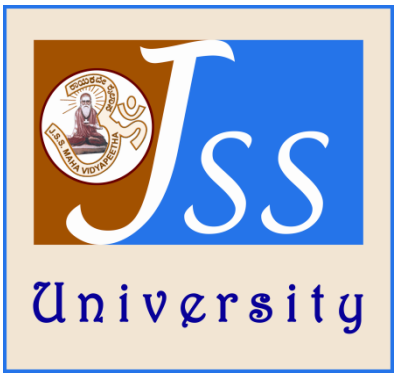
PG Diploma in Pharmacy

Regulations and Syllabus

2011-12



JSS UNIVERSITY

(Established under section 3 of UGC Act, 1956)

JSS Medical Institutions Campus, Sri Shivarathreeshwara Nagar, Mysore - 570 015,

PG Diploma in Dentistry

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REGULATIONS

&

SYLLABUS

POST GRADUATE DIPLOMA COURSES IN

PHARMACY

2011

JSS UNIVERSITY
SRI SHIVARATHREESHWARA NAGAR
MYSORE – 570 015

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-I Branches in Postgraduate diploma courses.

No.	Specialization	Code
1	Bio informatics	DBI
2	Pharmacovigilance	DPV
3	Pharmaceutical quality assurance	DQA
4	Herbal product & their standardization	DHP
5	Pharmaceutical regulatory affairs	DRA
6	Nanotechnology	DNT
7	Clinical research	DCR
8	Medicine and Poison Information	DMP

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

Sl. No.	Specialization	Paper	Name of the Subject	Code
1	Bio informatics	I	Basic cellular and Molecular Biology	DBI01
		II	Bioinformatics and *In Silico* Biology	DBI02
2	Pharmacovigilance	I	Principles of Pharmacovigilance	DPV01
		II	Regulatory Perspectives of Pharmacovigilance	DPV02
3	Pharmaceutical quality assurance	I	Quality Assurance and Quality Control	DQA1
		II	Pharmaceutical Validation	DQA2
4	Herbal products & their standardization	I	Herbal Drug Technology	DHP1
		II	Quality control of Herbal products	DHP2
5	Pharmaceutical regulatory affairs	I	Pharmaceutical cGMP and Validation	DRA01
		II	International Regulatory Requirments	DRA02
6	Pharmaceutical Nanotechnology	I	Nanocarriers for Drug Delivery	DNT1
		II	Characterization and Applications of Nanocarriers	DNT2
7	Clinical research	I	Clinical Development and regulations	DCR1
		II	Clinical Research	DCR2
8	Medicine and Poison information	I	Medicine Information	DMP1
		II	Poison Information	DMP2

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

	Examination				Total Marks
	Sessional		Annual		
	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**

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:

Sl. No.	CHAPTER	No. of hours
1.	Definition - Quality control and Quality assurance, concept and philosophy of TQM, GMP, ICH and ISO 9000.	**08 Hrs**
2.	Quality control test for containers, closers, caps, secondary packing materials and line clearance.	**08 Hrs**
3.	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 Hrs**
4.	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	**12 Hrs**

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:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

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 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)

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

Sl. No.	CHAPTER	No. of hours
1.	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 Hrs**
2.	A Review of Prospective, Concurrent, Retrospective Validation & Revalidation including the use of Statistical Process Control (SPC)	**05 Hrs**
3.	Validation of Water (Demineralised, Distilled and Water for Injection) & Thermal Systems, including Heat Ventilation and Air conditioning (HVAC), Facilities & Cleaning Validation	**05 Hrs**
4.	Process Validation of Active Pharmaceutical Ingredients (APIs) and finished products	**10 Hrs**
5.	Validation of Sterile and Non-Sterile Facility	**10 Hrs**
6.	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 Hrs**

RECOMMENDED BOOKS:

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

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

LECTUREWISE PROGRAMME:

Sl. No.	CHAPTER	No. of Hours
1.	History of the nanomedicine, Fundamentals and rationale of sustained/controlled/targeted drug delivery	05 Hours
2.	Needs and Requirements of Nanocarriers, Nanoparticle fl ow: Implications for drug delivery	10 Hours
3.	Polymers used for the formulation of nanoparticles- Classification and applications for polymers	10Hours
4.	Classifications of nanocarriers- Liposomes, Dendrimers, Polymeric micelles, Nanoparticles (Polymeric and Lipid based), Nanoemulsions,	15Hours
5.	Method of preparation,	10Hours

Paper II- Characterization and Applications of Nanocarriers (DNT2)

LECTUREWISE PROGRAMME:

Sl. No.	CHAPTER	No. of Hours
1.	Characterization of nanoparticles	05 Hours
2.	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.	20 Hours
3.	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,	15 Hours
4.	Societal Implications and Regulatory guidelines	05 Hours
5.	Medical applications	05 Hours

References:

1. Dr. Parag Diwan and Ashish Bharadwaj (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, Pornanong Aramwit, Glen S. Kwon (Eds.) Nanotechnology in drug delivery, Springer
4. Deepak Thassu, Michel Deleers, Yashwant Pathak (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. Jörg Kreuter (Ed.) Colloidal drug delivery systems, Marcel Dekker (1994).

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:

Sl. No.	CHAPTER	No. of Hrs
1	Concept of Quality, Total Quality Management. Quality by design, six sigma concept. Stability testing: ICH and WHO guidelines, Photostability studies.	8
2	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	8
3	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.	9
4	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	8

	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)	9
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	8

RECOMMENDED BOOKS

1. Pharmaceutical master validation plan: The ultimate guide to FDA, GMP and GLP Compliance by Syed Imitiaz Haider
2. Pharmaceutical dosage forms: Parenterals Vol-2, II Edition, by Kenneth EA and Leon Lachman
3. Pharmaceutical Process Validation**,** 3rd Edition, Edited by Robert Nash and Alfred Wachter, Marcel Dekker
4. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control From Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
5. Quality planning and Analysis by JM Juran and FM Gryna, Tata McGrawHill- India.
6. Total Quality Management, Dale H. Besterfield, Pearson Education, 3rd Ed., 2003.
7. Total Quality Management, Principles, Implementation & Cases, Sharma D.D., Sultan Chand & Sons, New Delhi, 2000.

Paper II-International Regulatory Requirements (DRA02)

50 Hours

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:

Sl. No.	**CHAPTER**	**No. of Hrs**
1	Generic Drug Product development: Introduction, 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,* Scale up Post approval changes, Post marketing surveillance. Outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations, Pharmaceutical Labeling, Advertising and	10

	Promotion.	
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.	10
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.	10
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)	10
5	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

RECOMMENDED BOOKS

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. 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.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

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.
9. Documentation for audits and inspection of manufacturing facilities.
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.
14. Preparation of a Clinical Trial Protocol for submission to Regulatory agency.
15. Preparation and documentation for Indian Patent.
16. Patent challenge / non infringement (Para IV) case studies.

PG Diploma in Herbal Products and Their Standardization DHP

Paper-I-Herbal Drug Research DHP1

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 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

Paper II- Industrial Herbal Drug Technology DHP2

50Hrs : (2Hrs/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. 08Hr

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:

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 Delhi,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 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:

CHAPTER **No. of Hours**

1. **Drug development process** **0**3 hours
   - Investigational new drug development
   - New drug development
   - Abbreviated New Drug Development
2. **Clinical drug development phases** 06 hours
   - 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?)
3. **Requirements in clinical research** 04 hours
   - Good clinical practice (ICH GCP E6)
   - Clinical trial materials (Documentation, Investigational drugs, logistical materials)
4. **Ethics issues in clinical research** 05 hours
   - Ethics committees, constitution and practices
   - Declaration of Helsinki and Informed consent process

- 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:

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 (DCR2)

THEORY **50 HOURS**

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:

Sl. No.	CHAPTER	No. of Hours
1	**Historical Perspectives:**	02 hours

- Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report
- The declaration of Helsinki
- Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

2 Informed Consent Process: 02 hours

- 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

3 Types and Design of clinical trials 10 hours

- Randomized trials and uncontrolled trials
- Crossover and factorial designs
- Equivalence, non-inferiority and superiority trials

- Bioequivalence and bioavailability studies
- blinding (single, double)

4 Clinical Trial Study Team 04 hours

Roles and responsibilities of:

- Investigators
- Study Coordinator
- Sponsor
- Monitor
- Contract Research Organization

5 Clinical Trial Documents 10 hours

- 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 10 hours

- 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:

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.

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

PG Diploma in Medicine and Poison information (DMP)

PAPER I- Medicine Information (DMP1)

50 Hours

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

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

References

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

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

Sl. No.		Topic	Hours
1		Definition, aim/objectives, Indian and global scenario of PIC	01
2		Organization and functions of PIC	04
3		Systematic approach to poison information queries	03
4		Role and responsibilities of poison information specialist	01
5		Preventive measures for accidental poisoning	01
6		General principles involved in the management of poisoning	04
7		Antidotes and the clinical applications	01
8		Supportive care in clinical Toxicology	02
9		Gut Decontamination	02
10		Elimination Enhancement	01
11		**Clinical symptoms and management of acute poisoning with the following agents**	
	A	Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, Pyrethroids, Aluminum and zinc phosphide	08
	B	Opiates overdose	01
	C	Antidepressants	03
	D	Barbiturates and benzodiazepines	02

	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:

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

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)

1. 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 **04 hrs**

2. Molecules of Life: Introduction to carbohydrates, proteins and lipids Nucleic acids-Purines, pyrimidines, Nucleosides and Nucleotides, structure of DNA, denaturation and renaturation of DNA **05 hrs**

3. DNA replication: Protien synthesis-Eukaryotic and Prokaryotic, Transcription and Translation **09 hrs**

4. 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.Mutation-Types of mutations,types of mutagenic agentsand their molecular mechanism;DNA repair,Chromosomal types and structure **06 hrs**

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 **06 hrs**

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 Inheritence in Man.Linkage map resources.Practical uses of genome maps:Locating genomic regions,target identification,arrangement of genes,SNP diagnosis,positional specific cloning. 10hrs

7. 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. 10hrs

REFERENCE:

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 *Insilico* Biology (DBI-2) Total: 50 hrs

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 **05 hrs**

2. Introduction to sequence aligment. Sudstitution matrices, scoring matrices – PAM and BLOSUM. Local and Global alignment concept, Dot plot. **10 hrs**

   Dynamic programming methodology: Needleman and Wunsch algorithm. Smith-Waterman algorithm. Statistics of aligment score. Multiple sequence alignment. Progressive alignment. Database search for similar sequences using FASTA and BLAST programs

3. Evolutionary analysis: distances, Cladistic and phenetic method. Clustering method. Rooted and unrooted tree representation.use of cluster and PHYLIP **05 hrs**

4. Concepts of secondary structure prediction of RNA and protein. **05 hrs**

   Probabilistic model: Markov chain, Hidden Markov Models-other applications

5. Gene finding methods. Gene prediction: Anaysis and prediction of regulatory regions. Fragment assembly. Genome sequence assembly, Restriction Mapping, Repeat sequence finder. **07 hrs**

6. Comparative Gnomics: purpose and Method of comparison, Tools for genomic comparison: Application of comparative Genomics, Reconstruction of metabolic pathway, Predicting regulatiry elements, Identifing targets, examination of domain function, analysis of conserved regions. Genome projects and Model Organism research –Yeast; C. Elegans; and Mouse – a comparative analysis **10 hrs**

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). **08 hrs**

REFERENCE:

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.

Bioinformatic (DBI)

Practical

1.Data retrival tools and methods

2.Biological Databanks Sequence Databases.

3.Structure Databases

4.Subcellular localization prediction

5.Database file formats

6.Molecular visualization

7.Gene structure and fuction prediction

8.sequence similarity searching(NCBI BLAST)

9.Protien sequence analysis(ExPASy proteomics tools)

10.Multiple sequence alignment(Clustal)

11.Molecular phylogeny(PHYLIP)

12.Analysis of protein and nucleic acids sequences

13.Protien 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 land mark judgments on IPR issues.

LECTUREWISE PROGRAMME:

Sl. No.	CHAPTER	No. of hours
1.	**Understanding Law And Legal System In General**: Introduction to law, understanding legal system, Various organs of Legal System, law enforcement in India.	**06 Hrs**
2.	**The Indian legal system:** What is a ' Constitution'?, The Nature of the Indian Constitution, Salient Features of the Indian Constitution, Basic structure of the Constitution, Citizenship, Fundamental Rights and Duties, Directive principles of state Policy, Structure of Government, Courts of Law, The Amendment of the Constitution.	**07 Hrs**
3.	**Law of property:** Nature of Property, Classification of property, Modes of holding ownership, Intellectual Property Rights.	**05 Hrs**
4.	**Fundamentals of Patent Law:**Criteria of Patentability, Invention, Novelty, Utility, Inventive step/ Non-obviousness, Non-patentable Inventions.	**06 Hrs**
5.	**Drafting of patent specification:** patent specification, provisional specification, complete specification.	**05 Hrs**

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. **05 Hrs**

7. **Patent infringement:** Infringement of a patent, Defenses, Compulsory licensing, Remedies. **05 Hrs**

8. **International patent regime:** An Introduction to European Patent Convention, Paris Convention; TRIPS Agreement; Budapest Treaty; Patent Cooperation Treaty I.P **06 Hrs**

9. **Patentability of software inventions:** Introduction, Comparision between India, US and Europe patentability of software inventions **05 Hrs**

RECOMMENDED BOOKS:

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

REFERENCE BOOKS:

1. B.L Wadhera- Intellectual Property
2. WIPO - Reading Material on Intellectual Property Law
3. Brainbridge, David – Cases and Materials in Intellectual Property Law
4. Cornish W.R - Cases and Materials in Intellectual Property Law
5. Dr.S.K Singh- Intellectual Property Rights Laws
6. Patents(Amendment) Act, 2002
7. Copy Right Act, 1957
8. Trade Marks Act, 1999.
9. The Biological Diversities Act, 2002
10. The Protection of Plant Varieties and Farmers' Right Act, 2001
11. Geographical Indications of Goods (Registration and Protection) Act, 1999

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:

Sl. No.	CHAPTER	No. of hours
1.	**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.	**05 Hrs**
2.	**Subject matter of copy right:** Literary Works, Dramatic Works, Musical Works; Artistic works, Cinematograph Films and Sound Recordings, Term of Protection.	**05 Hrs**
3.	**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.	**06 Hrs**
4.	**Computer Software, Digital Environmental and Intellectual Property Protect:** Copyright Protection,	**05 Hrs**
5.	**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.	**08 Hrs**
6.	**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	**05 Hrs**

trademark

7. **Concepts of trademark:** Procedure For Obtaining Registration of Trademark, Rights Of The Owner of Trademarks, Infringement of Trademark and Action for Passing Off. **05 Hrs**

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. **05 Hrs**

9. **Protection of Geographical Indications:** Justification for Protection, Definition; International Position, Geographical Indications Protection in India. **06 Hrs**

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.

Some selected case laws on IPR: (Common to Paper I & II)

1. Cadilla Health Care Ltd v. Cadilla Pharmaceuticals Ltd (2001) 5 SCC 73
2. Scotch Whisky Association v. Pravara Shanksr Karkhana AIR 1992 Bom 294
3. Diamond v. Chakraborthy 447 US 303 (1980)
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
13. Natco Pharma Ltd v. Bayer Corporation (13th March 2012)
14. Novartics AG v. Union of India (2013)
15. Kamal Trading Co v. Gillette U.K Ltd (1998) 1 PCR 135
16. Amrathadhara Pharmacy v. Satya Deo AIR 1963 SC 449
17. University London Press v. University Tutorial Press (1916) 2 Ch 601
18. Macmillan v. COOPER air 1924 PC 75
19. Express News Papers v. Liverpool Daily Post and Echople (1985) 1 WLR 1089
20. Najma Heptulla v. Orient Longman Ltd AIR 1989 Del 63
21. Walter v. Lane (1900) AC 539
22. Manu Bhandari v. Kala Vikas Pictures AIR 1987 Del 1
23. Amarnth Segal v. Union of India (2002) 25 PT 56
24. R.G Anand v. Delux Films AIR 1978 sc 1613.
25. Anil Gupta v. Kunal Das Gupta (2002) 25 PTC 1

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.
7. Case studies of current trademark infringements.
8. Case studies of current copyright infringements.
9. Case studies of current design infringements.
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.

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.

LECTUREWISE PROGRAMME:

Sl. No.	CHAPTER	No. of hours
1.	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.	**05 Hrs**
2.	Skin moisturization: Natural moisturizing factor, Ceramide lipids and occlusive layer	**02 Hrs**
3.	Pigmentation and skin whitening actives. Basic understanding of mechanism of action of the actives.	**02Hrs**
4.	Acne, Causes and anti-acne actives. Aging principles, Skin –anti-aging ingredients, and their mechanism of action.	**03 Hrs**
5.	Body odor and its causes. Mechanism of action of antiperspirants and deodorants. Prickly heat- causes and treatment	**03 Hrs**

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 pheylenediamine (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:

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 & 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:

Sl. No.	CHAPTER	No. of hours
1.	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.	**05 Hrs**
2.	Indian and EU regulation: Regulation with respect to preservative, Sunscreen, allergens and labelling requirements.	**05 Hrs**
3.	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	**04 Hrs**
4.	Introduction to Packaging materials Plastics, metals, laminates, glass, Paper and Paper Board. Classification and application	**06 Hrs**
5.	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 Hrs**

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
9. Private body regulation – Cosmos, Whole foods, Natural product association.
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, andappreciate):

- 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:

Sl. No.	CHAPTER	No. of Hours
1	History of the nanomedicine, Fundamentals and rationale of sustained/controlled/targeted drug delivery	**08**
2	Needs and Requirements of Nanocarriers in medicine: Systemic drug delivery and localized drug delivery	**15**
3	Classifications of nanocarriers- Liposomes, Dendrimers, Polymeric micelles, Nanoparticles (Polymeric and Lipid based), Nanoemulsions, Inorganic-based nanoparticles	**10**
4	Materials used for preparation of nanoparticles: Polymer, lipids, surfactants, inorganic salts	**05**
5	Method for the preparation of nanoparticles	**12**
	Total	**50**

Paper II - Characterization and Applications of Nanocarriers (DNT2)

THEORY **50 Hours**

LECTUREWISE PROGRAMME:

Sl. No.	CHAPTER	No. of Hours
1	Instrumentation techniques used for the characterization of nanoparticles	**10**
2	Medical applications of nanotechnology	**15**
3	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**
4	Human health and safety- Interaction of nanomaterials with biological systems, Toxicology of nanoparticles- Background, Reactive oxygen species, Biodistribution, Nanotoxicity studies, Immunogenicity of nanoparticles,	**10**

	Complications with nanotoxicity studies- Effect of aggregation of nanoparticles, Challenges of nanovisualization and related unknowns in nanotoxicology, Environmental impact	
5	Societal Implications and Regulatory guidelines of Nanotechnology	**05**
	Total	**50**

References:

1. Dr. Parag Diwan and Ashish Bharadwaj (Eds) Nanomedicine, Pentagon press (2006).
2. Vladimir P. Torchilin (Ed.) Nanoparticulates as drug carriers, Imperial College Press, NorthEastern University, USA (2006).
3. Melgardt M. de Villiers, Pornanong Aramwit, Glen S. Kwon (Eds.) Nanotechnology in drugdelivery, Springer
4. Deepak Thassu, Michel Deleers, Yashwant Pathak (Eds.) Nanoparticulate drug deliverysystems, Informa Healthcare (2007).
5. Ram B. Gupta, Uday B. Kompella (Eds.) Nanoparticle technology for drug delivery,Taylor andFrancis (2003).
6. Jörg Kreuter (Ed.) Colloidal drug delivery systems, Marcel Dekker (1994).

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