelines
6. Documentation for audits and inspection of manufacturing facilities.

PG DIPLOMA IN HERBAL PRODUCTS AND THEIR STANDARDIZATION

Paper-I-Herbal Drug Research

GOAL: The course imparts knowledge and skill in the area of herbal drug technology so as to develop expertise to work efficiently in the formulation development of herbal drugs, standardization, research and to become future leader in herbal drug technology and industry management.

OBJECTIVES: Upon completion of the course the candidate shall be able to:
1. Know the requirements for setting up the herbal drug industry.
2. Identify and authenticate the herbal drugs.
3. Isolate and evaluate therapeutically active ingredients / marker compounds from herbal drugs.
4. Chemical characterization of isolated phytomedicines
5. Formulation development and quality control methods.

50Hrs (2Hrs / Wk)

1. WHO Guidelines for Quality Control of herbal raw materials. Determination of pesticide residue, arsenic and heavy metals, afflatoxins and microbial contaminants. 6 HrS
2. Definition, principle of the various extraction techniques like maceration, percolation, hot continuous extraction, pilot scale extraction, microwave assisted extraction and supercritical fluid extraction. GMP for the production of quality botanicals. 12 Hrs
3. General methods for isolation and purification of active principles from medicinal plants. Application of chromatographic techniques in isolation & characterisation of phytochemical constituents viz., paper chromatography, thin layer chromatography, column chromatography, gaschromatography (GC), high performance liquid chromatography (HPLC) and high performance thinlayer chromatography (HPTLC). 18 Hrs
4. Role of chemical and biological markers in standardization of herbal products. 4 Hrs
5. General methods for structural elucidation of natural products, Application of spectroscopy for characterisation of phytoconstituents. 10 Hrs

Paper II- Industrial Herbal Drug Technology DHP2

50Hrs : (2 Hrs / Wk)

Herbal Drug Industry

1. Infrastructure of herbal drug industry involved in production of standardized extracts and various dosage forms. Entrepreneurship Development. Project selection, project report, technical knowledge, plant design, layout and construction. Pilot plant scale–up techniques, case studies of herbal extracts. Formulation production management. 08 Hr
2. Indian research institution and industries involved in herbal drug research and commerce. World trade and market of herbal drugs, Global marketing management. Indian and international patent law as applicable to herbal

drugs and natural products. Export –import (EXIM) policy, TRIPS,IPR. Quality assurance in herbal drug industry. Concepts of TDM, GMP, GLP, ISO-9000 etc. Integration of traditional systems of medicine. Ayurveda, Siddha and Unani with modern herbal medicine. 10 Hrs

3. Formulation and Development in herbal drugs, Ayurveda and traditional Ayurvedic formulations. Siddha and Siddha formulations. Unani medicine and traditional Unani formulations. Methods of single herb and polyherbal formulations their merits and demerits. Standardization of traditional formulations of herbal drugs. 12 Hrs
4. Formulation and development of herbal cosmetics and Nutraceuticals Role of herbs in cosmetics, Raw material of herbal origin used in cosmetics. Formulation of herbal cosmetics in various preparations, skin care, hair care and dental preparations. Methods of preparation and standardization of herbal cosmetics. Nutrients, Nutraceuticals, Dietary Supplements and DSHEA. Nutritive value of foods. Introduction to functional foods and nutraceuticals: Garlic, Lycopene, Tea polyphenols, Isoflavones, Probiotics and prebiotics and Omega 3 fish oils. 12 Hrs
5. 5. Regulatory affairs in herbal drug. Basic principles of clinical studies,Stability, Safety and toxicology of herbal drugs. Adverse drug reaction in herbal drugs. Effect of herbal medicines on clinical laboratory testing. Regulation and dispensing of herbal drugs. 08 Hrs

Herbal products & their standardization Practicals 100 Hrs

- Demonstration of various dosage forms of traditional systems.
- Simple preparations used in Ayurvedic, Siddha, Homoeopathy and their standardization
- Preparation of Asava and Arista
- Preparation of Churna
- Preparation of Lehya
- Determination of carbohydrate, protein and vitamin contents.
- Preparation of some herbal cosmetics
- Estimation of Phenol content
- Estimation of alcohol content
- Qualitative and quantitative estimation of phytochemicals using chromatographic and spectral methods.
- Isolation and characterisation like molecular determination, functional group analysis, chromatographic techniques for the identification of isolated and interpretation of UV, IR, TLC and HPTLC data for the following.
- Curcumin from turmeric
- Caffeine from tea dust
- Hesperidine from orange peel
- Eugenol from cinnamon

Reference books:

1. Chemical plant taxonomy, Swain, First edition, Academic press, London,1963.
2. Indian herbal pharmacopoeia, vol-1 and 2, RRL. Jammu and IDMA, Mumbai, 1998&2000.
3. PDR of herbal medicine, 2nd edition, Medicinal economic company, New jersey,2002.
4. Narural products, A laboratory guide, Rpphael ikhan, 2nd edition, Academic press, 1991.
5. Thin layer chromatography, 2nd edition, Acedaemic press Inc,New Del-

hi,1969.
6. Quality control of herbal drug, Mukherjee, P.K, 1st edition, Business Horizons Pharmaceutical Publisher, New Delhi, 2002.
7. Pharmacognosy by Trease and Evans

PG DIPLOMA IN PHARMACEUTICAL REGULATORY AFFAIRS

Program outcomes

- To create a thorough understanding of important regulatory concepts
- To create experts in the field of regulatory affairs documentation and research.
- To create an entry platform in the field of regulatory affairs for fresh graduates.
- To help students build their career in regulatory affairs and become regulatory affairs professionals.
- To provide students with a global knowledge of Regulatory Affairs.
- Finally Students can able to write Regulatory Document ,Create Regulatory Strategy , Get Marketing Authorization from different countries become an regulatory affairs professional.

Paper I – Pharmaceutical cGMP and Documentation

Scope

This course is designed to impart fundamental knowledge on various practices (viz., GMP, Quality related aspects) documentation requirements, laws and regulations for the manufacture of pharmaceuticals, the regulatory requirements for life cycle management of pharmaceuticals.

Objectives

At completion of the course, it is expected that students will be able to understand

- Key regulatory and compliance related to good manufacturing practices
- Know various documents pertaining to drugs in pharmaceutical industry
- Know different acts and regulations that regulate drugs and cosmetics in India
- Prepare for the readiness and conducts of audits and inspections

Course outcomes

- Know the key elements of current Good Manufacturing Practices, Good Laboratory Practices, Good Documentation Practices and Good Regulatory Practices.
- Know the various documents pertaining to drugs in pharmaceutical industry and understand the basics of regulatory compilation
- Know different Acts and guidelines that regulate Drugs & Cosmetics

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**cGMP:** cGMP of Pharmaceutical manufacturing: Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements and United States Food and Drug Administration (US FDA) guidelines on Pharmaceutical manufacturing.	**10**
II	**Quality:** Concept of Quality, Total Quality Management. Quality by design, six sigma concept. Stability testing: ICH and WHO guidelines. Good Laboratory Practices (GLP): Scope of GLP, QA unit, Standard operating procedures (SOP). Quality evaluation and batch release: Change Control, Deviation-(planned and unplanned), Corrective Action and Preventive Action (CAPA), Handling of non-conformance. NABL	**10**

III	**Documentation in Pharmaceutical Industry:** Batch Manufacturing Record, Master Formula Record, Distribution records, Drug Master Files. Chemistry, Manufacturing and controls (CMC). Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) Format.	**10**
IV	**Drugs and Cosmetics Act 1940 and its Rules 1945:** DPCO and NPPA Legal definitions of schedules to the Act and Rules, Import of drugs, Manufacture of drugs, Sale of Drugs, Labelling & Packing of drugs Registration of drugs in India	**10**
V	**Life cycle management:** Prior Approval Supplement (PAS), Post approval changes [SUPAC], annual report, post marketing reporting requirements, post approval labeling changes, lifecycle management, FDA inspection and enforcement, Establishment Inspection Report (EIR), warning letters, recalls, seizure and injunctions	**10**

Recommended Books/Sources:

1. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
2. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
3. How to practice GLP by PP Sharma, Vandana Publications.
4. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
5. Drugs & Cosmetics Act, Rules & Amendments
6. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
7. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
8. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
9. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

Paper II – International Regulatory Requirements

Scope

This course is designed to impart fundamental knowledge on drug development processes, regulatory approval process of generic drugs, medical devices, biologics and nutraceuticals in regulated and semi regulated countries. It prepares the students to learn the regulatory requirements and documentation requirements, registration procedures for marketing pharmaceuticals in regulated and semi regulated countries.

Objectives

At completion of the course, it is expected that students will be able to understand

- Process of drug discovery & development and generic drug product development
- Phases of clinical trials, regulatory requirements and conduct of clinical trials and research
- Basics of medical devices and IVDs, development and approval process
- Know the regulation and requirements for approval of biologics and nutraceuticals

Course outcomes

- Know the process of drug discovery and development and generic product development
- Know the regulatory Requirements for Biologics
- Understand the regulation for newly developed biologics and biosimilars
- Basics of medical devices and IVDs, process of development and quality considerations
- Know the history, regulations for approval of nutraceuticals and dietary supplements

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Generic drug product development:** Introduction to generics, Generic drug product development, Hatch-Waxman act and amendments, Code of Federal Regulations (CFR), Drug product performance- *in vitro,* ANDA regulatory approval process, Bioequivalence and Drug Product Assessment- *in vivo,* Post marketing surveillance.	**10**
II	**Clinical trials:** Introduction, phases of clinical trials, Developing clinical trial protocols, Institutional Review Board/ Independent Ethics committee-formation and working procedures, Informed consent-process and procedures, HIPAA- A new requirement to clinical study process. Pharmacovigilance-safety monitoring in clinical trials	**10**

III	**Medical devices:** Introduction, Classification of medical devices. differentiating medical devices from IVDs and Combination Products from pharmaceutical products, History of Medical Device Regulations, 510k Premarket notification and Premarket approval (PMA), Regulatory approval process of medical devices in USA, Product lifecycle of medical devices	**10**
IV	**Biologics:** Introduction to biologics, differentiating biological and biosimilar, different biological products, difference between generic drug and biosimilar; laws, regulations and guidance on biologics/ biosimilar, development and approval of biologics and biosimilar (IND, PMA, BLA, NDA, 510(k), pre-clinical and clinical development.	**10**
V	**Nutraceuticals:** Introduction, History of Food and nutraceutical regulations, definitions of nutraceuticals, dietary supplements, functional foods and their differences, WHO guidelines on nutrition. NSF International and its role in the dietary supplements and nutraceuticals industries, NSF certification, NSF standards for food and dietary supplements. Good manufacturing practices for nutraceuticals	**10**

Recommended Books/Sources:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. 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.
4. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
6. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
7. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
8. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
9. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
10. Biological Drug Products: Development and Strategies; Wei Wang , Manmohan Singh ; Wiley , 2013
11. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
12. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
13. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
14. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
15. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)

Recommended websites

1. EU Clinical Research Directive 2001: http://www.eortc.be/services/doc/clinical-eudirective-04-april-01.pdf
2. Code of Federal Regulations, FDA:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
3. Guidelines of International Conference on Harmonization: http://www.ich.org/products/guidelines.html
4. Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
5. Country Specific Guidelines from official websites.
6. Drugs & Cosmetics Act & Rules and Amendments

Practicals **100 Hrs**

Course outcomes

- Understand the documentation process in pharmaceutical industry
- Able to prepare the checklist for auditing in pharmaceutical industry
- Know the Protocol preparation for documentation
- Know the process of drug discovery and development and generic product development
- Protocol preparation for documentation for Biologics
- Understand the regulation for newly developed biologics and biosimilars
- Basics of medical devices and IVDs, process of development, ethical and quality considerations
- Know the ethics of clinical and biomedical research and evaluation

20 experiments/assignments:

1. Documentation for in process and finished products, Quality control tests for Solids
2. Documentation for in process and finished products, Quality control tests for liquids
3. Documentation for in process and finished products, Quality control tests for Semisolids
4. Documentation for in process and finished products, Quality control tests for sterile preparations.
5. Protocol preparation for documentation of BMR
6. Protocol preparation for documentation of MFR
7. Protocol preparation for documentation of Distribution records
8. Preparation of clinical trial protocol for registering trial in India
9. Case studies on response with scientific rationale to USFDA Warning Letter

10. Comparative study of DMF system in US, EU and Japan
11. GMP Audit Requirements as per CDSCO
12. Regulatory requirements checklist for conducting clinical trials in USA
13. Preparation of Biologics License Applications (BLA)
14. Checklists for 510k and PMA for US market
15. Preparation of a Clinical Trial Protocol for submission to Regulatory agency.
16. Preparation and documentation for Indian Patent.
17. Patent challenge / non infringement (Para IV) case studies.
18. Audit Checklist for Medical Device Facility
19. Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.
20. Regulatory requirements checklist for conducting clinical trials in India.

PG DIPLOMA IN PHARMACEUTICAL NANOTECHNOLOGY

Scope

- Course is designed to impart a fundamental knowledge on the art and science of various polymeric carriers and methods used to prepare nano particles.
- Nanotechnology is the current frontiers of all scientific and technological advancement. They deal with manipulation of materials at the nanometre scale. This essentially means rearranging bonds at the atomic level to create new substances with unheard of properties.
- Nanotechnology comprises one of the fastest-growing research and development areas in the world. The use of Nanotechnology is generating revenue in the pharmaceutical industries associated with Medicine-Healthcare, Automobiles, Biotechnology, Chemicals, Food, Electronics & Computing, Environment, , Textiles, etc.
- Nanotechnology is grabbing the attention of employers as well as jobseekers. Current applications of nanoscale science and technology, and thus career opportunities, exist in pharmaceuticals including drug delivery, cosmetics, biotechnology, medical fields ,etc..

Objectives

- Upon completion of course it is expected that students will be able to (know, do, and appreciate):
- To learn the developmental process for nanoparticles.
- To train the student about the handling of nanocarriers
- To train the student on application of polymers to prepare nanoparticles.
- To know the Interaction of nanomaterials with biological systems
- To learn the Medical applications of nanoparticles
- To appreciate and comprehend significance of quality control and quality assurance of nanoparticles

Program outcomes

The program prepares the students by providing knowledge in Nanotechnology, which extends to Nanofabrication and Nano Characterization techniques. The program constitutes a substantial portion of the nanotechnology in medicine and pharmacy. Performance in the nanotechnology is absolutely essential to achieve a good academic record in the program as well as to secure a promising career in industry or academia. In addition, the nanotechnology program is also unique in its emphasis of entrepreneurship and social impact of technology in its curriculum

Paper I – Nanocarriers for Drug Delivery (DPNT 01)

Course outcomes

A **nanocarrier** is nanomaterial being used as a transport module for another substance, such as a drug. Commonly used **nanocarriers** include micelles, polymers, carbon-based materials, liposomes and other substances. The course helps in gaining the knowledge on nanocarriers for drug delivery.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	History of the nanomedicine, Fundamentals and rationale of sustained/controlled/targeted drug delivery	**10**
II	Needs and Requirements of Nanocarriers, Nanoparticle flow: Implications for drug delivery	**10**
III	Polymers used for the formulation of nanoparticles- Classification and applications	**10**
IV	Classifications of nanocarriers- Liposomes, Dendrimers, polymeric Nanoparticles , lipid based nanoparticles (Nano/ micro emulsion, Self emulsifying , solid lipid nanoparticles and nano lipid carrieers)	**10**
V	Methods of preparation	**10**

Recommended Books/Sources:

1. Dr.ParagDiwan and AshishBharadwaj (Eds) Nanomedicine, Pentagon press (2006).
2. Vladimir P. Torchilin (Ed.) Nanoparticulates as drug carriers, Imperial College Press, Morth Eastern University, USA (2006).
3. Melgardt M. de Villiers, PornanongAramwit, Glen S. Kwon (Eds.) Nanotechnology in drug delivery, Springer
4. Deepak Thassu, Michel Deleers, YashwantPathak (Eds.) Nanoparticulate drug delivery systems, Informa Healthcare (2007).
5. Ram B. Gupta, Uday B. Kompella (Eds.) Nanoparticle technology for drug delivery, Taylor and Francis (2003).
6. JörgKreuter (Ed.) Colloidal drug delivery systems, Marcel Dekker (1994).

Paper II- Characterization and Applications of Nanocarriers

Course outcomes

Characterisation is one of the major criteria for nanoparticles since the size plays crucial role in different applications. Nano carriers finds its major use in many delivery systems especially targeted drug delivery. The course helps in gaining the knowledge on the Nano carriers and its applications.

Lecture wise program

Unit No.	Chapter	No. of Hours

I	Characterization of nanoparticles	**10**
II	Concept of targeting, Mechanisms of drug targeting, Nanoparticulate drug delivery systems for delivery of drugs to the gastrointestinal tract, Reticuloendothelial systems, Cardiovascular system, Lung, Brain and Lymphatics	**10**
III	Human health and safety- Interaction of nanomaterials with biological systems, Toxicology of nanoparticles- Background, Reactive oxygen species, Biodistribution, Nanotoxicity studies, Immunogenicity of nanoparticles, Complications with nanotoxicity studies- Effect of aggregation of nanoparticles, Challenges of nanovisualization and related unknowns in nanotoxicology, Environmental impact	**10**
IV	Societal Implications and Regulatory guidelines	**10**
V	Medical applications	**10**

Recommended Books/Sources

1. Dr.ParagDiwan and AshishBharadwaj (Eds) Nanomedicine, Pentagon press (2006).
2. Vladimir P. Torchilin (Ed.) Nanoparticulates as drug carriers, Imperial College Press, Morth
3. Eastern University, USA (2006).
4. Melgardt M. de Villiers, PornanongAramwit, Glen S. Kwon (Eds.) Nanotechnology in drug
5. delivery, Springer
6. Deepak Thassu, Michel Deleers, YashwantPathak (Eds.) Nanoparticulate drug delivery
7. systems, Informa Healthcare (2007).
8. Ram B. Gupta, Uday B. Kompella (Eds.) Nanoparticle technology for drug delivery, Taylor and
9. Francis (2003).
10. JörgKreuter (Ed.) Colloidal drug delivery systems, Marcel Dekker (1994).

Practical & Lab Procedure – 100 Hrs

Scope

Particle size reduction by different technologies (precipitation and milling) using the laboratory and sophisticated instrument helps in understanding the mechanism of nanoparticles production an atomic level.]

Objectives

To get hands on experience on production of nanopartilce and its characterization.

Course outcomes

The course helps in gaining the practical knowledge on the formulation development and characterisation of Nanoparticles.

Lecture wise program

Experiment	Chapter	No. of Hours (Total 100 Hours)
I	Laboratory Synthesis of Nanoparticles, Spontaneous Growth	**20**
II	Preparation Nanoparticle by Bottom up technology	**20**
III	Preparation of nanoparticles by top Down technology (Milling)	**20**
IV	Characterization of Nanoparticles(Structural)- Scanning electron microscopy (SEM) Transmission electron microscopy (TEM), Atomic force microscopy	**30**
V	Micrometric characterisation-Optical microscopy, Zeta sizer	**10**

Recommended Books/Sources

1. Scientific articles from reputed journals
2. Ram B. Gupta, Uday B. Kompella (Eds.) Nanoparticle technology for drug delivery, Taylor and Francis (2003).
3. JörgKreuter (Ed.) Colloidal drug delivery systems, Marcel Dekker (1994).

PG DIPLOMA IN CLINICAL RESEARCH

Program outcomes

This program aims to provide the students an opportunity to learn preclinical and clinical drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clincal research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

PAPER I- Clinical Development and Regulation

Scope

- To learn drug development process specially the phases of clinical trials.
- To train the student about the requirement for conducting clinical trials
- To train the student on the ethical requirement for conducting clinical trials
- To appreciate and protect the rights, safety and wellbeing of trial subjects
- To appreciate the importance and process of quality assurance and quality control in clinical trials

Objectives

Upon completion of course it is expected that students will be able to (know, do, and appreciate)

- Drug development process and different phases of clinical trials
- Ethical guidelines in conducting clinical trials and the challenges in implementing ethical guidelines.

- Regulatory requirements for conducting clinical trials in India
- Quality control and assurance in conduct of clinical trial
- Regulatory requirements for conducting clinical trials in foreign countries

Course outcomes

This course aims to provide the students the detailed drug development process, ethical guidelines governing clinical trials in India and foreign countries and the importance and process of maintain quality assurance and quality control.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Drug development process** A. Preclinical development of drugs • Investigational new drug application • Abbreviated new drug application • New drug application B. Clinical development of drugs • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, multinational, registration studies) • Phase IV studies (Post marketing authorization studies; pits and practices?)	**10**
II	**Ethics in clinical research** A. Historical Perspectives Declaration of Helsinki and Nuremberg Code, The Belmont Report Thalidomide study, Nazis Trials, Tuskegee Syphilis Study B. Ethical Principles in conducting clinical • Ethics guidelines in conducting clinical trial including special population • Challenges in implementing ethical guidelines while conducting Clinical trials C. Institutional Ethics Committee (IEC): Constitution, Functions and operating procedure of IEC D. Clinical trial Agreement and Liability and indemnity in clinical trials	**10**
III	**Regulations Governing Clinical Trials in India** • Origin and principles of ICH GCP in regulating clinical trials • Good clinical practice - ICH GCP E6 Clinical Research regulations in India – CDSCO guidelines	**10**

IV	Quality Assurance and Quality Control in Clinical Trials: • Types of audits, Audit criteria, Audit process • Responsibilities of stakeholders in audit process • Audit follow-up and documentation • Audit resolution and Preparing for FDA inspections • Regulatory inspections in clinical trials • Fraud and misconduct management	**10**
V	**Regulations Governing Clinical Trials in foreign countries** • Overview of USFDA regulations to conduct drug studies • Overview of Clinical Research regulations in UK – Medicines an Healthcare Products Regulatory Agency (MHRA) • Overview of Clinical Research regulations in Europe (EMEA).	**10**

Recommended Books/Sources

1. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone c.
2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
3. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
4. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
5. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
6. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

PAPER II-Clinical Research

Scope

This paper will provide the students

- An opportunity to learn drug development process specially the phases of clinical trials.
- Will teach the student about the requirement for conducting clinical trials
- Will also train the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

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

- Types and designs of different clinical trials
- Clinical trial startup activities
- Responsibilities of various stakeholders in clinical trial
- Preparation of Essential documents required to conduct clinical trial
- Clinical trial process involving informed consent process, monitoring and close-out visit, preparation of clinical trial report and data management process

Course outcomes

This course aims to provide the students the various procedures involved in conducting clinical trial starting from the start –up activities until the close –out and the data management process.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Types and Design of clinical trials** • Bioavailability and Bioequivalence studies • Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification) • Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) • Time Sequences (Prospective and Retrospective) • Sampling methods (Cohort study, case Control study and cross sectional study) • Health outcome measures (Clinical & Physiological, Humanistic and economic) • Blinding (single, double and triple) in clinical trials	**10**

II	**Clinical Trial Start-Up Activities**
	• Site Feasibility Studies
	• Site/Investigator selection
	• Vendor selection
	• Essential documents for clinical trial
	• Pre-study visit
	• ICF/PIS translation
	• Investigator meeting
	• Clinical trial agreement execution
	• Ethics committee document preparation and submission
	• Investigational Product procurement and Storage
	• Filing procedures
	  o Trial Master File preparation and maintenance
	  o Investigator Site File/Regulatory Binder
	  o Monitor File
	  o Pharmacy File
	• Site initiation
	• Site initiation Visit report and Follow up.
		10

III	**Clinical Trial Study Team** Roles and responsibilities of: • Investigators • Study Coordinator • Sponsor • Monitor/ Clinical research Associate • Contract Research Organization • Regulatory Agency	**10**
IV	**Clinical Trial Documents** • Guidelines to the preparation of documents • Preparation of synopsis and protocols • Preparation of Investigator Brochure • Preparation of Informed Consent Document • Preparation of case report forms • Preparation of clinical study reports and summaries • Preparation of contracts and agreements	**10**

V	**Clinical Trial Process** **Informed consent process** • Ethical principles governing informed consent process • Structure and content of a Patient Information Sheet • Structure and content of an Informed Consent Form • The process of taking informed consent and documentation **Clinical Trial Monitoring and Close-Out** • Planning of monitoring visit • Study monitoring visit (Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications etc.) • Safety reporting • Monitoring visit report and follow-up • Sponsor communication on critical findings. • Fraud and misconduct management • Close-Out visit o Study related documents collection o Archival requirement o IP reconciliation and destruction o Close-Out visit report **Clinical study reports – structure and content** **Data Management process in clinical trial.**	**10**

Recommended Books/Sources

1. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone c.
2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
3. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
4. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
5. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
6. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

Practicals - Clinical research Experiential Training 100 Hrs

Course outcomes

The experiential training provides the students an opportunity to develop skills to perform various procedures involved in conducting clinical trial by actively involving in various clinical trial activities for 100 hours over a period ten months.

15 experiments/assignments:

1. Design and evaluation of site feasibility questionnaire
2. Preparation for site initiation visit
3. Designing of clinical trial protocol
4. Preparation of Investigator's Brochure
5. Designing of an informed consent form
6. Perform the simulated informed consent process and prepare an ICF narrative
7. Preparation of Case Report Form
8. Reporting of serious adverse event
9. Management of Investigational Product
10. Preparation of different logs required to conduct clinical trials
11. Ethics committee submission procedures
12. Preparation and conduct of site monitoring visit
13. Preparation and conduct of site close out visit
14. Assessing the preparedness for the regulatory inspection in a study site
15. Preparation and assisting the auditors for the audit process.

PG DIPLOMA IN MEDICINE AND POISON INFORMATION

Program Outcomes

On successful completion of the program students will be able to:

- Describe the general principles involved in the management of poisoning
- Recognize the clinical symptoms and provide management protocols for common poisons
- Apply knowledge and skills of communication, literature evaluation, and Evidence based practice to provide complete and comprehensive medicine information.

PAPER I- Medicine Information

Scope

The realization of the importance of medicine information has been increasing among healthcare professionals and medicine information has become important core skill for the practicing pharmacist. This course is designed to impart both knowledge and skills in providing medicine information to both healthcare professionals and patients.

Objectives

- To train the student to identify proper resources to look-up and summarize information from many resources
- To gain an understanding of the various statistical tests used in published literature and interpret findings accurately
- To gain an understanding of the various pharmacoeconomic analyses and tools for framing and evaluation of guidelines
- To gain an understanding of different types of medication errors and preventive strategies

Course Outcomes

Upon completion of the subject student shall be able to

- Describe the significance, concept, and resources of medicine information
- Analyze and synthesize information in a stepwise manner to provide effective medicine information and recommendations and document the same
- Evaluate clinical evidences and categorize the quality of evidence to develop recommendations/ clinical decisions
- Recognize & accept legal and ethical aspects involved in medicine information practice

Lecture wise Program

Unit No.	Chapter	No. of Hours
I	**Concept of and Provision of Medicine Information** • Introduction to the Concept of Medicines Information • Modified Systematic Approach to Answering medicine information queries • Formulating Effective Responses and Recommendations: A Structured Approach • Medicine Information Resources • Electronic Information Management • Functions of Medicine Information Center • Establishing a Medicine Information Center	**10**

II	**Quality, Legal & Ethical aspects of Medicine Information** • Quality Assurance in Medicine Information • Documentation of medicine information services provided • Professional writing • Legal aspects of medicine information • Ethical aspects of medicine information • Assessing Drug Promotions • Pharmacy Informatics • Communication Skills	**10**
III	**Clinical Application of Statistical Analysis & Literature Evaluation** **A. Clinical Application of Statistical Analysis** • Populations and Sampling, Variables and the measurement of data, descriptive statistics, common probability distributions, epidemiological statistics, types of study design, Design and analysis of clinical trials, statistical inference, statistical tests and selecting the appropriate statistical test **B. Literature Evaluation** • Introduction to biomedical/pharmacy literature, Introduction to statistical terminology – null hypothesis, clinical trial objectives, endpoints, types of data & measures of central tendency, Type I & Type II errors, p-values and 95% confidence intervals, relative risk & absolute risk, relative risk reduction (RRR), absolute risk reduction (ARR), & Number needed to treat (NNT). • Approach to evaluating controlled clinical trials. Interpret clinical trial data and help in decision making process in applying the results to practice. • Evaluating Observational study designs, reports without control group, survey research, postmarketing surveillance studies, review articles, practice guidelines, health outcomes research, & dietary supplement medical literature.	**10**

IV	**Pharmacoeconomics & Evidence based practice** **A. Pharmacoeconomics** • Definition • Relationships of pharmacoeconomics to outcomes research • Models of Pharmacoeconomic analysis • Performing an economic analysis • Decision Analysis **B. Evidence based practice guidelines** • Evidence based medicine and clinical practice guidelines • guideline development methods • guideline evaluation tools • implementation of clinical practice guidelines, sources of clinical practice guidelines	**10**
V	**Medication Misadventures, Drug evaluation monographs & Investigational Drugs** A. **Medication Misadventures** • Definitions – Medication errors, adverse drug events and adverse drug reactions • Impact of errors on patients and health care systems • Identification and reporting of medication errors and adverse drug events • Classifying errors and patient outcomes • Managing an event reporting system • Types of safety event analysis • Risk factors for errors and events • Best practices for error prevention, Principles of error management B. **Drug Evaluation Monographs** • Definition, Drug evaluation monograph sections C. **Investigational Drugs** • History of Drug Development Regulations • Drug approval process • Orphan Drug Act • Institutional Review Board • Role of Pharmacist in Clinical Trial Process	**10**

Reference Books:

1. Patrick M Malone, Karen L Kier. Drug Information: A Guide for Pharmacists. 3rd Edition 2. Parthasarathi G, Karin Nyfort-Hansen, Milap Nahata. A Textbook of Clinical Pharmacy Practice: Essential Concepts and Skills
2. Bruce A. Berger Communication skills for pharmacists. Building relationships, improving patient care 3rd edition, American Pharmacists Association

PAPER II- POISON INFORMATION

Scope

This course is designed to impart knowledge of the relevant aspects of poison information including organization and functioning of poison information center, general principles and basic aspects of management of poisoning. Also to understand the role of antidotes and supportive care in clinical toxicology, and develop skills required for the provision of poison information services.

Objectives

- To gain an understanding of the general principles of poisoning management
- To train the student to provide poison management information in a systematic manner
- To gain an understanding of clinical symptoms and management of poisoning with selected poison agents.

Course Outcomes

Upon completion of the subject student shall be able to:

- Describe the significance, concept, and resources of poison information
- Analyze and synthesize information in a stepwise manner to provide effective medicine information and recommendations and document the same
- Describe the general principles involved in the management of poisoning
- Recognize the clinical symptoms and suggest management for acute poisoning of common poisoning agents, venomous snake bites, insect bites, environmental poisoning and substance abuse.

Lecture wise Program

Unit No.	Chapter	No. of Hours
I	• **Concepts and Organization of Poison Information Centre** Definition, aim/objectives, Indian and global scenario of PIC • Organization and functions of PIC • Systematic approach to answering poison information queries • Role and responsibilities of poison information specialist • Preventive measures for accidental poisoning	**10**
II	**Management of Poisoning** • General principles involved in the management of poisoning • Antidotes and their clinical applications • Supportive care in Clinical Toxicology • Gut Decontamination • Elimination Enhancement	**10**
III	**Clinical symptoms and management of acute poisoning with the following agents** **A. Pesticide poisoning:** • Organophosphorous compounds, Carbamates, Organochlorines, Pyrethroids, Aluminum and zinc phosphide **B. Opiates overdose**	**10**

IV	**C. Antidepressants** **D. Barbiturates & Benzodiazepines** **E. Alcohol: ethanol & methanol** **F. Paracetamol & Salicylates** **Substance Abuse: General Considerations** • Management of abuse due to Cannabis, Marijuana, Tobacco, LSD	**10**
V	**Poisoning due to heavy metals & Venomous bites** A. **Clinical symptoms and management of chronic poisoning with Heavy Metals** • Arsenic, lead, mercury, iron, and copper B. **Venomous Snake bites** • Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries **C. Insect & Scorpion bites**	**10**

Reference Books

1. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
2. V V Pillay. MODERN MEDICAL TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad
3. Lindsay Murray, Frank Dary, Mark little, Mikes cadogan, TOXICOLOGY HANDBOOK. Australia: Churchills Livingstone, Elsevier; 2007

Practicals– 100Hrs

Medicine and Poison information Experiential Training

Course Outcome: The experiential training provides the students an opportunity to develop skills to provide drug and poison information and evaluate literature and provide recommendations

15 Experiments/assignments

1. Designing of medicine and poison information centre (1 Number) Answering to medicine information queries relating to various categories (4 Numbers)
2. Answering to poison information queries relating to various categories (4 Numbers).
3. Evaluation of published biomedical literature and preparation of recommendations (3 Numbers).
4. Preparation of Drug Evaluation Monographs (2 Numbers).
5. Plan and execute a public awareness program on dangerous poisons (1Number).
6. Plan and execute a prevention of medication errors/continuing education program for paramedical staff (1 Number)

PG DIPLOMA IN COSMECEUTICS

Program outcomes

To impart knowledge on the fundamental principles of cosmetic and cosmeceutical product development and evaluation.

Paper I – Cosmeceutics Biology and Formulation Sciences

Scope

- To impart knowledge on the basic anatomy, physiology and functions of skin.
- To understand the effect of age on the structural differences of skin.
- To understand etiology of common skin, scalp, hair and oral problems and current treatment available.
- To impart knowledge in design and development of formulations for cosmeceutical actives focusing on safety, stability, sensory and delivery of actives.

Objectives

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

- Understand common problems that need skin, scalp, hair and oral care.
- Identify actives and their mechanism of action to treat the problems
- Gain knowledge on formulation science to develop product formulations.
- Combine actives and the formulation to develop cosmeceuticals with good efficacy, sensory, stability and safety.

Course outcomes

- To implement scientific basis in developing cosmeceutical products.
- To understand key ingredients used in cosmetics and cosmeceuticals
- To appreciate and contribute to areas of alternate to animal testing.

Lecture wise program

Unit No.	Chapter	No. of Hours
I	Skin: Structure and Function. Differences between baby skin and adult skin. Mechanism of allergic reaction and skin conditions. Different terms used to define various allergic conditions. Skin moisturization: Natural moisturizing factor, Ceramide lipids and occlusive layer Sunscreens: Organic and Inorganic sunscreens Pigmentation and skin whitening actives. Basic understanding of mechanism of action of the actives.	**10**

II	Acne, Causes and anti-acne actives. Aging principles, Skin –anti-aging ingredients, and their mechanism of action. Body odor and its causes. Mechanism of action of antiperspirants and deodorants. Prickly heat- causes and treatment Structure of Hair and Hair Growth Cycle. Dandruff, causes for dandruff. Antifungal ingredients used to treat dandruff Mechanism of hair coloring action of Para pheylenediamine (PPD) based hair colorants.	**10**
III	Surfactants, Emollients and humectants, their classification, examples and application in skin, hair and oral care products Preservatives – Antioxidants and antimicrobial agents, Classification, relative merits and demerits, Factors affecting microbial preservative efficacy. Rheology modifying agents used in cosmeceuticals – classification, examples and application. Perfumery- classification and allergens in perfumes.	**10**
IV	Fundamental approach to cosmeceutic product development Building block and examples of following formulations: Soap, face wash, Body-wash, (Shower gel), creams, shampoos, hair conditioners, mouth wash, and toothpaste Hair conditioning- principles and ingredients used. Polymers, Silicones, and Cationics, examples and benefits. Comparison of formulation of soaps and syndet bars Alternatives to animal testing for safety	**10**
V	Natural cosmeceuticals and formulation challenges in terms of selecting foaming agents, Emulsifiers, Viscosity modifying agents and preservatives with reference to Ecocert/Cosmos/ Whole Foods USA guidelines for green cosmetics. Common problems associated with oral care: Halitosis (Mouth Odor), Plaque, Cavities, Sensitive teeth. Basic understanding on the cause. Antibacterial, antioxidants and astringents used for oral care benefits of above mentioned conditions. Novel approaches in drug delivery systems for Topical application Principles and formulation of patches, liposomes, ethosomes, niosomes, transferosomes.	**10**

Recommended Books/Sources:

1. Harry's Cosmeticology 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
4. Cosmetic formulation of skin care products – Eric Jungerman (cosmetics and science technical series 3
5. Cosmetics –Formulation, manufacture and quality control PP.Sharma, 4th edition.
6. Cosmetic and Toiletries – Recent suppliers catalogue.
7. CTFA directory

Paper II – Cosmecutical Evaluation & Regulation

Scope:

- To have knowledge on the analytical principles of cosmetics.
- To have knowledge of instrumental evaluation on the efficacy of cosmeceutics.
- To learn the current EU and Indian regulation for cosmetics including GMP.
- To understand regulations for organic/ herbal cosmetics developed by private bodies

Objectives:

Upon completion of the course the students will be able to

- Design formulations meeting regulatory guidelines
- Evaluate formulation efficacy and quality, ability to combine actives and the delivery system to develop cosmeceuticals with excellent sensory, stability, safety and efficacy and adhering to regulatory guidelines.

Course outcomes

- To appreciate principles of performance evaluation of cosmetic products.
- To perform analysis of raw materials as well as finished cosmetic products
- To effectively design products and documentation that meets regulatory requirements

Lecture wise program

Unit No.	Chapter	No. of Hours
I	Definition of cosmetic products as per Indian and EU guidelines. Other regulatory definitions listed in EU/Indian Guidelines. Migration of cosmetics to cosmeceutics – Evaluating current market products and their fit in the EU definition of cosmetics and prediction of future trend in the products and regulatory of cosmetics and cosmeceutics. Indian and EU regulation: Regulation with respect to preservative, Sunscreen, allergens and labelling requirements.	**10**

II	Comparison of EU guidelines, with private organic green cosmetic guideline, Cosmos/ Ecocert in terms of restriction in use of color, preservative, and excipients. Concerns on environmental and consumer safety of ingredients Ex:Parabens, Triclosan, Phthalates, Petroleum oils, Sodium and ammonium laureth sulphate, Formaldehyde liberators. Introduction to Packaging materials Plastics, metals, laminates, glass, Paper and Paper Board. Classification and application	**10**
III	Principles of physical and chemical analysis of finished cosmetic products (Creams, Shampoo, Tooth paste, Tooth Powder, Hair Dyes, Depilatories, Hair oil) as per BIS guidelines	**10**
IV	Principles of equipment to measure skin and hair conditions - Sebumeter, corneometer, trans epidermal water loss, Skin color, hair tensile properties, hair combing properties.	**10**
V	Manufacturing, equipments and production principles of cosmecutical product including GMP and documentation: Creams, Shampoo and toothpaste. GMP Guidelines as Per Indian and ASEAN standards	**10**

Recommended Books/Sources:

1. Poucher's perfume cosmetics and Soaps, 10th edition
2. Cosmetics –Formulation, manufacture and quality control PP.Sharma, 4th edition
3. Harry's Cosmeticology 8th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic formulation of skin care products – Eric Jungerman (cosmetics and science technical series 30)
6. EU – Cosmetic regulations copy.
7. Indian Regulation on Cosmetics. Drugs and cosmetic act.
8. BIS specification for cosmetic ingredients and finished formulation
9. Private body regulation – Cosmos, Whole foods, Natural product association.
10. Access to REACH and cosmetics safety Data base.
11. IFRA guidelines for fragrance
12. International regulation for colors

Practicals – **100 Hrs**

Course outcomes

- To design and develop cosmeceuticals- focusing on safety, stability, sensory and delivery of actives.
- To determine physical constants of cosmetic raw materials as well as finished cosmetic products.
- To implement smooth transfer of technology from design stage to factory production.

15 experiments/assignments

1. Cytotoxicity studies using cell lines,
2. Preservative efficacy test.
3. In vitro assay for antibacterial efficacy.
4. Isolation and identification of DNA from various sources (Bacteria)
5. Isolation of RNA from yeast.
6. Estimation of RNA/DNA by UV Spectroscopy.
7. Gene amplification by PCR.
8. Cell viability assays (MTT/Trypan blue/SRB).
9. DNA damage study by Comet assay.
10. Development of skin cream, shampoo and toothpaste base.
11. Design and formulate unique Cream, face wash, , moisturizing gel, lip balm, hair oil.
12. Study private body guidelines for green/premium cosmetics of Ecocert/ Cosmos, and suggest changes in the formulations.
13. Design and Development of cosmeceutical product for the treatment of dry skin, wrinkles, acne, blemishes, dandruff, and bleeding gums.
14. Determination of foam height and SLS content of Shampoo.
15. Determination of total fatty matter in creams (Soap, Skin and hair Creams).

PG DIPLOMA IN REGULATORY TOXICOLOGY

Program outcomes

On successful completion of the program students will be able to:

- Describe the general principles and methods involved in preclinical toxicology
- Apply the knowledge on the designing, execution and documentation of toxicology studies
- Describe the principles of Good Laboratory Practice
- Describe the step-wise establishing GLP toxicology facility

PAPER I - Principles and Methods in Regulatory Toxicology

Scope

- The programme will facilitate to develop skilled manpower with theoretical and technical knowledge on regulatory toxicology studies
- The course will train the scientists to record, collate and interpret non-clinical regulatory toxicology data
- The programme will impart knowledge on the regulatory requirement for drug licensing and clinical trial/research processes
- Overall outcome of the programme will create individual with unique identity in job opportunities in toxicology research

Objectives

- To understand the use and care of animals in research, ethical rules and regulations of CPCSEA, Govt of India, IBSC requirements of DBT
- To understand the regulatory requirements of the regulatory requirements of ICH, US FDA, EMEA and DCGI
- To understand the principles of pharmaceutical and pesticide toxicology
- To learn the know-how of experimental methods involved in non-clinical toxicological studies
- To perform data analysis and interpretation of results for regulatory submission

Course Outcomes:

Upon completion of the subject student shall be able to:

- Describe the animal ethics procedure, animal models, husbandry and biological sampling
- Describe the concept and procedure involved in preclinical toxicology studies
- Analyse the preclinical toxicology data and interpretation of data
- Describe the alternate to animal models in toxicological studies

Lecture-wise Programme

Unit No.	CHAPTER	No. of hours

I	**Introduction to toxicology** • History, scope, importance and application of toxicology in drug discovery • in vitro systems including bacterial strains, cell lines, laboratory animals • common species and strains, sources, housing and maintenance, physiology, biochemical and behavioural aspects of laboratory small animals • dosing routes, dose calculation, dosing volume • biological sampling volumes, sampling sites • pain and distress management, anaesthesia and euthanasia procedures, disposal of carcass	**10**

II	**Principles of toxicology**	
	In vivo systemic toxicological testing - criterions to be considered for general routes of administration such as oral, dermal, inhalation and intravenous, principles and procedures of systemic toxicity studies as per OECD, ICH, Schedule Y, CIB and FDA test guidelines: **Acute studies** • Acute dermal • Acute inhalation • Acute inhalation – Acute toxic class method • Acute oral - fixed dose procedure • Acute oral - Acute toxic class method • Acute oral - Up and down procedure • Acute eye irritation • Skin sensitisation • Acute dermal irritation / corrosion **Repeated dose studies** • Repeated dose - 28 days • Repeated dose - 90 days • Repeated dose - dermal toxicity: 21/28-days • Repeated dose - dermal toxicity: 90-days • Repeated dose - inhalation toxicity: 28/14-days **Developmental and Reproductive toxicology**: • Prenatal developmental toxicity • Reproduction/Developmental Toxicity Screening Test • Combined Repeated Dose Toxicity Study with the reproduction / developmental toxicity screening test • Repeated dose - inhalation toxicity: 90-days **Neurotoxicology studies:** • Delayed Neurotoxicity • Neurotoxicity Study in Rodents • Developmental neurotoxicity **Carcinogenicity studies:** • Carcinogenicity studies • Combined chronic toxicity / carcinogenicity studies **Genotoxicity studies:** • Bacterial reverse mutation test • in vitro mammalian micronuclei assay • Mammalian erythrocyte micronucleus test • in vitro mammalian chromosomal aberration test • Mammalian bone marrow chromosomal aberration test • In vivo mammalian alkaline COMET assay **Ecotoxicology** - Acute toxicity to fish, Acute toxicity daphnia, Acute toxicity to earthworm, Acute toxicity to honey bee, Acute toxicity to bird, Acute toxicity to alga	**10**
III	**Toxicokinetics (TK) and bioanalysis** • Introduction • relationship with pharmacokinetics, • one / two - compartment models in TK, absorption, distribution, biotransformation and excretion	**10**

IV	**Alternatives in toxicological methods** • methods validation status and regulatory acceptance of alternatives, meeting industrial and regulatory need with alternatives, • in vitro approaches for systemic toxicological studies, human corneal equivalents model, in vitro dermal testing, skin equivalent model	**10**
V	**Biostatistics -** Introduction, mean, median, standard deviation, standard error mean, homogeneity, Parametric and non-parametric, Probit analysis, paired and unpaired Student 't' test, one and two way ANOVA	**10**

Recommended Books:

1. Bal-Price A, Jennings P. In vitro toxicology systems: Springer; 2014.
2. Barile FA. Principles of toxicology testing: CRC Press; 2013.
3. ChemWorx A, Archives C, Photonics A. Handbook of Toxicology. Edited by Michael J. Derelanko (Honeywell International Inc., Morristown, New Jersey) and Mannfred A. Hollinger (University of California, Davis). CRC Press: Boca Raton. 2002.
4. Derelanko MJ, Auletta CS. Handbook of toxicology: CRC press; 2014.
5. Derelanko MJ. Toxicologist's pocket handbook: CRC Press; 2000.
6. Faqi AS. A Comprehensive Guide to Toxicology in Nonclinical Drug Development: Academic Press; 2016.
7. Gad SC. Model selection in toxicology: principles and practice. International Journal of Toxicology. 1990;9(3):291-302.
8. Hayes AW, Kruger CL. Hayes' principles and methods of toxicology: CRC Press; 2014.
9. Hodgson E. A textbook of modern toxicology: John Wiley & Sons; 2004.
10. Hood RD. Developmental and reproductive toxicology: a practical approach: CRC Press; 2011.
11. Jacobson-Kram D, Keller KA. Toxicological Testing Handbook: Principles, Applications and Data Interpretation: CRC Press; 2006.
12. Smart RC, Hodgson E. Molecular and biochemical toxicology: John Wiley & Sons; 2013.
13. Wallace HA, Wallace H. Principles and methods of toxicology. Principles. 2001.

Paper II - Principles, documentation and implementation of Good Laboratory Practice

Scope

- Aspirants will be trained to understand the OECD principles of GLP and importance of documentations
- The course will yield trained manpower with basic knowledge on quality assurance functions
- The course will train the individual on various documents such as SOPs, formats including study plan and study report preparation and exercising.
- This paper is the first of its kind in academics

Objectives

- To learn the history and OECD principles of Good Laboratory Practice
- To learn the scope of various regulatory agencies such as OECD, EPA, ICH, etc.,

- To understand the essential divisions in safety pharmacology and regulatory toxicology laboratories
- To learn the know-how on the preparation and exercise the documents such as SOPs, formats, study plan, raw data and study report as per GLP
- To understand the concepts and importance of calibration and validation of instruments/equipment, computers
- To understand the processes involved in test item control office, information and technology, and archival divisions in GLP facility
- To train to face regulatory audits

Course outcomes

Upon completion of the subject student shall be able to:

- Describe the principles of Good laboratory Practice
- Describe the resources and guiding rules in regulatory toxicology studies
- Describe the roles and responsibilities of personnel involved in GLP studies
- Apply knowledge in step-wise implementation of GLP facility

Lecture-wise Programme

Sl. No.	CHAPTER	No. of hours
I	• Good Laboratory Practice (GLP) - Terminologies and acronyms, Various regulatory agencies, regulatory guidelines on testing of chemicals / toxicological studies, importance of regulatory agencies' assurance on the quality standard of toxicology data • Organisation for Economic Cooperation and Development (OECD), history, offices, functions and member countries, status of India with OECD, National GLP Compliance Monitoring authority (NGCMA) • Definition of GLP, OECD principles on GLP, scope of OECD GLP principles, mutual acceptance of data (MAD) between OECD member states • Required resources in GLP lab: information on department/ divisions / unit, personnel, facilities, equipment and instruments with respect to toxicology	10
II	• Roles and responsibilities of management, quality assurance department, study directors / study personnel / research scientists, test item control officer(s), study veterinarian(s), study pathologist(s) / Clinical biochemistry- pathologist(s), archivist(s), IT personnel(s) and document controller, study sponsor. • Roles and responsibilities of supportive services - HVAC plant, water plant, electricity unit, pest control, sewage units, biowaste disposal and fire and safety department.	10

III	• Guiding rules in the conduction of regulatory studies - preparation and implementation of study plan, standard operating procedures, formats • Study conduction and reporting - preparation of raw data and final report, archiving and archiving indexing procedures, and reporting (amendment, deviation procedures)	10
IV	• Test item control office: personnel, required facilities, test item characterisation, functions of test item control offices and its importance in regulatory toxicology • Archive: personnel(s), required facilities, archival procedure of test items, documents, tissue samples, soft copy (CD formats / scanned documents), external archiving, method archival indexing, Retention and disposal of archived material, closure of archives and contract archive facility • IT offices: personnel, facilities, application of GLP principles to computer systems, validation of computer hard and software, backup and mirroring policies and facilities	10
V	• Information on guidance for GLP monitoring authorities on compliance monitoring procedure, guidance on conduct of inspections and study audits, vendor validation • Establishing and Stepwise implementation of GLP	10

RECOMMENDED BOOKS:

1. Carson PA, Dent NJ. Good clinical, laboratory and manufacturing practices: techniques for the QA professional: Royal Society of Chemistry; 2007
2. Gad SC. Regulatory toxicology: CRC Press; 2001.
3. Good Clinical, Laboratory and Manufacturing Practices Techniques for the QA Professional, Edited by PA Carson and N Dent (2007)
4. http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm
5. OECD Principles on Good Laboratory Practice 1997. OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 15, Establishment and control of archive that operate in Compliance with GLP Principles
6. OECD Principles on Good Laboratory Practice 1997.OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, Number 1, National GLP Compliance Monitoring Authority.
7. Reichl F-X, Schwenk M. Regulatory Toxicology: Springer; 2014.
8. Sengupta R. Regulatory Toxicology: Essentially Practical Aspects. Narosa Publishing House. 2016.

Practicals: Toxicology and Good Laboratory Practice – 100Hrs

Course Outcome:
The experimental training provides the students hands on experience on animal handling, dose calculation and conversions, designing and conduction of toxicology studies, documentation processes in Good laboratory practice

- Test item characterisation using UV spectra, HPLC analysis and filling test item data sheet, collection, collation and interpretation of material safety data sheet
- Acute oral - Acute toxic class method - GLP mode
- Acute oral - Up and down procedure - Non-GLP
- Acute eye irritation - GLP mode
- Exposure skin sensitisation - - GLP mode
- Acute dermal irritation / corrosion -
- Bacterial reverse mutation test - Non-GLP
- Mammalian erythrocyte micronucleus test - Non-GLP
- In vitro mammalian chromosomal aberration test - Non-GLP
- Exposure to repeated dose - 28 days and 90 days studies. Demonstration on the use of biochemical analyser, hematology analyser, electrolyte analyse, urine analyser
- Demonstration on pathology techniques such as collection and fixation of tissues, trimming, tissue processing, embedding, sectioning, staining, fixing and microscopy.
- Demonstration on receiving, storing, archiving of test item and documents and other relevant materials.
- Statistics in toxicology, handling and operation of commercial biostatistics software(s)

Recommended Books

- Evans G. Animal hematotoxicology: a practical guide for toxicologists and biomedical researchers: CRC press; 2008.
- Gad SC. Animal models in toxicology: CRC Press; 2015.
- Handbook of Toxicology, Edited by Michael J Derelanko and Mannfred A Hollinger (2002)
- OECD Test guidelines
(http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm)
- Principles and Methods of Toxicology, Hayes A Wallace (2001)
- Timbrell JA. Biochemical mechanisms of toxicity: specific examples. Principles of Biochemical Toxicology, 4th ed Informa Health Care. 2008.
- Woolley A. A guide to practical toxicology: evaluation, prediction, and risk: Informa Healthcare New York; 2008.

PG DIPLOMA IN COMPUTER AIDED DRUG DESIGN

Program outcomes

- An ability to apply knowledge of Computer Aided Drug Design appropriate to the discipline.
- An ability to work with molecular modeling softwares to design new drug molecules
- An ability to identify, formulate, and develop solutions to computational challenges in new drug design
- An ability to design, implements, and evaluate a in silico virtual screening protocols to meet desired needs within realistic constraints
- An ability to interpret and correlate the Computer Aided Drug Design results

Paper I – Quantitative Structure Activity Relationships

Scope

Quantitative structure activity relationship (QSAR) deals with predicting biological activities of compounds by means of formulating equations or models using physicochemical properties calculated from its molecular structures. The derived relationship between molecular descriptors and activity is used to estimate the property of other molecules and/or to find the parameters affecting the biological activity. QSAR methods in drug design provides low-cost tools for the selection of novel "hits" and for "lead" optimization during drug discovery and development.

Objectives

- To explain the various CADD tools and their role in drug discovery
- To learn quantitative structure activity relationships using physicochemical parameters
- To apply the methods to calculate the physicochemical parameters
- To apply statistical methods to develop QSAR

Course outcomes

- Able to apply knowledge of various CADD tools in drug design
- Able to perform ligand based drug design
- Able to design, create analyze and interpret QSAR model
- Able to perform virtual screening protocol via QSAR

Lecture wise program

Unit No.	Chapter	No. of Hours
I	Introduction to Computer Aided Drug Design (CADD): History, different techniques and applications.	**10**
II	History and development of QSAR. Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters)	**10**

III	Experimental and theoretical approaches for the determination of physicochemical parameters for QSAR.	**10**
IV	Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.	**10**
V	3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.	**10**

PAPER II – Molecular Modelling and Virtual Screening Techniques

Scope

This course provides the data for development of computational models, molecuar modeling, virtual screening techniques and tools to predict biological activity of the new drug like molecules during the process of drug discovery research. These computational models also reduce the number of candidate molecules that needs to synthesized and tested, reducing both cost and time in the process of drug discovery. The course also is designed to impart knowledge on the current techniques involved in computer aided drug design that would help candidates contribute later in drug discovery research.

Objectives

- To explain the various CADD tools and their role in drug discovery
- To learn energy minimization techniques and force fields
- To perform molecular modeling and docking techniques
- To demonstrate De Novo drug design, ADMET predictions and virtual screening protocols

Course outcomes

- Apply the knowledge of principles of various CADD tools in drug design
- Apply techniques to perform structure based drug design
- An ability to work with modeling and docking softwares in drug design
- An ability to design, implements, and evaluate a in silico virtual screening protocols
- An ability to interpret and correlate the Computer Aided Drug Design results

Lecture wise program:

Unit No.	Chapter	No. of Hours
I	Molecular and Quantum Mechanics in drug design. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation.	**10**
II	Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as HMG-CoA reductase and HIV protease Agents acting on PPAR receptors.	**10**

III	Prediction and analysis of ADMET properties of new molecules and its importance in drug design. De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.	**10**
IV	Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.	**10**
V	In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based in silico virtual screening protocols.	**10**

Recommended Books/Sources

Stroud, Robert M., and Janet Finer-Moore. Computational and structural approaches to drug discovery: l*igand-protein interactions*. Vol. 8. Royal Society of Chemistry, 2008.

1. Martin, Yvonne C. Quantitative drug design: a critical introduction. CRC Press, 2010.
2. Ariëns, Everhardus Jacobus, ed. Drug Design: Medicinal Chemistry: A Series of Monographs. Vol. 4. Elsevier, 2013.
3. Smith, H. John, and Hywel Williams. Smith and Williams' introduction to the principles of drug design and action. CRC Press, 2005.
4. Silverman, Richard B., and Mark W. Holladay. The organic chemistry of drug design and drug action. Academic press, 2014.
5. Wolff, Manfred E. "Burger's Medicinal Chemistry and Drug Discovery ."American Journal of Therapeutics 3.8 (1996): 608.
6. Patrick, Graham L. An introduction to medicinal chemistry. Oxford university press, 2013.
7. Jaime, N. Delgado, and A. Remes William. "Wilson and Gisvolds text book of organic medicinal and Pharmaceutical chemistry." (1997).
8. Hansch, Corwin, Peter George Sammes, and John Bodenhan Taylor.Comprehensive medicinal chemistry: the rational design, mechanistic study & therapeutic applications of chemical compounds. Vol. 5. Pergamon Pr.
9. Textbook of Drug Design and Discovery, Third Edition, Povl Krogsgaard-Larsen, CRC Press.
10. The Practice of Medicinal Chemistry, by Wermuth C.G. (Author), Publisher: Elsevier Exclusive.

Practicals – **100 Hrs**

Students are expected to perform the following activities for 100 hours over a period of 10 months as a part of experiential training

Course outcomes:

- to make students to understand various CADD tools
- to perform both ligand based and structure based drug design protocols
- to design, and create 2D QSAR, 3D QSAR and to interpret QSAR model
- to perform virtual screening protocols

15 experiments/assignments

1. Sketching small molecules, naming and visualization using Chem Draw software
2. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
3. Screening drugs for Lipinski's RO5
4. Calculation of ADMET properties of drug molecules and its analysis using softwares.
5. Pharmacophore modeling
6. 2D-QSAR based two experiments
7. 3D-QSAR based two experiments
8. Docking based experiments two experiments
9. De novo drug design experiment
10. Virtual screening based experiment
11. Assignment on 2D QSAR
12. Assignment on CoMFA
13. Assignment on CoMSIA
14. Assignment on Docking
15. Assignment on Pharmacophore mapping

PG DIPLOMA IN FOOD & DRUG ANALYSIS

Program outcome

- An ability to apply knowledge of analytical techniques for the analysis of food and drugs.
- An ability to demonstrate the handling of sophisticated analytical instruments in the analysis of food and drugs
- An ability to design, implements, and evaluate analytical protocols to meet demand of analysis of food and drugs
- An ability to interpret and correlate the Analytical Data

PAPER-I: Food Analysis

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course emphasize on the analysis of food additives, Pigments and synthetic dyes and, milk and dairy products.

Objectives:

- To explain the principles of analytical techniques employed in the analysis of foods.
- Able to list the classification, properties and general methods of analysis food constituents, food additives and milk products
- Able to perform the determination of food constituents, additives and finished products

Course outcomes

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

- perform extraction and quantification of food constituents from different sources using analytical techniques
- perform detection and quantification of food additives, pigments and synthetic dyes in food products
- analyze and identify the adulteration in food products

Lecture wise program

Chapter No	CHAPTER	No. of Hours
I	**Carbohydrates** – Classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates	**10 Hrs**

II	**Proteins** - Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins	**10 Hrs**
III	**Lipids** – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.	**10 Hrs**
IV	**Food additives** – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents. **Pigments and synthetic dyes** - Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes.	**12 Hrs**
V	General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.	**8 Hrs**

RECOMMENDED BOOKS/SOURCES:

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone,
2. Edinburgh London, 1976.
3. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
4. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
5. Analysis of Food constituents – Multon, Wiley VCH.
6. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005

PAPER-II: Drug Analysis

Scope

This course is designed to impart knowledge on analytical spectroscopic, hyphenated analytical techniques and chromatographic separation techniques in quantitative and qualitative analysis of drugs and pharmaceuticals. The course emphasize on analytical and bioanalytical method development & validation; Extraction of drugs and metabolites from biological matrices.

Objectives

- To explain the principles of spectroscopic and hyphenated analytical techniques used in the analysis of drugs
- To explain the principles of chromatographic techniques used in the analysis of drugs
- To understand various regulatory guidelines of Analytical and bioanalytical

method development and validation
- To know techniques in the extraction of drugs and metabolites from biological matrices

Course outcomes:

Upon completion of the course, the student shall be able to
- Apply knowledge and skills of spectroscopic, chromatographic and hyphenated analytical techniques in the analysis of drugs and pharmaceuticals
- Perform extraction and quantification of drugs from biological samples using different analytical techniques
- Perform analytical and bioanalytical method validation.

Lecture wise program

S.No	CHAPTER	No. of Hrs
I	**Spectroscopic analytical Techniques:** Introduction, principle, theory and instrumentation associated with UV-Visible spectroscopy and IR spectroscopy.	**6 Hrs**
II	**Chromatographic separation techniques** Principle, apparatus, instrumentation, a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid Chromatography.	**10 Hrs**
III	**Hyphenated analytical techniques**: Principle, Instrumentation and Applications of the following: a) GC-MS b) LC-MS c) ICP-MS d) LC-NMR e) CE-MS f) High Performance Thin Layer chromatography g) Super critical fluid chromatography h) Ion Chromatography i) I-EC (Ion-Exclusion Chromatography) j) Flash chromatography	**14 Hrs**
IV	**Analytical and bioanalytical method development and validation**-ICH and USFDA guidelines	**4 Hrs**
V	**Biological matrix and Problems with analysis of biological matrices:** Analysis of drugs in use and drugs in research and development, Types and Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, safety considerations.	**10 Hrs**
VI	**Extraction of drugs and metabolites from biological matrices** General principle and procedure involved in the bio-analytical methods such as protein precipitation, Liquid - Liquid extraction and Solid phase extraction and Membrane Filtration	**6 Hrs**

RECOMMENDED BOOKS/SOURCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines.

PRACTICALS **100 Hrs**

Course outcomes

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

- Determine of drugs (single/combination) using UV-Visible spectrophotometer.
- Validate of analytical methods by ICH standard guidelines
- Determine drugs from biological fluids and validate the methods according to USFDA guidelines
- Identify functional groups of organic compounds IR spectroscopy
- Perform quantitative analysis of food products according food safety and standard authority guidelines.

List of experiments

1. Analysis of Pharmacopoeal compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Interpretation of organic compounds by FT-IR
6. Bio molecules separation utilizing various sample preparation techniques and quantitative analysis of components by HPLC techniques
7. Determination of total reducing sugar
8. Determination of proteins
9. Determination of saponification value, Iodine value and Acid value in food

products
10. Determination of fat content and peroxide value in food products
11. Analysis of natural and synthetic colors in food
12. Determination of preservatives in food
13. Demonstration of LC/MS and GC/MS instruments
14. Demonstration of separation of drugs by HPTLC

PG DIPLOMA IN INTELLECTUAL PROPERTY RIGHTS

Program outcomes

Our programme helps you understand the importance of Patents, Copyrights and Designs, Trademarks and Geographical Indications in socioeconomic and technological concerns

PAPER I – Introduction to Law & Law of patents

Scope

- The course is designed with a view to create patents consciousness; and familiarize the learners about the documentation and administrative procedures relating to patent law in India.

Objectives

- Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)
- To understand the patent procedures in various stages and corresponding formalities involved in perceiving patent application in India.
- To impart training in drafting the patent from Indian perspective.

Course outcomes

- Demonstrate of theoretical knowledge of patent law and land mark judgments on IPR issues

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Understanding Law And Legal System In General**: Introduction to law, understanding legal system, Various organs of Legal System, law enforcement in India.	10
II	**Fundamentals of Patent Law:**Criteria of Patentability, Invention, Novelty, Utility, Inventive step/ Non-obviousness, Non-patentable Inventions and **Drafting of patent specification:** patent specification, provisional specification, complete specification	10

III	**Patent procedure in India:** Main Steps for prosecution of the application; Applications, Preliminary scrutiny of the document, Publication of Patent Application; Publication: time limit, Consequences of Publication Examination, Request for Examination, Request for Examination in respect of WTO applications field u/s. 5(2), Application in which secrecy direction is imposed, In case of divisional application, Examination of application, Compliance with the Requirements as stated in FER, Pre-grant Opposition; Grounds for filing representation, Grant and Sealing of Patent, Post-Grant Opposition; Notice of Opposition, Grounds of Opposition, Procedure for Opposition and **Patent infringement**	**10**
IV	**Patenting Biotechnology and software inventions :** USA, Europe and India	**10**
V	**International patent regime:** An Introduction to European Patent Convention, Paris Convention; TRIPS Agreement; Budapest Treaty; Patent Cooperation Treaty I.P	**10**

Recommended Books/Sources

1. Dr. Kalyan C. Kankanala, Arun Narasani and Vinita Radhakrishnan, Indian Patent Law and Practice, OUP Publications, ISBN: 0-19-806774-7 978-0-19-8066740.
2. P. Narayanan, Patent Law, Eastern Law House, 4th edition, 2006, ISBN: 81-7177-1785.
3. Thomas G. Field, Introduction to Intellectual Property, California Academic Press, 2003 edition, ISBN: 0-089089-236-9
4. Basudurga das, the Constitutional Law of India, (8th edition. Vol.3, 2008) Lexis Nexis Butter Worths Wadhwa, Nagpur.
5. Constitutional Law of India , Dr. J. N.Pandey
6. B.L Wadhera- Intellectual Property
7. WIPO - Reading Material on Intellectual Property Law
8. Brainbridge, David – Cases and Materials in Intellectual Property Law
9. Cornish W.R - Cases and Materials in Intellectual Property Law
10. Dr.S.K Singh- Intellectual Property Rights Laws
11. Patents(Amendment) Act, 2002
12. The Biological Diversities Act, 2002
13. The Protection of Plant Varieties and Farmers' Right Act, 2001

PAPER II - LAW OF COPY RIGHTS, DESIGNS, TRADEMARKS & GEOGRAPHICAL INDICATION

Scope

- To familiarize students with the basic principles of Copy Rights, Designs, Trademarks & Geographical Indication

Objectives

Upon completion of the course, it is expected that the students will be able to (know, do and appreciate)

- To understand the characteristics and significance of trademark, design, copyright and geographical indication.
- Details of registration and/or application procedure and different grounds

of refusals for registration and concepts Copy Rights, Designs, Trademarks & Geographical Indication and its relevance in the trade economy.

Outcomes

- Trace the development of copyright and trade mark law locally and internationally
- Identify and apply the relevant legal principles applicable to Copy Rights, Designs, Trademarks & Geographical Indication and

Lecture wise program

Unit No.	Chapter	No. of Hours
I	**Understanding copy right law**: Historical Overview, Justifications for Copyright Law, The natural law justification, The economic rationale of the Copyright clause, Berne Convention, TRIPS Agreement, Universal Copyright Convention, WCT, WPPT and **Subject matter of copy right:** Literary Works, Dramatic Works, Musical Works; Artistic works, Cinematograph Films and Sound Recordings, Term of Protection	**10**
II	**Concepts under copy right law:** Idea-Expression Dichotomy, Originality/Creativity, Fixation, Limitations, Rights of the Copyright Owner, Term of Copyright, Assignment and Licensing of Copyright, Rights of the Performers and Broadcasting Organisations, Computer software, Infringement of Copyright	**10**

III	**Basic Principles of Design Rights:** Historical Perspective; Justifications for protecting designs; Subject Matter of Design Law, Definition, Law relating to Industrial Design in USA, Registration of Designs in India, Rights of the Owner of Designs and Tests for Infringement	**10**
IV	**Principles Of Trademark:** Justification; What is a Trademark; Definition**:** Historical evolution of Trademark Law: Definition, Registration, Rights conferred, Registered user, Assignment and transmission, Well-Known trademarks, domain name, collective trademark and **Concepts of trademark:** Procedure For Obtaining Registration of Trademark, Rights Of The Owner of Trademarks, Infringement of Trademark and Action for Passing Off	**10**
V	**Protection of Geographical Indications:** Justification for Protection, Definition; International Position, Geographical Indications Protection in India and **Domain Name Protection:** Legal Definition of Domain Name; Domain Name and Intellectual Property, Registration of Domain Names , Disputes Under IPR, Concurrent Claims, Cyber-squatting, Domain Name Disputes Policies	**10**

RECOMMENDED BOOKS

1. Bainbridge. D (2006) Intellectual Property, 6th edition. Longman Publishers
2. Bently. L & Sherman. B. (2004) Intellectual Property Law, 2nd edition, Oxford University Press.
3. WIPO Summer School Reading Material (2008) prepared by WIPO.
4. Blankeney. M (1996) Trade Related Aspects of Intellectual Property Rights: A Concise Guide to TRIPS Agreement, Sweet and Maxwell.
5. K.V. Swaminathan - Guiding Principles in the Decisions on Patent Law, Bahari Brothers, Delhi, 2000.
6. W.R. Cornish - Intellectual Property Rights, 4th edition, Sweet & Maxwell,1999
7. Rodneg D. Rayder- Intellectual Property and the Internet, Lexus Nexus,
8. N.R. Subbaram - Patent Law
9. Copinger & Skone James - Copyright, 13th edition. Sweet & Maxwell, London.
10. Cadilla Health Care Ltd v. Cadilla Pharmaceuticals Ltd (2001) 5 SCC 73
11. Scotch Whisky Association v. Pravara Shanksr Karkhana AIR 1992 Bom 294
12. Diamond v. Chakraborthy 447 US 303 (1980)
13. Basmathi Case
14. Neem Case
15. Turmeric Case
16. U.S v. Canada (Mail Box Provisions Case)
17. Natco Pharma Ltd v. Bayer Corporation (13th March 2012)
18. Novartics AG v. Union of India (2013)
19. Kamal Trading Co v. Gillette U.K Ltd (1998) 1 PCR 135
20. Amrathadhara Pharmacy v. Satya Deo AIR 1963 SC 449

PRACTICALS **100 Hrs**

Assignments to be carried out and submitted on the aforementioned theoretical aspects like

1. Preparation and documentation for Indian Patent.
2. Drafting of patent
3. Check list preparation for Patent, trademark, copyright, design and Geographical Indication of Goods
4. Patent challenge / non- infringement (Para IV) case studies.
5. Comparison of patent laws prevailing in India, US and Europe.
6. Case studies of current patent infringements(03)
7. Case studies of current trademark infringements(03)
8. Case studies of current copyright infringements(02)
9. Case studies of current design infringements(02)
10. National and regional listing of Geographical indication.
11. Preparation of a Chart on Indian Legal system/Judiciary/Executive/Legislature.
12. Visit to a corporate office or any premier research institutions in Mysore to study the Information to Patent of inventions/ Geographical indication of goods. (Visit to CFTRI/ Central Sericulture Research Institute, Mysore etc.). Preparation of a report on the field visit.

POST-GRADUATE DIPLOMA IN MEDICAL DEVICES

Program outcomes

- To create a thorough understanding of important medical device concepts
- To create experts in the field of medical device regulatory documentation and research.
- To create an entry platform in the field medical device.
- To provide students with a global knowledge of medical device.

PAPER – I Regulated Markets (50 Hours)

Objectives

Special challenges related to registry design, data collection, and analysis include the need for unique identification of devices, including device modifications and device components; information on user interface information on ancillary technology and therapies; detection of device performance issues; the need for follow-up; and the impact of health care provider experience and learning.

Course outcomes

The data required for U.S. Food and Drug Administration (FDA) approval, and their management of product quality and patient safety. The data currently required for device approval at various countries.

Introduction

Introducing Medical Devices, Classification of Medical Devices.differentiating medical devices from IVDsand Combination Products. History of Medical Device Regulation. Product Lifecycle of Medical Devices.

Ethics

Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485, Quality Risk Management of Medical Devices: ISO 14971

IMDRF/GHTF

Introduction, Organizational Structure, Purpose and Functions. Regulatory Guidelines, Working Groups. Summary Technical Document (STED). Global Medical Device Nomenclature (GMDN).

US

Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements 21 CFR Part 820, Labeling requirements 21 CFR Part 801

EU

Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification. Unique Device Identification (UDI).

PAPER – II Rest of the World Markets

Medical Device Regulations in World Health Organization (WHO)

Registration Procedures, Quality System requirements and Regulatory requirements.

Medical Device Regulations in Latin America
Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Brazil, Mexico, Argentina and Colombia.

Medical Device Regulations in Asia
Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for:

1. China
2. India
3. Malaysia
4. Singapore
5. Thailand
6. South Korea

Medical Device Regulations in GCC
Clinical Trial Regulations specific for Medical Devices, Registration Procedures, Quality System requirements and Regulatory requirements for Saudi Arabia and UAE.

Harmonization of Medical Device Regulations in Asia
Asian Harmonization Working Party, Asia Pacific Economic Cooperation, Harmonization of Medical Devices in ASEAN.

Practicals **100 Hrs**

1. Checklists for 510k and PMA for US market
2. Checklist for CE marking for various classes of devices for EU
3. STED Application for Class III Devices
4. Audit Checklist for Medical Device Facility
5. Clinical Investigation Plan for Medical Devices
6. Checklists for various countries like China, India, Malaysia, Singapore, Thailand, South Korea, Brazil, Mexico, Argentina, Colombia, Saudi Arabia, UAE, Russia and WHO.

PG DIPLOMA IN PHYTOPHARMACEUTICALS & INDUSTRIAL APPLICATION

Program outcomes

The programme enables student to

- Implement all regulatory requirements pertaining to herbal drugs and herbal drug industry
- An in individual can become an independent entrepreneur establishing herbal drug industry.
- An expert in phytochemistry, standardization of extracts and in analysis of cosmetics.

Paper I – Regulatory considerations for Herbal products

Scope

The course is designed to impart fundamental knowledge on phytopharmaceutical regulations in India. It prepares the students to understand basic regulatory requirements of herbal products for manufacture, marketing authorization and intellectual property rights and basic concepts of GMP, GLP and its implementations.

Objectives:

Upon completion of the course, the students shall be able to know:

- The approval process and regulatory requirements for herbal drug industry.
- The concepts of quality control of Herbal products and its implementation.
- Regulatory guidelines like WHO, ICH and other relevant procedures.
- Documentation, SOPs, GMP and Good Laboratory Practices.

Course outcomes

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

- Prepare the documentation and apply for licensing to manufacture of AYUSH drugs independently.
- Initiate and implement the GMP operations in manufacturing of herbal drugs.
- Know the Regulatory guidelines like WHO, ICH, SOP, protocols to conduct nonclinical & clinical testing of AYUSH drugs.

Lecture wise program:

Unit No.	Chapter	No. of Hours
I	Regulatory requirements and approval procedures for: • Traditional Drugs • Ayurvedic Cosmetics • Nutraceuticals	**10**
II	Rules with latest Amendments: Legal definitions of schedules to the Act and Rules. GMP requirements for Manufacturing, Labelling, Packaging and Storage of ayurvedic drugs. Regulatory status of herbal medicines, Regulation on ayurvedic medicines, Registration system for Ayurvedic medicines.	**10**

III	Intellectual Property Rights: Patent, Copyright, Trademark, Industrial Designs and Geographical Indications.	**10**
IV	Documentation in Ayurvedic Industry: Batch Formula Record, Master Formula Record, Quality audit reports and documents, quality reports, distribution records, complaints and evaluation of complaints, Handling of return goods, recalling and waste disposal.	**10**
V	Good Laboratory Practices: Scope of GLP, Quality assurance unit, SOP, protocols to conduct nonclinical & clinical testing (AYUSH Guidelines), CPCSEA Guidelines, report preparation and documentation.	**10**

Recommended Books/Sources:

1. Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New Delhi 2006.
5. ICH E6 Guideline — Good Clinical Practice-by ICH Harmonised Tripartite
6. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
7. Guidelines from official website of CDSCO

Paper II – Phytochemistry

1. Scope

Students shall have the knowledge of various phytochemicals present in the herbal drugs, their identification and their importance in identification and standardization of herbal medicine. Students shall also know guidelines for standardization, commercial aspects of cosmeceuticals and methods in chromatography for isolation, purification and identification of phytoconstituents. Student shall able to identify the phytochemicals and standardize the crude drug.

2. Objectives

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

- Know the different classes of phytoconstituents and their properties
- Know the process of isolation, purification and identification of phytoconstituents.
- Identify the phytochemicals by preliminary chemical tests and by chromatographic techniques.
- Carryout standardization of herbal drugs.

Course outcomes

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

1. Isolate and identify various constituents present in herb and extract.
2. Carryout standardization of herbal drugs.
3. Able to analyze herbal cosmetics

Lecture wise program:

Unit No.	Chapter	No. of Hours
I	Introduction to phytochemicals: Definition, classification, properties and general test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins.	**10**
II	Phytochemical Screening: Preliminary phytochemical tests for identification of phytoconstituents.	**10**
III	Extraction, Isolation and Identification of phytochemicals**:** Study of different types of extracts and preparations. Basic Principles, various methods of extraction, application of chromatography (Emphasize to be given for column chromatography, TLC, Prep.TLC, HPLTC and HPLC with suitable examples). Role of marker compounds in identification of medicinal plants and extracts.	**10**
IV	Standardization of herbal drugs: WHO guidelines for the standardization of herbal drugs.	**10**
V	Cosmeceuticals and their Analysis: Classification of Ayurvedic cosmetics and Economic aspects. Analysis of Cosmetics, Toxicity screening and test methods, Quality control and toxicity studies as per Drug and Cosmetics acts.	**10**

Recommended Books/Sources:

1. C.K.Kokate, Purohit, Ghokhale, Text book of Pharmacognosy, 4th edition, NiraliPrakasshan, 1996.

2. Trease and Evans, Pharmacognosy, 16thedn., Saunders/Elsevier, 2009
3. Wallis TE, Text book of Pharmacognosy, 4thedn.,.& A. Churchill, [label: distributed by Little, Brown, Boston], 2008
4. Anees A Siddiqui and SeemiSiddiqui, Natural Products Chemistry Practical Manual.
5. Peach & M.V. Tracey, Modem Methods of Plant Analysis- Vol. I&II
6. Pulok K Mukharjee, GMP for Botanicals - Regulatory and Quality issues on Phytomedicine (2003), IstEdition, Business horizons Robert Verpoorte, New Delhi.
7. Pulok K Mukarjee, Quality control of herbal drugs (2002), Ist Edition, Business Horizons Pharmaceutical Publisher, New Delhi.
8. H.Wagner and S.Bladt, Plant drug analysis, 2nd edition, Springer, Berlin.
9. V. Rajpal, Standardization of Botanicals. Testing and extraction methods of medicinal herbs (2004), Vol.I, Eastern Publisher, New Delhi.
10. J.B.Harborne, Phytochemical Dictionary. Handbook of Bioactive Compounds from Plants, (1999), IIndEdition, Taylor and Francis Ltd, UK.
11. Panda H. 2007. Herbal Cosmetics (Hand book), Edition I, Asia Pacific Business Press Inc, New Delhi.
12. Thomson EG. 2006. Modern Cosmetics, Edition I, Universal Publishing Corporation, Mumbai.
13. P.P.Sharma. 2008. Cosmetics- Formulation, Manufacturing & Quality Control, Edition 4, Vandana Publications, New Delhi.

Practicals **100 Hrs.**

Phytopharmaceuticals & Industrial applications
Course outcomes
Upon completion of the course, the student shall be able to:
1. Develop the monograph of herbal drugs
2. To prepare Ayurvedic, Siddha, Homoeopathic formulations

15 experiments/assignments

1. Simple preparations used in Ayurvedic, Siddha, Homoeopathy and their standardization
2. Preparation of herbal cosmetics
3. Determination of stomatal number and index
4. Determination of vein islet and vein termination number
5. Determination of Ash values &extractive value
6. Determination of volatile oil content of a drug
7. Determination of moisture content
8. Determination of bitterness value
9. Determination of foaming index
10. Method of extraction
11. Preliminary Phytochemical screening
12. Isolation of starch from potato
13. Isolation of Curcumin from turmeric
14. Isolation of caffeine from tea dust
15. Isolation of Hesperidin form orange peel

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