# PG Diploma in Dentistry

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Postgraduate Diploma Programmes in Pharmacy

## Content

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<td></td>
<td>PG Diploma in Bioinformatics</td>
<td>33-35</td>
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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 UNIVERSITY, MYSORE”. They shall come into force from the academic year 2011-12 session. The regulation and syllabi are subject to modifications by the Academic Council from time to time.

SECTION I - REGULATIONS

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 (PG Dip.PQA)
2. Pharmaceutical Regulatory Affairs (PG Dip.PRA)
3. Nanotechnology (PG Dip.Nanotech.)
4. Bioinformatics (PG Dip.Bioinfo.)

A candidate who has passed B.Pharm, MBBS, BDS, BAMS 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. Herbal Products and their standardization

1.1 Physical fitness certificate

Every candidate before admission to the course shall submit to the Principal of the Institution a Certificate of Medical Fitness from an authorized Medical Officer that the candidate is physically fit to undergo the academic course and does not suffer from any disability or contagious disease.

2. REGISTRATION

A candidate admitted to the postgraduate diploma course in any one of the constituent colleges of the JSS University, Mysore, shall submit the duly filled application form for registration along with prescribed fee and declaration in the format, to this 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>
<thead>
<tr>
<th>No.</th>
<th>Specialization</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bio informatics</td>
<td>DBI</td>
</tr>
<tr>
<td>2</td>
<td>Pharmacovigilance</td>
<td>DPV</td>
</tr>
<tr>
<td>3</td>
<td>Pharmaceutical quality assurance</td>
<td>DQA</td>
</tr>
<tr>
<td>4</td>
<td>Herbal product &amp; their standardization</td>
<td>DHP</td>
</tr>
<tr>
<td>5</td>
<td>Pharmaceutical regulatory affairs</td>
<td>DRA</td>
</tr>
<tr>
<td>6</td>
<td>Nanotechnology</td>
<td>DNT</td>
</tr>
<tr>
<td>7</td>
<td>Clinical research</td>
<td>DCR</td>
</tr>
<tr>
<td>8</td>
<td>Medicine and Poison Information</td>
<td>DMP</td>
</tr>
</tbody>
</table>

Table-I Branches in Postgraduate diploma courses.
Table-II: Subjects to be studied in different branches of PG Diploma courses

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Specialization</th>
<th>Paper</th>
<th>Name of the Subject</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Bio informatics</td>
<td>I</td>
<td>Basic cellular and Molecular Biology</td>
<td>DBI01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Bioinformatics and <em>In Silico</em> Biology</td>
<td>DBI02</td>
</tr>
<tr>
<td>2</td>
<td>Pharmacovigilance</td>
<td>I</td>
<td>Principles of Pharmacovigilance</td>
<td>DPV01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Regulatory Perspectives of Pharmacovigilance</td>
<td>DPV02</td>
</tr>
<tr>
<td>3</td>
<td>Pharmaceutical quality assurance</td>
<td>I</td>
<td>Quality Assurance and Quality Control</td>
<td>DQA1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Pharmaceutical Validation</td>
<td>DQA2</td>
</tr>
<tr>
<td>4</td>
<td>Herbal products &amp; their standardization</td>
<td>I</td>
<td>Herbal Drug Technology</td>
<td>DHP1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Quality control of Herbal products</td>
<td>DHP2</td>
</tr>
<tr>
<td>5</td>
<td>Pharmaceutical regulatory affairs</td>
<td>I</td>
<td>Pharmaceutical cGMP and Validation</td>
<td>DRA01</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>International Regulatory Requirements</td>
<td>DRA02</td>
</tr>
<tr>
<td>6</td>
<td>Pharmaceutical Nanotechnology</td>
<td>I</td>
<td>Nanocarriers for Drug Delivery</td>
<td>DNT1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Characterization and Applications of Nanocarriers</td>
<td>DNT2</td>
</tr>
<tr>
<td>7</td>
<td>Clinical research</td>
<td>I</td>
<td>Clinical Development and regulations</td>
<td>DCR1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Clinical Research</td>
<td>DCR2</td>
</tr>
<tr>
<td>8</td>
<td>Medicine and Poison information</td>
<td>I</td>
<td>Medicine Information</td>
<td>DMP1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>II</td>
<td>Poison Information</td>
<td>DMP2</td>
</tr>
</tbody>
</table>
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 as a full time student. No candidate is permitted to work as an employee in any laboratory/college/industry/ pharmacy, etc., while studying course.  
   ii. Entire year shall be taken as a unit for the purpose of calculating attendance.  
   iii. Every student shall attend symposia, seminars, conferences, journal review meetings and lectures during each year as prescribed by the department/college/university and not absent himself/herself without valid reason  
   iv. Candidate who has put in a minimum of 80% of attendance in the theory and practical assignments separately shall be permitted to appear for examination.  
   v. Any student who fails to complete the course in the manner stated above shall not be permitted to appear for the University examinations.  
   vi. There shall be no condonation of lack of attendance in PG Diploma courses.  
   vii. Every candidate shall maintain a laboratory work diary and record of his /her participation in the training programmes conducted by the department such as journal reviews, seminars, etc. The work diary/record shall be scrutinised and certified by the Head of the Department and Head of the Institution.

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 award 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 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. University Examination
There shall be two examinations (annual and supplementary) conducted by the 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 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.

I. 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 shall apply for re-totaling through the College.

10. NUMBER OF APPEARANCE(S)
A Candidate registered for Post-Graduate Diploma course must qualify in the Examinations within two years of the date of his / her admission.

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.

12. RE-ADMISSION AFTER BREAK OF STUDY
Re-admission shall be made as per the University Common Regulations duly condoning the break of study for all courses.

13. AUTHORITY TO ISSUE TRANSCRIPT
The Registrar shall be the Authority for issuing Transcript of marks after remitting the prescribed fee to the University.
**PG DIPLOMA EXAMINATION**

Table – III: Scheme of Examination for all Branches

<table>
<thead>
<tr>
<th>Examination</th>
<th>Sessional</th>
<th>Annual</th>
<th>Total Marks</th>
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<tbody>
<tr>
<td></td>
<td>Duration (Hrs)</td>
<td>Marks</td>
<td>Duration (Hrs)</td>
</tr>
<tr>
<td>Paper – I</td>
<td>02</td>
<td>50</td>
<td>02</td>
</tr>
<tr>
<td>Paper – II</td>
<td>02</td>
<td>50</td>
<td>02</td>
</tr>
<tr>
<td>Practical examination</td>
<td>03</td>
<td>50</td>
<td>03</td>
</tr>
<tr>
<td>Total</td>
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</tbody>
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PG Diploma in Pharmaceutical Quality Assurance (DQA)

PAPER I - Quality Assurance and Quality Control (DQA1)

THEORY 50 HOURS

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

LECTUREWISE PROGRAMME:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Definition - Quality control and Quality assurance, concept and philosophy of TQM, GMP, ICH and ISO 9000.</td>
<td>08 Hrs</td>
</tr>
<tr>
<td>2.</td>
<td>Quality control test for containers, closers, caps, secondary packing materials and line clearance.</td>
<td>08 Hrs</td>
</tr>
<tr>
<td>3.</td>
<td>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.</td>
<td>10 Hrs</td>
</tr>
<tr>
<td>4.</td>
<td>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</td>
<td>12 Hrs</td>
</tr>
</tbody>
</table>
products.

5. Quality control of radio pharmaceutical and radio chemical methods in analysis. 06 Hrs

6. GLP: Scope of GLP, Quality assurance unit, SOP, protocols for conduct of clinical & non clinical testing, control on animal house, report preparation and documentation. 06 Hrs

RECOMMENDED BOOKS:


7. ICH guidelines

8. ISO 9000 and total quality management


PG Diploma in Pharmaceutical Quality Assurance (DQA)

PAPER II - Pharmaceutical Validation (DQA2)

THEORY 50 HOURS

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 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)
- Concepts of validation and its implementation
- Validation of process, equipment and products
- Analytical method validation

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of hours</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>An Introduction to the Basic Concepts of Process Validation &amp; How it</td>
<td>10 Hrs</td>
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<tr>
<td></td>
<td>Differs from Qualification (Installation Qualification (IQ), Operational</td>
<td></td>
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<tr>
<td></td>
<td>Qualification (OQ) &amp; Performance Qualification (PQ) Procedures,</td>
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<td></td>
<td>Validation master plan (VMP)</td>
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<tr>
<td>2.</td>
<td>A Review of Prospective, Concurrent, Retrospective Validation &amp;</td>
<td>05 Hrs</td>
</tr>
<tr>
<td></td>
<td>Revalidation including the use of Statistical Process Control (SPC)</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Validation of Water (Demineralised, Distilled and Water for Injection) &amp;</td>
<td>05 Hrs</td>
</tr>
<tr>
<td></td>
<td>Thermal Systems, including Heat Ventilation and Air conditioning (HVAC),</td>
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<td></td>
<td>Facilities &amp; Cleaning Validation</td>
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<tr>
<td>4.</td>
<td>Process Validation of Active Pharmaceutical Ingredients (APIs) and</td>
<td>10 Hrs</td>
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<td></td>
<td>finished products</td>
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<tr>
<td>5.</td>
<td>Validation of Sterile and Non-Sterile Facility</td>
<td>10 Hrs</td>
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<td>6.</td>
<td>Validation of Analytical Methods, Automated Systems, Validation of</td>
<td>10 Hrs</td>
</tr>
<tr>
<td></td>
<td>process: mixing, granulation, drying, compression, filtration, filling,</td>
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<tr>
<td></td>
<td>Validation of sterilization methods and equipments: dry heat sterilization,</td>
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<td></td>
<td>autoclaving, membrane filtration. Validation of analytical procedures,</td>
<td></td>
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<tr>
<td></td>
<td>Validation of air handling equipments and facilities in sterile and non sterile areas.</td>
<td></td>
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</tbody>
</table>
RECOMMENDED BOOKS:

1. Lachman L Liberman Theory and practice of industrial pharmacy by 3rd edition
10. The Pharmaceutical Sciences; the Pharma Path way ‘Pure and applied Pharmacy’ by D. A Sawant, Pragathi Books Pvt Ltd.
PG Diploma in Pharmaceutical Quality Assurance (DQA)

Experiential Training

PRACTICAL  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

- Documentation for in process and finished products Quality control tests for Solid, Semisolid, ophthalmic, modified release and Sterile preparations.
- Protocol preparation for documentation of various types of records (BFR, MFR, DR, etc.)
- Report preparation of GLP for non-clinical testing
- Analytical methods Validation
- Accelerated and Photostability studies on dosage forms as per ICH Guidelines
- Documentation for audits and inspection of manufacturing facilities.
PG Diploma in Pharmaceutical Nanotechnology (DNT)

Paper I : Nanocarriers for Drug Delivery (DNT1)

THEORY

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 are the current frontiers of all scientific and technological advancement. They deal with manipulation of materials at the 10^{-9} m scale. This essentially means rearranging bonds at the atomic level to create new substances with unheard of properties.

- Nanotechnology comprise 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
<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>History of the nanomedicine, Fundamentals and rationale of sustained/controlled/targeted drug delivery</td>
<td>05 Hours</td>
</tr>
<tr>
<td>2.</td>
<td>Needs and Requirements of Nanocarriers, Nanoparticle flow: Implications for drug delivery</td>
<td>10 Hours</td>
</tr>
<tr>
<td>3.</td>
<td>Polymers used for the formulation of nanoparticles- Classification and applications for polymers</td>
<td>10 Hours</td>
</tr>
<tr>
<td>4.</td>
<td>Classifications of nanocarriers- Liposomes, Dendrimers, Polymeric micelles, Nanoparticles (Polymeric and Lipid based), Nanoemulsions,</td>
<td>15 Hours</td>
</tr>
<tr>
<td>5.</td>
<td>Method of preparation,</td>
<td>10 Hours</td>
</tr>
</tbody>
</table>
Paper II- Characterization and Applications of Nanocarriers (DNT2)

LECTUREWISE PROGRAMME:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Characterization of nanoparticles</td>
<td>05 Hours</td>
</tr>
<tr>
<td>2.</td>
<td>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.</td>
<td>20 Hours</td>
</tr>
<tr>
<td>3.</td>
<td>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,</td>
<td>15 Hours</td>
</tr>
<tr>
<td>4.</td>
<td>Societal Implications and Regulatory guidelines</td>
<td>05 Hours</td>
</tr>
<tr>
<td>5.</td>
<td>Medical applications</td>
<td>05 Hours</td>
</tr>
</tbody>
</table>

References:
3. Melgardt M. de Villiers, Pornanong Aramwit, Glen S. Kwon (Eds.) Nanotechnology in drug delivery, Springer
Pharmaceutical Nanotechnology (DNT)

Practical & Lab Procedure

Duration: 100 Hrs

- Laboratory Synthesis of Nanoparticles,
  
  **Spontaneous Growth**

- Vapor (or Solution) liquid solid (VLS or SLS) growth

  **Electrospinning**

- Laboratory Synthesis of Thin Films

  **Vapor –Liquid – Solid method**

- Evaporation

- Characterization of Nanostructured Material

  **Structural Characterization**

    - X –ray diffraction (XRD)
    - Scanning electron microscopy (SEM)
    - Transmission electron microscopy (TEM)
    - Atomic force microscopy (SPM)
    - Gas adsorption

  **Chemical Characterization**

    - Optical spectroscopy
    - Absorption and transmission spectroscopy
PG Diploma in Regulatory Affairs (DRA)

Paper- I-Pharmaceutical cGMP and Validation (DRA01)  50 Hours

THEORY

Scope:

- To learn the concept of validation and process of validation
- To train the students about the importance and requirement of good clinical 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 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)

- Concepts of quality, quality management 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
- Environment protection and occupational health safety requirements and requirements
- Validation of process, equipments and products

LECTUREWISE PROGRAMME:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of Hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Concept of Quality, Total Quality Management. Quality by design, six sigma concept. Stability testing: ICH and WHO guidelines, Photostability studies.</td>
<td>8</td>
</tr>
<tr>
<td>2</td>
<td>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</td>
<td>8</td>
</tr>
<tr>
<td>3</td>
<td>cGMP of Pharmaceutical manufacturing · Evolution and Principles of cGMP, Schedule-M, WHO-GMP requirements and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing.</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>Documentation in pharmaceutical industry: Batch Formula Record, Master Formula Record, Distribution records, Drug Master Files. Brief study of following laws Drugs and Cosmetics Act 1940 and its rules 1945</td>
<td>8</td>
</tr>
</tbody>
</table>
The Environmental Protection Act-1986 & Occupational Safety and Health Administration (OSHA)

5 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)

6 A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC). Process Validation of Active Pharmaceutical Ingredients (APIs) and finished products

RECOMMENDED BOOKS

1. Pharmaceutical master validation plan: The ultimate guide to FDA, GMP and GLP Compliance by Syed Imitiaz Haider
THEORY

Scope:

- To learn the concept of generic drug and their development
- To understand the requirements for filing process of IND, NDA and ANDA
- To know the approval process of various regulatory filings in different countries
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for submitting regulatory documents
- To learn the importance and different phases of clinical trials
- To learn about pharmacovigilence and process of monitoring in clinical trials

Objectives:

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

- Concepts of innovator and generic drugs, drug development process
- Regulatory guidance’s and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials

LECTUREWISE PROGRAMME:

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of Hrs</th>
</tr>
</thead>
</table>
2 Regulatory requirements for product approvals: Active Pharmaceutical Ingredients, Biologics, Novel therapies obtaining New Drug Application (NDA), Abbreviated New Drug Application (ANDA) for generic drugs, ways and means of US Registration for foreign drugs.

3 Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs, Regulation for combination products (Controlled release systems), and medical devices. Common Technical Document (CTD)/ electronic Common Technical Document (eCTD) Format, Industry and FDA Liaison.

4 Non-clinical drug development: Global submission of Investigational New Drug application (IND), New Drug application (NDA), Abbreviated New Drug Application (ANDA), Investigation medicinal product Dossier (IMPD) & Investigator Brochure (IB)


RECOMMENDED BOOKS


Pharmaceutical regulatory affairs (DRA)

PRACTICALS 100 Hrs

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

1. **Documentation** for in process and finished products Quality control tests for Solid, Semisolid and Sterile preparations.
2. **Protocol** preparation for documentation of various types of records (BFR, MFR, DR, etc.)
3. Preparation of protocols on various validation requirements
4. Validation of machines & analytical instruments used for Pharmaceutical formulations.
5. Process Validation of various pharmaceutical dosage forms.
6. Preparation of SOPs for various equipments and manufacturing processes as per ISO requirements.
7. Accelerated and Photostability studies on dosage forms as per ICH Guidelines
8. Preparation of final clinical trial report (Phase I,II and III) for submission to regulatory authorities.
10. Preparation of regulatory compliance checklist tabulating cGMP requirements as per 21 CFR 210 and 211.
11. Preparation of global list of documents for registration of IND, NDA, ANDA as per ICH CTD format.
12. Case studies on response with scientific rationale to USFDA Warning Letter
13. Preparation of an IMPD for EU submission.
15. Preparation and documentation for Indian Patent.
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, aflatoxins and microbial contaminants 6 Hr

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, gas chromatography (GC), high performance liquid chromatography (HPLC) and high performance thin layer chromatography (HPTLC). 18Hrs

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
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. 08Hrs

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 10Hrs

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 12Hrs

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. 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. 08Hrs
Herbal products & their standardization (DHP)

Practicals 100 Hrs

- Demonstration of various dosage forms of traditional systems.
- Simple preparations used in Ayurvedic, Siddha, Homoeopathy and their standardization
- Determination of carbohydrate, protein and vitamin contents.
- Preparation of some herbal cosmetics
- 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:
7. Pharmacognosy by Trease and Evans.
PG Diploma in Clinical research (DCR)

PAPER I- Clinical Development and Regulations (DCR1)

THEORY  50 HOURS

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 train the students on conceptualizing, designing, conducting, managing and reporting of 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
- Material and regulatory requirements for conducting clinical trials
- Types of clinical trial designs
- Responsibilities of key players involved in clinical trials
- Preparing clinical study reports and reporting in common technical document
- Quality control and assurance in conduct of clinical trial

LECTUREWISE PROGRAMME:

<table>
<thead>
<tr>
<th>CHAPTER</th>
<th>No. of Hours</th>
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<tbody>
<tr>
<td>1. Drug development process</td>
<td>03 hours</td>
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<tr>
<td>• Investigational new drug development</td>
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<td>• New drug development</td>
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<tr>
<td>• Abbreviated New Drug Development</td>
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<tr>
<td>2. Clinical drug development phases</td>
<td>06 hours</td>
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<tr>
<td>• Phase 0 studies</td>
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<tr>
<td>• Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points</td>
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<td>• Phase II studies (proof of concept or principle studies to establish efficacy)</td>
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<td>• Phase III studies (Multi ethnicity, multinational, registration studies)</td>
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<td>• Phase IV studies (Post marketing authorization studies; pits and practices?)</td>
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<tr>
<td>3. Requirements in clinical research</td>
<td>04 hours</td>
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<tr>
<td>• Good clinical practice (ICH GCP E6)</td>
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<tr>
<td>• Clinical trial materials (Documentation, Investigational drugs, logistical materials)</td>
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<tr>
<td>4. Ethics issues in clinical research</td>
<td>05 hours</td>
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<tr>
<td>• Ethics committees, constitution and practices</td>
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<tr>
<td>• Declaration of Helsinki and Informed consent process</td>
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</tbody>
</table>
• Liability and indemnity in clinical trials (Insurance and Indemnity: roles and responsibility)
• Misconduct and Fraud in clinical research
• Ethics and clinical trials in special population

5. **Safety Monitoring in Clinical Trials (ICH E2)** 04 hours
• Adverse event and serious adverse event reporting in clinical trials; emphasis on SUSARs, managing and reporting of events.

6. **Analysis and reporting clinical trials (ICH E3 and E9)** 04 hours
• Clinical study reports – structure and content
• Critical appraisal of clinical study report
• Reporting clinical trials in common technical document
• Electronic reporting in clinical trials

7. **Quality and clinical research** 04 hours
• Quality control, assurance and types of audits
• Clinical study audit – conduct and reporting
• Regulatory inspections in clinical research

8. **Regulations Governing Clinical Trials** 20 hours
• ICH –GCP guidelines,
• Clinical Research regulations in India – CDSCO guidelines,
• Clinical trial application requirements in India- IND, ANDA, AADA and NDA.
• USFDA regulations to conduct drug studies
• Clinical Research regulations in UK – Medicines and Healthcare Products Regulatory Agency (MHRA)
• Clinical Research regulations in Europe (EMEA).

**RECOMMENDED BOOKS:**
PAPER II-Clinical Research (DCR2)

THEORY

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):
- Drug development process and different phases of clinical trials
- Material and regulatory requirements for conducting clinical trials
- Types of clinical trial designs
- Responsibilities of key players involved in clinical trials
- Site initiation, monitoring and close-out activities
- Safety monitoring and reporting in clinical trials
- Preparing clinical study reports and reporting in common technical document
- Quality control and assurance in conduct of clinical trial

LECTUREWISE PROGRAMME:

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<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of Hours</th>
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<tbody>
<tr>
<td>1</td>
<td>Historical Perspectives:</td>
<td>02 hours</td>
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<tr>
<td></td>
<td>Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report</td>
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<td></td>
<td>The declaration of Helsinki</td>
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<td></td>
<td>Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines</td>
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<tr>
<td>2</td>
<td>Informed Consent Process:</td>
<td>02 hours</td>
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<tr>
<td></td>
<td>Ethical principles governing informed consent process</td>
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<tr>
<td></td>
<td>Structure and content of a Patient Information Sheet</td>
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<td></td>
<td>Structure and content of an Informed Consent Form</td>
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<td></td>
<td>The process of taking informed consent and documentation</td>
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<tr>
<td>3</td>
<td>Types and Design of clinical trials</td>
<td>10 hours</td>
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<tr>
<td></td>
<td>Randomized trials and uncontrolled trials</td>
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<tr>
<td></td>
<td>Crossover and factorial designs</td>
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<tr>
<td></td>
<td>Equivalence, non-inferiority and superiority trials</td>
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</table>
Bioequivalence and bioavailability studies
blinding (single, double)

4 Clinical Trial Study Team

Roles and responsibilities of:
- Investigators
- Study Coordinator
- Sponsor
- Monitor
- Contract Research Organization

5 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

6 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
    - Trial Master File preparation and maintenance
    - Investigator Site File/Regulatory Binder
    - Monitor File
    - Pharmacy File
- Site initiation
Site initiation Visit report and Follow up.

7 Clinical Trial Monitoring and Close-Out 08 hours

- 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
  - Study related documents collection
  - Archival requirement
  - IP reconciliation and destruction
  - Close-Out visit report

8 Audit and Inspections 04 hours

- Types of audits
- Audit criteria
  1. Audit process
  2. Responsibilities of stake holders in audit process
  3. Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections

RECOMMENDED BOOKS:

Clinical research (DCR) Experiential Training

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

- Design and evaluation of site feasibility questionnaire
- Preparation for site initiation visit
- Designing of clinical trial protocol
- Preparation of Investigator’s Brochure
- Design and execution of Informed consent process
- Preparation of Case Report Form
- Reporting of serious adverse event
- Management of Investigational Product
- Ethics committee submission procedures
- Preparation and conduct of site monitoring visit
- Preparation and conduct of site close out visit
Purpose and 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.

Upon completion of the subject student shall be able to:

1. Understand the significance and concept of medicine information
2. Understand and practice evidenced based medicine
3. Handle the medicine information queries
4. Understand legal and ethical aspects involved in medicine information practice

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Topics</th>
<th>Hrs</th>
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<tbody>
<tr>
<td>1.</td>
<td>Introduction to the Concept of Medicines Information</td>
<td>01</td>
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<tr>
<td>2.</td>
<td>Modified Systematic Approach to Answering medicine information queries</td>
<td>03</td>
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<td>3.</td>
<td>Formulating Effective Responses and Recommendations: A Structured Approach</td>
<td>01</td>
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<tr>
<td>4.</td>
<td>Medicine Information Resources</td>
<td>04</td>
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<td>5.</td>
<td>Electronic Information Management</td>
<td>01</td>
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<td>6.</td>
<td>Documentation of medicine information services provided</td>
<td>01</td>
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<td>7.</td>
<td>Communication Skills</td>
<td>02</td>
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<tr>
<td>8.</td>
<td>Literature Evaluation</td>
<td>07</td>
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<td>9.</td>
<td>Pharmacoeconomics</td>
<td>04</td>
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<td>10.</td>
<td>Evidence-Based Practice</td>
<td>07</td>
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<tr>
<td>11.</td>
<td>Clinical Application of Statistical Analysis</td>
<td>03</td>
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<tr>
<td>12.</td>
<td>Professional Writing</td>
<td>02</td>
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<tr>
<td>13.</td>
<td>Legal Aspects of medicine Information Practice</td>
<td>01</td>
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<tr>
<td>14.</td>
<td>Ethical Aspects of medicine Information Practice</td>
<td>01</td>
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<tr>
<td>15.</td>
<td>Functions of medicine Information Centre</td>
<td>02</td>
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<tr>
<td>16.</td>
<td>Drug Evaluation Monographs</td>
<td>02</td>
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<tr>
<td>17.</td>
<td>Quality Assurance in medicine Information</td>
<td>02</td>
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<tr>
<td>18.</td>
<td>Establishing a medicine information centre</td>
<td>02</td>
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<td>19.</td>
<td>Medication Misadventures: Medication Errors and Adverse Drug Reactions</td>
<td>04</td>
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</tbody>
</table>

References
PAPER II- POISON INFORMATION (DMP2)

50 Hours

Purpose and scope:
This course is designed to impart knowledge of the relevant aspects of poison information including organisation 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.

Upon completion of the subject student shall be able to:

1. Understand the significance of poison information service
2. Handle the poison information queries
3. Recognize and deal with general principles involved in the management of poisoning
4. Recognize the clinical symptoms and management of acute poisoning of common poisoning agents, venomous snake bites, plant poisoning, food poisoning, environmental poisoning and substance abuse
5. Understand the preventive aspects of toxicology

Lecture wise programme

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Topic</th>
<th>Hours</th>
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<tbody>
<tr>
<td>1</td>
<td>Definition, aim/objectives, Indian and global scenario of PIC</td>
<td>01</td>
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<tr>
<td>2</td>
<td>Organization and functions of PIC</td>
<td>04</td>
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<td>3</td>
<td>Systematic approach to poison information queries</td>
<td>03</td>
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<td>4</td>
<td>Role and responsibilities of poison information specialist</td>
<td>01</td>
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<tr>
<td>5</td>
<td>Preventive measures for accidental poisoning</td>
<td>01</td>
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<td>6</td>
<td>General principles involved in the management of poisoning</td>
<td>04</td>
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<tr>
<td>7</td>
<td>Antidotes and the clinical applications</td>
<td>01</td>
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<td>8</td>
<td>Supportive care in clinical Toxicology</td>
<td>02</td>
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<td>9</td>
<td>Gut Decontamination</td>
<td>02</td>
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<td>10</td>
<td>Elimination Enhancement</td>
<td>01</td>
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<tr>
<td>11</td>
<td>Clinical symptoms and management of acute poisoning with the following agents</td>
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<tr>
<td></td>
<td>A Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, Pyrethroids, Aluminum and zinc phosphide</td>
<td>08</td>
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<td>B Opiates overdose</td>
<td>01</td>
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<td></td>
<td>C Antidepressants</td>
<td>03</td>
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<tr>
<td></td>
<td>D Barbiturates and benzodiazepines</td>
<td>02</td>
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</table>
E Alcohol: ethanol and methanol 02
F Paracetamol and salicylates 02
12 Clinical symptoms and management of chronic poisoning with the following agents – Heavy Metals: Arsenic, lead, mercury, iron and copper 05
13 Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries 05
14 Substance abuse: General Considerations 02

References:
3. Lindsay Murray, Frank Dary, Mark little, Mikes cadogan, TOXICOLOGY HANDBOOK. Australia: Churchills Livingstone, Elsevier; 2007

Medicine and Poison information (DMP)

Experiential Training

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 medicine information centre (2 Numbers)
- Answering to medicine information queries relating to various categories (8 Numbers)
- Designing of poison information centre (2 Numbers)
- Answering to poison information queries relating to various categories (8 Numbers)
- Evaluation of published biomedical literature and preparation of clinical report (3 Numbers)
- Preparation of written response relating to medicine information (2 Numbers)
PG Diploma in Bioinformatics (DBI)

Paper I-Basic Cellular and Molecular Biology (DBI-1)


3. DNA replication: Protein synthesis-Eukaryotic and Prokaryotic, Transcription and Translation


5. 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

6. 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 Inheritance in Man. Linkage map resources. Practical uses of genome maps: Locating genomic regions, target identification, arrangement of genes, SNP diagnosis, positional specific cloning.


REFERENCE:

1. Introduction to bioinformatics, classification of biological databases, Biological data formats, Application of bioinformatics in various field. Introduction to single letter code of aminoacids, symbols used in nucleotides, data retrieval- Entrez  


3. Evolutionary analysis: distances, Cladistic and phenetic method. Clustering method. Rooted and unrooted tree representation. use of cluster and PHYLIP


6. Comparative Gnomics: 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

7. Functional Genomics: Gene expression analysis by cDNA micro arrys, SAGE, strategies for generating ESTs and full length inserts; EST clustering and assembly; EST databases (DBEST, UNIGENE).

REFERENCE:

3. The Molecular Biology Database Collection: Updated Compilations of Biological
Bioinformatic (DBI)

Practical

1. Data retrieval tools and methods
2. Biological Databases Sequence Databases.
3. Structure Databases
4. Subcellular localization prediction
5. Database file formats
6. Molecular visualization
7. Gene structure and function prediction
8. Sequence similarity searching (NCBI BLAST)
9. Protein sequence analysis (ExPASy proteomics tools)
10. Multiple sequence alignment (Clustal)
11. Molecular phylogeny (PHYLIP)
12. Analysis of protein and nucleic acids sequences
13. Protein structure prediction
14. Sequence analysis using EMBOSS or GCG Wisconsin Package
15. Staining technique
16. Chemical mutagenesis
17. Isolation of bacterial genomics DNA
18. Agarose Gel Electrophoresis
19. Estimation of DNA
20. Isolation of plasmid DNA
21. Estimation of RNA
22. Replica Plating
23. Polymerase Chain Reaction Technique
24. Western Blotting.
PG Diploma in Intellectual Property Rights Law (IPRL)

PAPER I – Introduction to Law & Law of patents

THEORY 50 HOURS

Scope:
This course is designed to impart fundamental knowledge of Indian Legal System, and impart insight into the evolution of patent law, objectives of patent law and patentability requirements.

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

- To learn the concept of Law, Legal systems and patents.
- 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.
- To acquaint with the cases and landmark judgments on IPR issues.

LECTUREWISE PROGRAMME:

<table>
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<tr>
<th>Sl. No.</th>
<th>CHAPTER</th>
<th>No. of hours</th>
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<tbody>
<tr>
<td>1.</td>
<td><strong>Understanding Law And Legal System In General</strong>: Introduction to law, understanding legal system, Various organs of Legal System, law enforcement in India.</td>
<td>06 Hrs</td>
</tr>
<tr>
<td>3.</td>
<td><strong>Law of property</strong>: Nature of Property, Classification of property, Modes of holding ownership, Intellectual Property Rights.</td>
<td>05 Hrs</td>
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<tr>
<td>4.</td>
<td><strong>Fundamentals of Patent Law</strong>: Criteria of Patentability, Invention, Novelty, Utility, Inventive step/ Non-obviousness, Non-patentable Inventions.</td>
<td>06 Hrs</td>
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<tr>
<td>5.</td>
<td><strong>Drafting of patent specification</strong>: patent specification, provisional specification, complete specification.</td>
<td>05 Hrs</td>
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</tbody>
</table>
6. **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.

7. **Patent infringement:** Infringement of a patent, Defenses, Compulsory licensing, Remedies.

8. **International patent regime:** An Introduction to European Patent Convention, Paris Convention; TRIPS Agreement; Budapest Treaty; Patent Cooperation Treaty I.P

9. **Patentability of software inventions:** Introduction, Comparision between India, US and Europe patentability of software inventions

**RECOMMENDED BOOKS:**
5. Constitutional Law of India, Dr. J. N.Pandey

**REFERENCE BOOKS:**
1. B.L Wadhera- Intellectual Property
2. WIPO - Reading Material on Intellectual Property Law
5. Dr.S.K Singh- Intellectual Property Rights Laws
6. Patents(Amendment) Act, 2002
7. Copy Right Act, 1957
9. The Biological Diversities Act, 2002
10. The Protection of Plant Varieties and Farmers’ Right Act, 2001
PAPER II - Law of Copy Rights, Designs, Trademarks & Geographical Indication

THEORY  50 HOURS

Scope:
This course is designed to impart fundamental knowledge of Intellectual Property Rights like trademark, copyright, design and 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 of its relevance in the trade economy.

LECTUREWISE PROGRAMME:

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<th>Sl. No.</th>
<th>CHAPTER</th>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>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.</td>
<td>05 Hrs</td>
</tr>
<tr>
<td>2.</td>
<td>Subject matter of copy right: Literary Works, Dramatic Works, Musical Works; Artistic works, Cinematograph Films and Sound Recordings, Term of Protection.</td>
<td>05 Hrs</td>
</tr>
<tr>
<td>3.</td>
<td>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, Infringement Of Copyright.</td>
<td>06 Hrs</td>
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<td>4.</td>
<td>Computer Software, Digital Environmental and Intellectual Property Protect: Copyright Protection,</td>
<td>05 Hrs</td>
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<tr>
<td>5.</td>
<td>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.</td>
<td>08 Hrs</td>
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<tr>
<td>6.</td>
<td>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</td>
<td>05 Hrs</td>
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</tbody>
</table>
7. **Concepts of trademark:** Procedure For Obtaining Registration of Trademark, Rights Of The Owner of Trademarks, Infringement of Trademark and Action for Passing Off.  

8. **Domain Name Protection:** Legal Definition of Domain Name; Domain Name and Intellectual Property, Registration of Domain Names 4.7 Disputes Under IPR, Concurrent Claims, Cyber squatting, Domain Name Disputes Policies.  

9. **Protection of Geographical Indications:** Justification for Protection, Definition; International Position, Geographical Indications Protection in India.  

**RECOMMENDED BOOKS:**  
3. WIPO Summer School Reading Material (2008) prepared by WIPO.  
7. Rodneg D. Rayder- Intellectual Property and the Internet, Lexus Nexus,  
8. N.R. Subbaram - Patent Law  

**Some selected case laws on IPR: (Common to Paper I & II)**  
4. Basmathi Case  
5. Neem Case  
6. Turmeric Case  
7. U.S v. Canada ( Mail Box Provisions Case)  
8. Nirmala Chemical worksPvt Ltd v. Nirman High School and others AIR 2011 (NOC) Guj  
9. Shelke Beverages Pvt Ltd v. Rasiklal Manickchand Dhariwal AIR 2010 (NOC) 1064  
10. Satyam Infoway Ltd v. Sifnet Solutions Pvt Ltd AIR 2004 SC3540  
11. Rediff Communications Ltd v. Cyberbooth AIR 2000 Bom 27
12. Goenalka Institute of Education and Research v. Anjani Kumar Goenaka 2009(40) PT 393 Del
18. Macmillan v. COOPER air 1924 PC 75
21. Walter v. Lane (1900) AC 539
22. Manu Bhandari v. Kala Vikas Pictures AIR 1987 Del 1

PRAC TICALS

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
5. Comparison of patent laws prevailing in India, US and Europe.
6. Case studies of current patent infringements.
7. Case studies of current trademark infringements.
8. Case studies of current copyright infringements.
9. Case studies of current design infringements.
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.
PG Diploma in Cosmeceutics

PAPER I – Cosmeceutics Biology and Formulation Science

THEORY 50 HOURS

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 (know, do and appreciate)

• Know common problems that need skin, scalp, hair and oral care.
• Understand actives and their mechanism of action to treat the problems
• Knowledge on formulation science to develop product formulations.
• Ability to combine actives and the formulation to develop cosmeceuticals with good efficacy, sensory, stability and safety.

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<tbody>
<tr>
<td>1.</td>
<td>Skin: Structure and Function. Mechanism of allergic reaction and skin conditions. Different terms used to define various allergic conditions. Differences between baby skin and adult skin.</td>
<td>05 Hrs</td>
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<tr>
<td>2.</td>
<td>Skin moisturization: Natural moisturizing factor, Ceramide lipids and occlusive layer</td>
<td>02 Hrs</td>
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<td>3.</td>
<td>Pigmentation and skin whitening actives. Basic understanding of mechanism of action of the actives.</td>
<td>02 Hrs</td>
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<tr>
<td>4.</td>
<td>Acne, Causes and anti-acne actives. Aging principles, Skin –anti-aging ingredients, and their mechanism of action.</td>
<td>03 Hrs</td>
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</table>
6. Structure of Hair and Hair Growth Cycle. Dandruff, causes for dandruff. Antifungal ingredients used to treat dandruff 03 Hrs

7. 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. 04 Hrs

8. Alternatives to animal testing for safety 01 Hr

9. Fundamental approach to cosmeceutic product development
   Surfactants, Emollients and humectants, their classification, examples and application in skin, hair and oral care products
   Rheology modifying agents used in cosmeceuticals – classification, examples and application. 08 Hrs

10. Preservatives – Antioxidants and antimicrobial agents, Classification, relative merits and demerits, Factors affecting microbial preservative efficacy. 04 Hrs

11. 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.
   Sunscreens: Organic and Inorganic sunscreens 06 Hrs

12. Comparison of formulation of soaps and syndet bars
   Mechanism of hair coloring action of Para pheylanediamine (PPD) based hair colorants.
   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.
   Perfumery- classification and allergens in perfumes. 04 Hrs

13. Novel approaches in drug delivery systems for Topical application
   Principles and formulation of patches, liposomes, ethosomes, niosomes, transferosomes. 05 Hrs

RECOMMENDED BOOKS:
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
7. CTFA directory
PAPER II
Cosmeceutical Evaluation & regulations

THEORY 50 HOURS

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.

LECTUREWISE PROGRAMME:

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<tbody>
<tr>
<td>1.</td>
<td>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.</td>
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<td>05 Hrs</td>
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<td>2.</td>
<td>Indian and EU regulation: Regulation with respect to preservative, Sunscreen, allergens and labelling requirements.</td>
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<td>05 Hrs</td>
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<td>3.</td>
<td>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</td>
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<td>04 Hrs</td>
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<td>4.</td>
<td>Introduction to Packaging materials Plastics, metals, laminates, glass, Paper and Paper Board. Classification and application</td>
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<td>06 Hrs</td>
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<td>5.</td>
<td>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</td>
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<td>10 Hrs</td>
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</table>
6. Principles of equipment to measure skin and hair conditions - Sebumeter, corneometer, trans epidermal water loss, Skin color, hair tensile properties, hair combing properties. 10 Hrs

7. 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 Hrs

RECOMMENDED BOOKS:

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
10. Access to REACH and cosmetics safety Data base.
11. IFRA guidelines for fragrances
12. International regulation for colors
Experiential Training

PRACTICALS

100 Hrs

100 hours over a period of 10 months as a part of experiential training

1. Design and Development of following formulation using traditional ingredients.
   Face wash, Bodywash, Creams, Lotions, shampoo, toothpaste, Lip Balm

2. Study private body guidelines for green/premium cosmetics of Ecocert/Cosmos and whole foods (USA), design and formulate Face wash, Bodywash, Creams, Lotions, shampoo, toothpaste, Lip Balm to suit these regulations.

3. Design and Development of a cosmeceutical product selected from the treatment of dry skin, wrinkles, acne, dark spots, dandruff, sensitive teeth, and bleeding gums, that may also include new delivery system and submit a report on the formulation design principles, etiology of the condition, chemistry and mechanism of action of the active, and specification of the product. (A report about 20 Pages)

4. Quantitative determination of cosmetics

5. Quality control tests for cosmetics.
PG Diploma in Pharmaceutical Nanotechnology (DNT)

Paper I: Nanocarriers for Drug Delivery (DNT1)

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 10^-9 m 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.
** THEORY 50 Hours **

**LECTUREWISE PROGRAMME:**

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<tr>
<td>1</td>
<td>History of the nanomedicine, Fundamentals and rationale of sustained/controlled/targeted drug delivery</td>
<td>08</td>
</tr>
<tr>
<td>2</td>
<td>Needs and Requirements of Nanocarriers in medicine: Systemic drug delivery and localized drug delivery</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>Classifications of nanocarriers- Liposomes, Dendrimers, Polymeric micelles, Nanoparticles (Polymeric and Lipid based), Nanoemulsions, Inorganic-based nanoparticles</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Materials used for preparation of nanoparticles: Polymer, lipids, surfactants, inorganic salts</td>
<td>05</td>
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<td>5</td>
<td>Method for the preparation of nanoparticles</td>
<td>12</td>
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<td><strong>Total</strong></td>
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**Paper II - Characterization and Applications of Nanocarriers (DNT2)**

** THEORY 50 Hours **

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<tbody>
<tr>
<td>1</td>
<td>Instrumentation techniques used for the characterization of nanoparticles</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>Medical applications of nanotechnology</td>
<td>15</td>
</tr>
<tr>
<td>3</td>
<td>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.</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Human health and safety- Interaction of nanomaterials with biological systems, Toxicology of nanoparticles- Background, Reactive oxygen species, Biodistribution, Nanotoxicity studies, Immunogenicity of nanoparticles,</td>
<td>10</td>
</tr>
</tbody>
</table>
Complications with nanotoxicity studies- Effect of aggregation of nanoparticles, Challenges of nanovisualization and related unknowns in nanotoxicology, Environmental impact

References:
3. Melgardt M. de Villiers, Pornanong Aramwit, Glen S. Kwon (Eds.) Nanotechnology in drugdelivery, Springer

Pharmaceutical Nanotechnology (DNT)

PRACTICAL & LAB PROCEDURE

100 Hours

Part 1: Synthesis of Nanoparticles
1. Synthesis of gold nanoparticles by three different methods
   a) Sodium borate reduction method
   b) THPC reduction method
   c) Citrate stabilized method.
2. Synthesis of magnetic NPs by two different methods
   a) Co-precipitation method
   b) Thermal decomposition method
3. Synthesis of Quantum dots by two different methods
   a) Microwave assisted method
   b) Conventional hot plate method
4. Synthesis of polymeric nanoparticles by two methods
   a) Precipitation method
   b) Solvent evaporation method
5. Synthesis of lipid micelles
6. Synthesis of liposomes
7. Synthesis of nanoemulsions
8. Synthesis of organic-inorganic hybrid systems
   a) Magnetic NPs inside micelles
   b) Magnetic NPs inside liposomes
9. Synthesis of drug-loaded nanoparticle systems
   a) Magnetic nanoparticles-drug loaded micelles
   b) Drug loaded micelles
   c) Drug loaded liposomes
   d) Drug loaded nanoemulsion

**Part 2: Characterization of Nanoparticles**

**Physical Characterization**

Particle size and zeta potential (3 experiments)
- Size and size distribution of various NPs
- Effect of pH, buffer, solvents, chemicals on the size, size distribution and surface charge.

**Chemical Characterization**

Use of UV-vis spectrophotometer for the following: (3 Experiments)
- Size determination of QDs
- Size determination of Au NPs and Au NRs
- Quantification of drug loading in polymer NPs