CHAITANYA

(Deemed to be University)

Gandipet,Himayathnagar(Vil),Moinabad(Md),Hyderabad,Telanagana.

M.PHARM. SYLLABUS

M. Pharm (Drug Regulatory Affairs)

I SEMESTER

Theory Papers

I. Drug Regulatory Affairs-I
II. Drug Regulatory Affairs-II
III. IPR & Forensic Pharmacy
IV. Laws related to Drug Product Design, Safety & Environment

Practicals

I. Drug Regulatory Affairs-I & II
II. Pharmaceutical Jurisprudence and Laws related to Product design

II.SEMESTER (Theory Papers)

I. Drug Development & Approval Process
II. Regulation of Clinical and Preclinical Studies
III. Good Manufacturing Practices
IV. Formulation Production Management

Practicals

I. Drug Development & Approval Process
II. Formulation Production Management

III.SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV.SEMESTER

Final Seminar on Dissertation (Results)
Dissertation

M.Pharm. I Semester

M.Pharm I Year Semester - I							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1	MDRA-I T	Drug Regulatory Affairs-I	4	4	30	70	100
2	MDRA-II T	Drug Regulatory Affairs-II	4	4	30	70	100
3	MIPR-I T	IPR & Forensic Pharmacy	4	4	30	70	100
4	MLPD- T	Laws related to Drug Product Design, Safety & Environment	4	4	30	70	100
5	MDRA-I&II	Drug Regulatory Affairs-I&II	9	9	30	70	100
6	MIPR &LPD	IPR & Forensic Pharmacy and Laws related to Product design	9	9	30	70	100
7		Seminar					50
8		Assignment					50
		TOTAL	32	**32**	180	420	**700**

M.Pharm. II Semester

M.Pharm I Year Semester - II							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1	MDDAP -T	Drug Development & Approval Process	4	4	30	70	100
2	MRCPS-T	Regulation of Clinical and Preclinical Studies	4	4	30	70	100
3	MGMP – T	Good Manufacturing Practices	4	4	30	70	100
4	MFPM – T	Formulation Production Management	4	4	30	70	100
5	DDAP&RCPS	Drug Development & Approval Process	9	9	30	70	100
6	GMP&FPM	Good Manufacturing Practices	9	9	30	70	100
7		Seminar					50
8		Assignment					50
		TOTAL	32	**32**	180	420	**700**

M.Pharm. III Semester

	Marks
Seminar (Pertaining to the topic of research and work plan)	50
Comprehensive viva-voce	50
Total	**100**

M.Pharm. IV Semester

	Marks
Seminar (Experimental Work, Results, Discussion and Conclusion)	50
Dissertation evaluation	200
Dissertation Viva-Voce	50
Total	**300**

PAPER I. DRUG REGULATORY AFFAIRS – I (As per USA): (Theory) **4hrs/week**

Scope

This subject deals with various regulatory authorities and stages of drug development process for Obtaining approval by FDA

Learning outcomes/Objectives:

After completion of course student is able to understand:

- Introduction to regulatory affairs which include historical overview and current scenario.
- Understand steps for development of new chemical entities
- Data presentation/Dossier preparation
- Various regulatory requirements for drug approval which includes different Applications
- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process

Unit-1

Regulatory Affairs: Introduction, Historical overview of regulatory affairs, Regulatory Authorities, role of regulatory affairs department, Responsibility of regulatory affairs department.

Unit-II

Drug Regulatory Aspects (India)

Central Drug Standard Control Organization (CDSCO), State Licensing authority,

Central and State regulatory bodies (FDA)

Unit-III

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, cosmetics and biotechnological products, with special emphasis on:

a. History of drug regulation in USA.
b. Organization and functions of FDA.
c. General definitions.
d. Adulterated & misbranded drugs/cosmetics/biotechnological products.
e. OTC drugs, Orphan drugs, Orange Book and Fast Track Products.
f. Common Technical Document (CTD).

Unit-IV

A detailed study of Federal Food, Drugs and Cosmetics Act of USA, restricted to human drugs, with special emphasis on:

Principles of General Drug discovery and development: Introduction, Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA).

Unit-V

Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance.

TEXT BOOKS:

1. Guidebook for drug Regulatory submissions by Sandy Weinberg, Clayton state university, Copyright © 2009 by John Wiley & Sons, Inc. Published by John Wiley & Sons, Inc., Hoboken, New Jersey
2. Real World Drug Discovery, A Chemist's Guide to Biotech and Pharmaceutical Research by Robert M. Rydzewski Copyright _ 2008 Elsevier Ltd Elsevier The Boulevard, Langford Lane, Kidlington, Oxford OX5 1GB, UK, Radarweg 29, PO Box 211, 1000 AE Amsterdam, The Netherlands
3. Reliable design of medical devices / Richard C. Fries.--2nd ed Published in 2006 by CRC Press Taylor & Francis Group 6000 Broken Sound Parkway NW, Suite 300 Boca Raton, FL 33487- 2742

REFERENCES:

1. New Drug Approval Process, R.A.Guarino,4th Edition , Marcel Dekker, NY
2. New Drug Approval Process Global Challenges and Solutions RICHARD A. GUARINO., Fifth Ed. informa Healthcare
3. DRUGS From Discovery to Approval, Second Edition RICK NG, A-Bio Pharma Pte Ltd, Singapore, Copyright © 2009 Published by John Wiley & Sons, Inc., Hoboken, New Jersey
4. New Drug Development: Regulatory Paradigms for Clinical Pharmacology and Biopharmaceutics, edited by Chandrahas G. Sahajwalla
5. Drug discovery from Bedside to Wall Street Tamas Bartfai& Graham V. Lees, 2006, ElsevierInc Elsevier Academic Press, 30 Corporate Drive, Suite 400, Burlington, MA 01803, USA
6. Drug discovery and development / edited by Mukund S. Chorghade Copyright © 2007 by John Wiley & Sons, Published by John Wiley & Sons, Inc., Hoboken, New Jersey.
7. FDA administration enforcement manual/ Florence R. Parker, © 2005 by CRC Press LLC, CRC Press LLC, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431.(Taylor & Francis roup, the academic division of T&F Informa plc.)
8. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition Published by *Commercial* Law Publishers (India) Pvt. Ltd., Dehli.
9. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
10. Protection of Industrial Property rights by P.Das and Gokul Das
11. Websites: fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org
12. Marketing authorization of pharmaceutical Products with special reference to Multisource (generic) products: A manual for drug regulatory authorities WHO Division of Drug Management and Policies in Geneva from 7 to 8 April and 6 to 8 July 1998

PAPER II. DRUG REGULATORY AFFAIRS – II (Highly Regulated Markets like EU and Japan): (Theory) 4 hrs/week

Scope

This course is designed to impart the fundamental knowledge on Registration of drugs, clinical development process of drugs, pharmaceuticals and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, Japan and EU. It prepares the students to learn in detail on various laws, legislations and guidance related to safety, efficacy, ethical conduct and regulatory approval of clinical research.

Objectives

- Upon completion of the course, the student shall be able to (know, do and appreciate)
- Clinical drug, medical device development process and different types and phases of clinical trials
- Regulatory requirements and guidance for conduct of clinical trials and research
- To study about safety and adverse effects of drugs

UNIT – I

a. Drug regulatory authorities in European Union (EU)/Japan-- Introduction, Organizationand General Guidelines.

b. Regulatory consideration for pre-clinical testing and clinical testing in EU.

UNIT – II

a. Registration application for marketing approval (IND, NDA, ANDA) in EU.

b. Drug Master Files in EU.

UNIT – III

Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU. Marketing procedure of drugs/drug products in EU and Japan

UNIT – IV

The WHO Guidelines – The WHO Guidelines and their relevance in international registration. The WHO certification scheme on the quality of pharmaceutical products moving in international commerce.

UNIT – IV

Introduction to Pharmacovigilance.

REFERENCES

1. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
2. HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4. Reviewing Clinical Trials: A Guide for the Ethics Committee; Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong.
5. International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.

6. New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
7. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
8. Country Specific Guidelines from official websites.
9. Textbook on clinical research: A guide for Aspiring professionals and Professionals, Guru
10. Clinical trials of drugs & biopharmaceuticals; Chi-Jen Lee, Lucia H. Lee, Christopher L. Wu, Benjamin R. Lee, Mei-Ling Chen, CRC press
11. Drug Screening Methods by S.K.Gupta
12. Basic Principles of clinical Research & Technology by S.K.Gupta

PAPER III. Intellectual Property Rights & Forensic Pharmacy: (Theory) 4 hrs/Week

Scope: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India.

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

- The Pharmaceutical legislations and their implications in the development and marketing
- Various Indian pharmaceutical Acts and Laws
- The clear information about the patent laws, intellectual property rights and drug regulation in India and abroad is gained by the students.
- The code of ethics during the pharmaceutical practice

A detailed study of the following laws, including latest amendments in India:

UNIT – I

The Drugs and Cosmetics Act, 1940 and Rules there under (Including Manufacturing,Distribution, Import, Export and Sales) and The Drugs (Prices Controls) Order, 1955.

UNIT – II

a. Drug Registration Application for marketing approval as applicable in India.
b. Regulatory requirements for Biosimilars.

UNIT – III

Introduction, Types of Intellectual Property Rights (Patents, Trademarks, Copyrights, Geographical Indications Industrial Designs and Trade secrets), Patentable Subject Matter (Novelty, Non- Obviousness, Utility, enablement and Best mode).

UNIT – IV

Property Rights:

a. Types of IP, definition, scope, objectives Patents, types, contents of patent, claims and types of claims, key terminology used in patents- inventor, anticipation, obviousness, infringement and invalidation. Patent information and research.
b. Indian patent act and post 1995 amendments, US and European patent act.

Unit-V

Salient features of Indian Patents (Amendments) Act 1999, 2002 and 2005. US and European Patent System, b. Background, Salient Features and Impact of International Treaties / Conventions like

1. Paris Convention, Berne convention
2. World Trade Organization (WTO)
3. World Intellectual Property Organization (WIPO)
4. Trade Related Aspects of Intellectual Property Rights (TRIPS)
5. Patent Co-operation Treaty (PCT) and Paris convention

Reference:

1. Guidelines of various countries like MCA, TGA, ICH.
2. Drug and cosmetic act 1940 and rules their under
3. IPR Lecture notes
4. GLP regulation by Alen Hirsch Vol 38 Marcel Decker series
5. GMP for pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
6. I.P., B.P., U.S.P. International Pharmacopoeia
7. Pharmacokinetics, Regulatory, Industrial, academic prospective by P. G. Willing and F.T.S. Tse.
8. Law and Drugs, Law Publications by S.N. Katju
9. Laws of drugs in India, Hussain 8. New drug approval process, 5th edition, byGuarino 9. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition
10. Drugs and Cosmetics act by Vijay Malik
11. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
12. fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org
13. Current good manufacturing practices for pharmaceuticals by Manohar A. Potdar

PAPER IV. LAWS RELATED TO DRUG PRODUCT DESIGN, SAFETY & ENVIRONMENT: (Theory) 4 hrs/week

Scope: This course is designed to impart basic knowledge on Laws and safety of drugs.

Unit- I

An introductory study of following laws of that affect drug product design, manufacture and distribution in India (with latest amendments) :

a. The Environmental Protection Act

b. Consumer Protection Act c. Law of Torts

Unit -II

I. An introductory study of following laws of that affect drug product design, manufacture and distribution in India (with latest amendments): a. Law of Contracts b. Monopolistic & Restrictive Trade Practices Act

II. Auditing of manufacturing facilities by International regulatory agencies. The ISO 9000 series of quality systems standards & ISO 14000.

Unit -III

Industrial Safety

Industrial hazards due to fire, accident, mechanical, electrical equipment, monitoring and Preventive system (Safety measures including insurance).Effluent testing, treatment and waste management.

Unit -IV

Globalization of drug industries: Export import policy of drugs, WHO –certification, Trademarks and copyrights.

Unit -V

Schedule M & U requirements- Product development stage documentation, factory procedures – Standard Operating Procedures (SOPs) and Standard Test Procedures (STPs).

. Reference Books:

1. Drugs and Cosmetics Act, 1940 and its rules, published by Ministry of health and family welfare,
2. Government of India. Pharmaceutical Jurisprudence, G.K. Jani.
3. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
4. Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices – John J.Tobin and Gary Walsh.
5. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus .

6. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu.
7. Pharmaceutical Patent Law – John R. Thomas.
8. http://cdsco.nic.in
9. Original laws published by Govt. of India.
10. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
11. Laws of Drugs in India by Hussain.
12. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.

I-Semester

(PRACTICALS)

PAPER I. DRUG REGULATORY AFFAIRS – I & II **9 hrs/ week**

Based on the contents of the theory Paper I and II including mock inspections, auditing and document/ report writing and evaluation of reports. Preparation of dossiers for filing.

PAPER II. . LAWS RELATED TO DRUG PRODUCT DESIGN, SAFETY & ENVIRONMENT 9 hrs/ week

Based on the contents of the theory Paper III and IV
Preapration of Documents/reports, Writing, auditing and inspection and evaluation. Preparation of dossiers for filing.

II– Semester

PAPER I DRUG DEVELOPMENT &APPROVAL PROCESS: 4hrs/week

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing and safety management.

Student Learning Outcomes/Objectives:

At completion of this course it is expected that students will be able to:

- Understand about drug development stages and process for filing
- Understand about environmental problems among learners.
- Understand about patenting of developed lead molecule.
- Impart basic knowledge about the environment and its allied problems
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an idea to clear mechanism and management in different kinds of hazard management system

UNIT – I

Drug development stages: target selection, pre-clinical development and clinical development.

UNIT – II

New Drug approval process:

A. National drug regulatory requirements, national drug policy, Drugs and Cosmetics Act and its amendments, Overview of schedules, details of schedule M, Schedule Y.
B. FDA guidelines on IND, new drug approvals (NDA), ANDA approvals. European regulatory agency, types of filing process (Centralized, de-centralized, RMS countries).

UNIT – III

Generic drugs and Drug product approval:

Generic and product development (Orange book), 505 (b) (2) applications launch, post-launch and life cycle management.

UNIT – IV

Drug development in industry:

Company organization, Setup of drug development in large, medium, small and virtual pharmaceutical companies, interdisciplinary project teams and interactions.

UNIT – V

Registration of Drugs products in overseas Market:

Procedure for export of pharmaceutical products, Technical documentation,Drug master file,Electronic common technical document (eCTD), ASEAN common technical document (ACTD) research.

TEXT BOOKS:

1. New Drug Approval Process, R.A.Guarino,4th Edition , Marcel Dekker, NY
2. New Drug Approval Process Global Challenges and Solutions RICHARD A.GUARINO., Fifth Ed. informa Healthcare
3. DRUGS From Discovery to Approval, Second Edition RICK NG, A-Bio Pharma Pte Ltd, Singapore, Copyright © 2009 Published by John Wiley & Sons, Inc., Hoboken, New Jersey
4. New Drug Development: Regulatory Paradigms for Clinical Pharmacology and
5. Biopharmaceutics, edited by Chandrahas G. Sahajwalla Published by Informa Healthcare
6. Drug discovery from Bedside to Wall Street Tamas Bartfai& Graham V. Lees, 2006,ElsevierInc Elsevier Academic Press, 30 Corporate Drive, Suite 400, Burlington, MA 01803, USA
7. Drug discovery and development / edited by Mukund S. Chorghade Copyright © 2007 by John Wiley & Sons, Published by John Wiley & Sons, Inc., Hoboken, New Jersey.

REFERENCES:

1. New drug development Design methodology and, analysis by J. Rick Turner , 2007, WILEYINTERSCIENCE A John Wiley & Sons, Inc., Publication Published by John Wiley & Sons, Inc., Hoboken, New Jersey
2. Drug-like Properties: Concepts,Structure Design and Methods:from ADME to Toxicity Optimization, Edward H. Kerns and Li Di, Copyright © 2008, Elsevier Inc, Academic Press is an imprint of Elsevier , 30 Corporate Drive, Suite 400, Burlington, MA 01803, USA
3. FDA administration enforcement manual/ Florence R. Parker, © 2005 by CRC Press LLC, CRC Press LLC, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431.(Taylor & Francis Group, the academic division of T&F Informa plc.)
4. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition Published by *Commercial* Law Publishers (India) Pvt. Ltd., Delhi.
5. Drugs and Cosmetics act by Vijay Malik Publisher: Eastern Book Company
6. Protection of Industrial Property rights by P.Das and Gokul Das
7. Law and Drugs, Law Publications by S.N. Katju
8. Original Laws Published by Govt. of India
9. Websites: fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org

PAPER II: Regulation of Preclinical and Clinical Studies: 4hrs/week

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GCP for Pharmaceuticals and to know about how to do clinical trials.

Objectives:

After completion of this course students are able to understand

1. Development of lead molecules and their characteristics.
2. Regulatory authorities to conduct clinical trials.
3. Clinical trial methods and development

UNIT – I

Developability of drug molecules

a.Drug properties (solubility, permeability), optimization and selection of lead candidates.

b. BCS classification of drugs. C. Preformulation studies (compatibility, polymorphism)

UNIT – II

Regulation of preclinical studies

a. Lead Molecule Selection: Pharmaceutical Profiling and Toxicity Assessments, Toxicity Evaluations, Utilizing the Preclinical Database to Support Clinical Drug Development
b. Regulations and issues related to preclinical evaluation of drugs and biologics in animal models/alternate to animal models.

UNIT – III

Regulation of Good Laboratory Practices:

FDA GLP regulations, Indian, and International (OECD) regulation, Regulation of Computer systems, Implementing GLPS in non- GLP analytical Laboratory, Controlling the good laboratory practices inspection process.

UNIT – IV

Design of clinical studies

a. Study design and methodology in clinical trials, ethical aspects of design and methodology, responsibilities of sponsor, monitor and investigator
b. Enrollment strategy, study completion best practices, detection of fraud and misconduct.

UNIT – V

Regulation of clinical studies

a. Efficacy & safety assessment in clinical trials, Adverse Events (AEs) versus Serious Adverse Events (SAEs). Assessment, recording and medical management of AEs, Unblinding because of an AE, expedited reporting of SAE and handling a subject death in a clinical trial (Phamacovigilance strategies and reporting).

b. Global regulations for Good Clinical Practices (GCPs): Obligationsof Investigators, Sponsors, and Monitors, Quality Assurance, Managing and Monitoring Clinical Trials,

Text Books:

1. Drug Discovery and Evaluation Safety and Pharmacokinetic Assays _by H. GerhardVogel (Ed.)
2. Franz Jakob Hock, Jochen Maas,Dieter Mayer Springer-Verlag Berlin Heidelberg New York 2006, Printed in Germany
3. Hand Book of Drug Screening by Ramakrishna S, and Prabavathi B F volume 114, 2001 ,
4. Marcel Dekker, Inc. 270 Madison Avenue, New York, NY 10016
5. Clinical Drug Trials and Tribulations Second Edition\Clinical Drug Trials and Tribulations Second Edition, M eedited by Allen Cato, Lynda Sutton, Cato Research Ltd. Durham, North Carolina, Allen Cato III, Cato Research Ltd.San Diego, California2002Marcel Dekker, Inc.Marcel Dekker, Inc. New York • Basel
6. Clinical Research in Pharmaceutical Development, edited by Barry Bleidt and Michael Montagne c 2002 Marcel Dekker, Inc. Marcel Dekker, Inc. 270 Madison Avenue, New York, NY 10016
7. Drug Products for Clinical Trials: An International Guide to Formulation, Production, Quality Control, edited by Donald C. Monkhouse and Christopher T. Rhodes Marcel Dekker, Inc. New York.

REFERENCES:

1. FDA regulatory affairs : a guide for prescription drugs, medical devices, and biologics edited by Douglas J. Pisano, David Mantus. © 2004 by CRC Press LLC CRC Press LLC, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431, Printed in the United States of America
2. Global Regulatory Issues for the Cosmetics Industry Volume 1Edited by C. I. Betton Delphic HSE Solutions Ltd, England, Copyright © 2007 by William Andrew Inc Published by: William Andrew Inc. 13 Eaton Avenue, Norwich, NY 13815
3. New Drug Development: A regulatory Overview by Mark Mathieu
4. FDA Regulatory: A guide for prescription drugs, Medical Devices, & Biologics. Douglas J. Pisano, David Mantees. CRC Press
5. Good Drug Regulatory Practices-A Regulatory Affairs Quality Manual by Heleene Dumetriu. CRC Press
6. US FDA guidelines - www.**fda**.gov
7. CDSCO guidelines - www.**cdsco**.nic.in
8. EMEA guidelines - www.**emea**.europa.eu
9. ICH guidelines - www.**ich**.org

PAPER III: GOOD MANUFACTURING PRACTICES: (THEORY) 4hrs/week

Scope

This course is designed to impart fundamental knowledge on various Good Regulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals.

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives

Upon completion of this course the student should be able to

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.
- Prepare and implement the check lists and SOPs for various Good Regulatory Practices.
- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

UNIT – I

GXPs in pharmaceutical industry

a. Concepts of GXP, importance of documentation, good laboratory practices (GLPs), goodclinical practices (GCPs) and good manufacturing practices (GMPs).

UNIT – II

Good Laboratory Practices: Good Laboratory Practices (GLP): Scope of GLP, Quality assurance unit, Standard operating procedures (SOP), protocols for conduct of non clinical testing, control on animal house, report preparation and documentation.

UNIT – III

Quality Management Systems.

a. ISO: Introduction to ISO certification procedure.
b. TQM: Principles of TQM, Six sigma concept .
C. Role of Quality Assurance in Manufacturing and compliance.

UNIT – IV

GMPs

Good manufacturing practices for active pharmaceutical ingredients (bulk drug substances),pharmaceutical excipients, pharmaceutical products, sterile pharmaceutical products, biological products.

a. Inspections

Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices.

b.Audits

GMP compliance audit, Definition Summary, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Preparation for Audit, Conducting audit, audit analysis,audit report.

UNIT – V

Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation.

Text Books:

1. Good Clinical, Laboratory and Manufacturing Practices Techniques for the QA Professional, Edited by PA Carson,and N Dent,, The Royal Society of Chemistry 2007, Published by The Royal Society of Chemistry, Thomas Graham House, Science Park, Milton Road, Cambridge CB4 0WF, UK
2. Good laboratory practice: the why and how by Seiler Publisher: Springer; 2ndedition
3. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, VOLUME 2
4. Regulations, Standards, and Guidelines, by Leonard Steinborn, © 2005 by CRC Press, CRC Press, 2000 N.W. Corporate Blvd., Boca Raton, Florida 33431
5. Quality assurance of pharmaceuticals : a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. – 2nd ed. © World Health Organization 2007 WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland.
6. Good Manufacturing Practices for Pharmaceuticals Sixth Edition edited by Joseph D. Nally *Nallianco LLC New Vernon, New Jersey, U.S.A.*

REFERENCES:

1. Good manufacturing practices of Pharmaceuticals by Willig Publisher: C B S Publishers & Distributors
2. cGMP current good manufacturing practices for Pharmaceuticals by Potder
3. Good manufacturing practices for pharmaceuticals by Manohar A Potder
4. How To Practice Glp Good Laboratory Practice Publisher: Vandana Publications
5. A WHO guide to good manufacturing practice (GMP) requirements , New York
6. GMP Audit Template, EU Guidelines, (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4 en.htm)
7. "Frontmatter" CRC handbook of laboratory Safety Edited by A. Keith Furr 5th edition CRC Press, BOCARATON, Florida.

PAPER IV: PHARMACEUTICAL PRODUCTION AND MANAGEMENT: (THEORY)

4hrs/week

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and Optimization techniquesand methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives

Upon completion of this course the student should be able to

- To understand the Pilot –plant techniques and Lay out.
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management

UNIT – I

Pilot plant scale-up technique

a. Pharmaceutical pilot plant, pilot plant design, case studies for tablets, capsules,liquid orals, parenterals, and ointment preparations.

b. Basic requirements-design of product, facility, equipment selection and personnel.

c. API – Synthesis, Pilot study, Technology transfer and bulk drug production,stability testing.

UNIT – II

Nature and scope of production management: locating production and service facilities: Layout planning and analysis: Types of Manufacturing systems and layout – mass production, batch production and selection: Process planning: Aggregate planning and Master production scheduling: Project management – project planning project scheduling PERT and CPM use.

UNIT – III

Materials Management: An introduction to materials management. Material requirement Purchase management, Inventory control, Material handling: Vendor selection Make or buy decision Negotiation: Cost-reduction techniques – Standardization codification and variety reduction: waste management: Value analysis: Determination and description of material quality acceptance sampling plan.

UNIT – IV

Optimization techniques in Pharmaceutical Formulation and Processing: Introduction, Optimization parameters, classical optimization, statistical design, appliedoptimization methods like EVOP, Simplex and Langrangian techniques.

UNIT – V

Formulation and production management:

Plant site selection and layout, Material handling for various pharmaceutical products, service facilities and preventivemaintenance in pharmaceutical companies-Group and individual replacement

BOOKS:

1. The theory and practice of Industrial Pharmacy Leon Lachman, Ph.D.,Lachamn Consultant Services, Inc. Garden City, New York. Herbert A. Lieberman, Ph.D., H.H. Lieberman Associates Inc. Consultant Services, Livingstom, New Jersey, Joseph L. Kanig, Ph.D, Kanig Consulting and Research Associates, Inc Ridgefield Connecticut. Third Edition (Indian Edition) Varghese Publishing House, Hind Rajasthan Building, Dadar Bombay 400017.1987.

2. Pharmaceutical Dosage Forms and Drug Delivery Systems Fifth Edition Howard C. Ansel, Ph.D., Professor and Dean, College of Pharmacy, The University of Georgia. Nicholas G. Popovich , Ph.d., Professor, School of Pharmacy and Pharmaceutical Sciences, Purdue University. Published by Lea & Febiger, Philadelphia, London. 1990.

3. Industrial Pharmacy, Dr. N. Udupa, 1992, II Edition Varghese Publishing House, Bombay.
4. Admn. E.E. and Ebert RJ: Production and Operations Management, 6th Edition, New Delhi prentice Hall of India 1995.
5. Chunawalla and Patel: Production and Operations Management, Himalaya Publishing House.
6. Gopalakrishnan.P and Sundarshan M Hand Book Materials Management New Delhi Prentice Hall of India. 1994.
7. Dutta A.K. Integrated Materials Management New Delhi PhI1986.
8. Buffa E.S. and Sareen: Modern Production Management, New York, John Wiley 2002.
9. GMP for Pharmaceuticals forth edition by S. Willing, J. Stocker Marcel Decker series 1997.
10. I.P.., B.P., U.S.P. International Pharmacopoeia.
11. Pharmaceutical Production and Management by C.V.S.Subrahmanyam

II – Semester

(PRACTICALS)

PAPER I. Drug Development & Approval Process (Practicals) 9 hrs/ week

Practical shall be based on theory Paper I and II. Example experiments:

1. IND protocols
2. NDA protocols
3. Developing a plan that will be suitable from development to approval for new compounds
4. Developing a plan that will be suitable for generic drugs.
5. SUPAC protocols

PAPER II. PHARMACEUTICAL PRODUCTION AND MANAGEMENT (Practicals)
(9 hrs/ week)

Practicals

Student shall carry out a project and submit an assignment consisting of a write up on project suggested for the year which may include.

Organization/ Business case presentations.

Survey of market research to collect information regarding management of a given diseases and disorder (disease management is not there in the theory)

Group discussions and case studies based on theory.

Layouts for API (Tablets, capsules, ophthalmic, parenteral and other formulations)

Evaluation of Glass as packing material.

Evaluation of Plastic as packing material.

M. PHARM (Industrial Pharmacy)

I SEMESTER

1. Bio Pharmaceutics & Pharmacokinetics
2. Pharmaceutical Formulation Technology } *
3. Pharmaceutical Production Management
4. Quality Assurance
5. Seminars/Assignments

II SEMESTER

1. Novel drug delivery systems-I } *
2. Nano based drug delivery systems
3. Pharmaceutical equipment
4. Cosmetic technology
5. Seminars/Assignments

* **Practicals for both papers**

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar on Dissertation (Results)
Dissertation

M.Pharm I Year Semester - I							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1	MBPPK.T	Bio Pharmaceutics & Pharmacokinetics	4	4	30	70	100
2	MPFT.T	Pharmaceutical Formulation Technology	4	4	30	70	100
3	MPPM.T	Pharmaceutical Production Management	4	4	30	70	100
4	MQA.T	Quality Assurance	4	4	30	70	100
5	MBPPK.P	Bio Pharmaceutics & Pharmacokinetics	9	9	30	70	100
6	MPFT.P	Pharmaceutical Formulation Technology	9	9	30	70	100
7		Seminar					50
8		Assignment					50
		TOTAL	32	**32**	180	420	**700**

M.Pharm I Year Semester - II							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1	MNDDS.T	Novel Drug Delivery Systems-I	4	3	30	70	100
2	MNBDDS.T	Nano Based Drug Delivery Systems	4	3	30	70	100
3	MPE.T	Pharmaceutical Equipment	4	3	30	70	100
4	MCT.T	Cosmetic Technology	4	3	30	70	100
5	MNDDS-I	Novel Drug Delivery Systems-I	9	9	30	70	100
6	MNBDDS.P	Nano Based Drug Delivery Systems	9	9	30	70	100
7		Seminar					50
8		Assignment					50
		TOTAL	32	**32**	180	420	**700**

MBPPK- BIO PHARMACEUTICS & PHARMACOKINETICS - 4 hrs/week

Objectives: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, nonlinear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Outcomes: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for nonlinear kinetics.

Unit-I

a. Bio-availability, Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Tests of significance, t-Test, ANOVA.

b. Physico-Chemical properties affecting bioavailability, pH-partition theory, dissolution, surface area, adsorption, complexation, polymorphism etc., and techniques used to enhance dissolution rate.

c. Formulation factors affecting bioavailability of drug in dosage forms of tablets, capsules, Parenterals, liquid orals and topical dosage forms.

Unit-II

Basic concepts of Pharmacokinetics: Compartmental models: one, two and non compartmental approaches to pharmacokinetics. Merits and demerits of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

i. Absorption: Absorption rate constant. Absorption half life, lag time and extent of absorption, AUC.

ii. Distribution: Apparent volume of distribution and its determination.

iii. Metabolism: Metabolic rate constant and its determination.

iv. Elimination: Over all apparent elimination rate constant and half life.

Under the following conditions:

a) Intra venous bolus injection

b) Intra venous infusion

c) Single dose oral administration

d) Multiple dose injections

e) Multiple dosage oral administration

v. Concept of clearance: Organ clearance, total clearance, hepatic clearance, guts wall clearance, lung clearance and renal clearance.

Unit-III

a.Non-linear Pharmacokinetics: concepts of linear and non linear pharmacokinetics, Michaelis-Menten kinetic characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological response.

b.Non compartmental Pharmacokinetics.

Unit-IV

a. **Clinical Pharmacokinetics**: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver and renal disease states.

b. Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chrono pharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Unit-V

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

REFERENCE BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. 2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. 3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh
4. Prakashan.2010.
5. 4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
6. 5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz
7. . Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
8. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
9. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
10. Drug drug interactions, scientific and regulatory perspectives by Albert P. G.

MPFT.T- PHARMACEUTICAL FORMULATION TECHNOLOGY 4hrs/week

Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, and sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control.

Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, and aerosols.

Unit-I

Preformulation studies:

a) Goals of preformulation, preformulation parameters, Methodology, Solid state properties Solubility and Partition coefficient, Drug excipient compatibility by DSC &FTIR.,

b) Various excipients used in pharmaceutical dosage forms.

c) Properties and selection criteria for various excipients like surfactants, viscosity promoters, diluents, coating materials, plasticizers, preservatives, and colours.

Unit-II

a.Solid dosage forms: Improved production techniques for tablets: New materials process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

b.Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalations dosage forms.

Unit-III

Liquid and Semi-solid dosage forms: Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation and evaluation of suspensions, dry syrups and semi- solid dosage forms.

Unit-IV

Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

Unit-V

a. Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers.Manufacturing of small and large volume parenterals and quality control.

b. Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water and air, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

RECOMMENDED BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013.

MPPM.T- Pharmaceutical Production Management: 4hrs/week

Scope:

The course deals with the good manufacturing of the concepts, techniques and applications of production and operation management.

Objectives: Upon completion of this course the student should be able to

- ✓ To understand the Pilot –plant techniques and Lay out.
- ✓ To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- ✓ To elucidate necessary information to transfer technology of existing products between various manufacturing places
- ✓ Ensure safety standards in pharmaceutical industry
- ✓ Provide comprehensive knowledge on the safety management

Unit-I

Pilot Plant Scale-up techniques significance, Pilot study of some important dosage forms like tablets, capsules, sustained release dosage forms and liquid orals. Discussion of parameters like formula, equipment, product uniformity, raw material processing, physical layouts, personal requirements and reporting responsibilities.

Unit-II

Production, Planning, Control and documentation: Production scheduling, forecasting, Render development, Capacity assessment, Production management, Production organization, Productivity, guide to manufacturing facilities of tablets, liquid orals and capsules.

Unit-III

Nature and scope of production management: locating production and service facilities: Layout planning and analysis: Types of Manufacturing systems and layout – mass production, batch production and selection: Process planning: Aggregate planning and Master production scheduling: Project management – project planning project scheduling PERT and CPM use.

Unit-IV

Human resource Development: Personnel training, job specification, job enlargement, labour welfare and training. Business leadership.

Unit-V

Pharma Promotion Management, Strategic issues in Pharma marketing, consumer behaviour in pharmaceuticals, market research, sales management, Brand management, supply management.

REFERENCE BOOKS

1. Industrial Pharmacy, Dr. N. Udupa, 1992, II Edition Varghese Publishing House, Bombay.
2. Chunawalla and Patel: Production and Operations Management, Himalaya Publishing House.
3. Gopalakrishnan.P and Sundarshan M Hand Book Materials Management New Delhi Prentice Hall of India. 1994.
4. Dutta A.K. Integrated Materials Management New Delhi PhI1986.
5. Buffa E.S. and Sareen: Modern Production Management, New York, John Wiley 2002.
6. Pharmaceutical Production and Management by C.V.S.Subrahmanyam

MQA.T-QUALITY ASSURANCE 4hrs/week

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcomes:

On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards

Unit-I

Plant Design: Design of manufacturing facility as per current good manufacturing practices for the bulk production of different pharmaceutical dosage forms.

Unit-II

a. Equipment Validation: Installation, validation and maintenance of typical equipment used in bulk manufacture of pharmaceutical dosage forms with reference to GMP requirement.

b.Process Validation: Regulatory basis, validation of solid dosage forms, liquid dosage forms, and sterile products, Process validation of raw materials, validation of analytical methods.

Unit-III

a. Quality Control: Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and its applications in process control. Testing programme and methods for testing quality of pharmaceutical dosage forms. Adulteration and misbranding.

b. Stability studies: ICH guidelines and stability protocols for different pharmaceutical dosage forms.

Unit-IV

Industrial Safety: Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals.Monitoring and prevention systems.

Unit-V

Applications of optimization techniques: Optimization parameters, statistical design and techniques in product development and evaluation. Product optimization and its importance.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Delhi.

II – SEMESTER

MNDDS.T- NOVEL DRUG DELIVERY SYSTEMS – I
4 hrs/week

Objectives

Novel drug delivery system is to provide a therapeutic amount of drug to the appropriate site in the body to accomplish promptlan and maintained desired drug concentration.

Novel drug delivery system should deliver drug at a rate control by the necessarily of the body

Over a specified term of treatment

Outcomes

- Novel drug delivery systems referrers to the approaches, formulations, technologies and systems for transporting a pharmaceutical compound in the body as needed to safely achieve it's desired therapeutic effects.
- Novelist a system for delivery of drugs other than conventional drug delivery system
- Novelist a combination of advanced technique and new dosage forms which are far better than conventional dosage forms
- Novel drug delivery systems are optimum dose at the right time and right location, efficient
  use of expensive drugs and reduction in production cost beneficial to patients, better therapy improved comfort and standard of living.

Unit-I

Review of Fundamentals of controlled drug delivery systems:
Fundamentals, rationale of sustained/controlled drug delivery, factors influencing the design and performance of sustained/controlled release products, Pharmacokinetic/ Pharmacodynamic basis of controlled drug delivery. Types and structure of polymers, Use of polymers and biocompatible polymers in controlled release of active agents.
Unit-II
Transdermal drug delivery systems, Iontophoresis, Electro oration and Micro needles, Gastro Retentive Drug Delivery System, oro dispersible tablets, Dendrimers.

Unit-III

Design and fabrication of controlled release drug delivery system:

Principle involved and formulation of**:** Oral dosage forms – Diffusion system, Reservoir devices, Osmotic systems, Systems utilizing dissolution and ion exchange resins, prodrugs, Multiple Emulsions.

Unit-IV

Parenteral dosage forms, intramuscular injections, implantable therapeutic systems, Transmucosal systems and mucoadhesive systems, Nasal delivery, intravaginal and intrauterine systems, Lung delivery systems. Ocular drug delivery.

Unit-V

Carrier Based Delivery Systems: Principle involved and formulation of Micro particulate drug carriers, Liposomes, Niosomes,Microspheres,Magnetic microspheres, Nanoparticles. Resealed erythrocytes.

Reference Books

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Kha
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y. Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

Practicals: Based on theory

MNBDDS.T-- NANO BASED DRUG DELIVERY SYSTEMS 4hrs/week

Objective : To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Outcomes : The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT - I – Introduction to Nanotechnology a. Definition of nanotechnology b. History of nanotechnology c. Unique properties and classification of nanomaterials d. Role of size and size distribution of nanoparticles properties. e. Marketed formulations based on nanotechnology and science behind them

UNIT - II – Synthesis of Nanomaterials Physical, chemical and biological Methods Methods for synthesis of Gold nanoparticles• Magnetic nanoparticles• Polymeric nanoparticles• Self – assembly structures such as liposomes, Niosomes, transferasomes, micelles,• aquasomes and nanoemulsions

UNIT - III - Biomedical applications of Nanotechnology a. Nanotechnology products used for in vitro diagnostics b. Improvements to medical or molecular imaging using nanotechnology c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT - IV Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

REFERENCE BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)

7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016

MPE.T- PHARMACEUTICAL EQUIPMENT **4hrs/week**

Course Objective:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcome: Upon completion of the subject student shall be able to

- ❖ Explain the aspect of validation
- ❖ Carryout validation of manufacturing processes
- ❖ Apply the knowledge of validation to instruments and equipments

Installation, Validation, Maintenance and working of the following:

Unit-I

Tablet Machines: Rotary tablet, Multi punch

Coating Equipment: Pans, fluidized bed dryer.

Unit-II

Dryers: Freeze, spray, fluidized bed and tray dryer

Granulators: Rapid mixer, extruder-spheronizer

Unit-III

Mixers/Milling: Planetary, double cone, triple roller mill, colloidal mill

Filters: Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room.

Unit-IV

Sterilization: Autoclave

Homogenizers and High Pressure Homogenizer

REFERENCES:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam.

MCT.T COSMETIC TECHNOLOGY 4hrs/week

Course Objectives: Upon completion of the course, the students shall be able to understand

- ❖ Key ingredients used in cosmetics and cosmeceuticals.
- ❖ Key building blocks for various formulations.

- ❖ Current technologies in the market
- ❖ Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- ❖ Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products.

Unit-I

Preformulations studies: Preformulation studies and stability testing of Cosmetic products – Shelf–life determination of Cosmetic products, Effects of environmental factors like light, temperatures etc., on product stability.

Raw materials used for Cosmetic preparation: Detailed knowledge of various raw materials used in cosmetic industry, like surfactants, humectants, perfumes and colours.

Unit-II

Hair Care Products: Introduction, Hair structure, Antidandruff shampoos, setting lotion, Hair dyes.

Skin Care Products: Introduction, anatomy and physiology of skin, formulation of skin cleaners, moisturizers, sunscreen products, anti acne products, anti-ageing creams.

Unit-III

Colour cosmetics: Introduction lip sticks, nail polish, face make-up and eye make- up.

Herbal Cosmetics: Introduction, use of plants and plant materials in formulation of cosmetics with emphasis on dentifrices, skin care products and personal hygiene products.

Unit-IV

Personal Hygiene Products: Shaving creams and after shave products, Antiperspirants and deodorants.

Unit-V

Safety testing of Cosmetic Products: Microbiology in Cosmetics. Knowledge of the various microbial contaminants in cosmetic products. Knowledge of various preservative systems for cosmetic products. Selection criteria for preservatives. Efficacy and safety testing of Preservatives in cosmetic products.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

M.PHARMACY -PHARMACEUTICAL ANALYSIS

I SEMESTER

Theory

1.1.T Advanced Pharmaceutical analytical techniques
1.2.T Pharmaceutical Analysis-I
1.3.T Quality control of Pharmaceutical dosage forms
1.4.T Biological standardization

Practicals

1.1.P Advanced Pharmaceutical analytical techniques
1.2.P Pharmaceutical Analysis-I

II SEMESTER

Theory

2.1.T Quality assurance
2.2.T Pharmaceutical Analysis-II
2.3.T Analytical method development and validation
2.4.T Regulatory Affairs

Practicals

2.1. P Analytical method development and validation
2.2.P. Pharmaceutical Analysis-II

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

M.Pharm I Year Semester - I							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1.	APAT.T	Advanced Pharmaceutical analytical techniques	4	4	30	70	100
2.	PA.T	Pharmaceutical Analysis-I	4	4	30	70	100
3.	QCPD.T	Quality control of Pharmaceutical dosage forms	4	4	30	70	100
4.	BS.T	Biological standardization	4	4	30	70	100
5.	APAT.P	Advanced Pharmaceutical analytical techniques	9	9	30	70	100
6.	PA.P	Pharmaceutical Analysis-I	9	9	30	70	100
7.		Seminar					50
8.		Assignment					50
		TOTAL	34	**34**	180	420	**700**

M.Pharm I Year Semester - II							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1.	QA.T	Quality assurance	4	3	30	70	100
2.	PA.T	Pharmaceutical Analysis-II	4	3	30	70	100
3.	AMDV.T	Analytical method development and validation	4	3	30	70	100
4.	RA.T	Regulatory Affairs	4	3	30	70	100
5.	AMDV.P	Analytical method development and validation	9	9	30	70	100
6.	PA.P	Pharmaceutical Analysis-II	9	9	30	70	100
7.		Seminar					50
8.		Assignment					50
		TOTAL	32	**32**	180	420	**700**

1.ADVANCED PHARMACEUTICALANALYTICALTECHNIQUES- 4 hrs/week

Scope

This subject deals with the applications of instrumental methods in qualitative and quantitative analysis of drugs. This subject designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic chromatographic technique. This also emphasize on theoretic and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives

Upon completion of the course the student shall be able to

- Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
- Understand the chromatographic separation and analysis of drugs
- Perform quantitative and qualitative analysis of drugs using various analytical instruments.

Unit-I

a. Thin Layer Chromatography:
   Theory, preparation, procedures, detection of compounds and applications for pharmaceutical analysis.
b. HPTLC:
   Theory, Instrumentation and various applications for pharmaceutical and herbal products.
c. Paper Chromatography:
   Theory, different techniques employed, filter papers used, qualitative and quantitative analysis
d. Electrophoresis:Theory,instrumentationandvarioustechniques(e.g.paper, Capillary electrophoresis etc). Applications for analysis pharmaceuticals.

Unit-II

a. GasChromatography: Introduction, fundamentals, instrumentation, and columns: Preparation and operation, detectors, derivitazation and pharmaceutical applications: GC-MS and application mentioned for the substances in IP.
b. HPLC: Principles and instrumentation,columns and detectors used, pharmaceuticalapplications.
c. LC-MS, MS-MS and its applications for analysis or drug substances as mentioned inIP,BPand USP.

Unit-III

a) UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromospheres concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy.
b) IR spectroscopy: Basic principles- Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications.

Unit-IV

Mass Spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, interpretation of spectra and applications for identification and structure determination.

Unit-V

NMR: Theory, instrumentation, and it applications in analysis of pharmaceuticals

REFERENCES:

1) InstrumentalMethodsofChemicalAnalysis-B.KSharma
2) Organicspectroscopy-Y.RSharma
3) A Text book of PharmaceuticalAnalysis- KerrenthA. Connors
4) Vogel'sTextbookofQualitativeChemicalAnalysis-A.I.Vogel
5) Practical Pharmaceutical Chemistry-A.H.Beckett and J.B.Stenlake
6) Organic Chemistry - I.L. Finar
7) Organicspectroscopy-WilliamKemp
8) QuantitativeAnalysis ofDrugs - D.C. Garrett
9) QuantitativeAnalysisofDrugsinPharmaceuticalFormulations- P.D.Sethi
10) Spectrophotometricidentification ofOrganic Compounds- Silverstein
11) HPTLC-P.D.Seth
12) IndianPharmacopoeia -2007

Practicals

Advanced Pharmaceutical analytical techniques: The experiments should be conducted based on theory

2. PHARMACEUTICALANALYSIS–I 4 hrs/week

Scope

This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives

Upon completion of the course student shall be able to

- Understand the principles of volumetric and electrochemical analysis
- carry out various volumetric and electrochemical titrations
- develop analytical skills

Unit-I

An advanced study of the principles and procedures involved in Non–Aqueous, Complexometric, Oxidation–reduction and Diazotization Methods.

Unit-II

An advanced study of the principles and procedures involved in the Electro metric methods: Conductometry, Potentiometry, Polarography and Amperometry.

Unit-III

Detailed study of the principles and procedures involved in the quantitative determination of the organic functional groups: Amines, Aldehydes, Ketones, Ester and Hydroxy.

Unit-IV

Principles and procedures involved in using the following reagents in Pharmaceutical analysis with suitable examples

i. MBTH(3-methyl–2-benzothiazolonehydrazone)
ii. F.C.Reagent(Folin –Ciocalteau)
iii. PDAB(ParaDimethylAmnioBenzaldehyde)
iv. 2,6–DichloroquinoneChlorimide

v. 2,3,5triphenyltetrazoliumsalt

vi. 1,2 napthoquinone-4-sulfonate reagent

Unit-V

Principles and Procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of the Alkaloids (Pilocarpine and quinine sulphate) Antibiotics (Cephalosporins, Griseofulvin), Vitamins (A and E), Glycosides (Sennoside and Diosgenin), Steroids (dexamethasone and estrogens) and Diuretics (Spiranolactone, Frusemide).

REFERENCES

1) Remington'sPharmaceuticalSciences–AlfonsoandGennaro
2) PharmaceuticalChemistry– BecketandStanlake
3) QuantitativeAnalysisof DrugsinPharmaceuticalFormulations– P.D.Sethi
4) PharmaceuticalAnalysis– Higuchi,Bechmman andHassan
5) TheoryandPracticeofIndustrialPharmacy–LiebermannandLachmann
6) IndianPharmacopoeia –1996
7) InstrumentalMethods ofChemical Analysis– B.K.Sharma
8) AText Book of Pharmaceutical– Kenneth A. Conners
9) Journals(IndianDrugs,IJPSetc.)

Practicals

PPharmaceuticalanalysis-I:Theexperimentsshouldbeconductedbasedontheory

3. QUALITY CONTROL OF PHARMACEUTICAL DOSAGE FORMS 4 hrs/week

Scope

Course able the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objective

Upon completion of the course the student shall be able to

- Know the various pharmaceutical dosage forms and their manufacturing techniques.
- Know various considerations in development of pharmaceutical dosage forms.
- Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality
- AnalysisofPharmaceuticalDosageformmonographsasmentionedinvarious Pharmacopoeias(I.P., B.P., E.P and U.S.P).

Unit-I

Solid dosage forms (Tablets, Capsules, Powders),Semi solid dosage forms (Ointments, Creams)

Unit-II

Liquidoralpreparations,(suspensions,gels,Emulsions,solutionsandelixirs)
Eye/Ear and Nasal Drops

Unit-III

Parenterals (large volume and small volumes), Inhalations (Aerosols, Nebulizers).

Unit-IV

Topical preparations, Transdermal drug delivery systems, Sprays, Suppositories, Pessaries, Surgical Dressings, and Novel Drug Delivery Systems

Unit-V

Various in process quality control tests carried on the following dosage forms. Tablets, capsules, parentals, liquid orals and dosage forms

RECOMMENDEDBOOKS:

1. Remington's Pharmaceutical Sciences–Alfonso and Gennaro
2. Microbiological Assays–BartonJ. Wright
3. Pharmaceutical Chemistry– Becket and Stanlake
4. Quantitative Analysis of Drugs in Pharmaceutical Formulations– P.D. Sethi.
5. Pharmaceutical Analysis– Higuchi, Bechmman and Hassan
6. Theory and Practice of Industrial Pharmacy–Liebermann and Lachmann
7. Indian Pharmacopoeia –1996

4. BIOLOGICALSTANDARDIZATION 4 hrs/week

Scope

This subject has long promise to revolutionize the biological sciences and technology. The microbiological assays, biological assays could be a sort of bioassays designed to analyse the compounds that have impact on microorganisms.

Objective

Upon completion of the course the student shall be able to

- Understanding the importance of microbial assays, biological assays in pharmaceutical industries.
- Appreciate the use of microorganisms in fermentation technology.

Unit-I

Detailed study of principles & procedures involved in bioassay of.

(a) Heparin, Insulin, Posterior Pituitary

(b) Diphtheria, Typhoid

Unit-II

Principles and Procedures involved in Biological tests of the following.

(a) Living contaminants in vaccines.

(b) Endotoxins

(c) Histamine like substances

(d) Toxic elements

Unit-III

Microbiological assay of

(a) Vitaminse.g.cyanocobalamin

(b) Antibiotics such as Neomycin sulphate,

(c) Vaccinee.g.Diptheria.

Unit-IV

a) Biologicalassayevaluationofoxytocin,rabbiesvaccineandtetanusantitoxin

b) Radioimmunoassay: General principles, scope of limitations R.I.A of Insulin and digitalis, ELISA (instrumentation, Principle and application for analysis of pharmaceuticals)

C) Radiopharmaceuticals (indium (^{111}In) pentetate injection, strontium (^{89}Sr) chloride injection, Technitium (^{99m}Tc) macrosalibinjection

Unit-V

Detailed study of principles & procedures involved in bio assay of estrogens, Hepatitisvaccine, Biological assay of Gas-gangrene antitoxin, Blood and blood related products (Anti-blood grouping serum, Human albumin, Human plasma protein fraction, Human coagulation factors), Biotechnology products (erythropoietin, Interferon's, streptokinase).

BooksMaterialRecommended

1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, NewDelhi.
2. Bochmman&Hassan, PharmaceuticalAnalysis, editedby: Higuchi.
3. DC Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
4. RVSmith, JTS tewart, Textbook of Bio Pharmaceutical Analysis.
5. Pulok K Mukherjee: Quality Control of Herbal Drugs, Business HorizonsPharmaceuticalPublishers, New Delhi.
6. British Pharmacopeia, Department of HealthU.K.
7. Classification of cosmetic raw material.

II-Semester

2.1. QUALITY ASSURANCE 4 hrs/week

Objective:

- This course deals with the various aspects of quality assurance aspects of pharmaceutical industries.
- It covers the important aspects like GMP, GLP and cGMP, QA tests, documentation, quality certifications, GLP and regulatory affairs.
- Students are required to perform a wide variety of quality assurance activities which include, developing standard operating procedures to ensure compliance with GMP, GLP, and FDA, analyzing data and interpreting results.
- An exposure of cGLP and various guidelines enable the students to be skilled personnels who are marketable in pharmaceutical industry.

Outcome:

Upon completion of this course the student should be able to;

- Understand the GLP, GMP & cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of Quality assurance departments.

Unit I

Concept of quality assurance, total quality management, electronic quality management system (eQMS). Philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NBL and OSHA 18000,

Unit II

a) Organization and personal, responsibilities, training hygiene
b) Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile area, control of contamination
c) Equipments: selection, purchase, specifications, maintenance, clean in place, sterilized in place - Raw – materials; purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

Unit III

Manufacture and controls on dosage forms

a. Manufacturing documents, master formula records, batch formula records, standard operating procedures, Quality audits of manufacturing processes and facilities

b. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.
c. Guideline for Quality Assurance of Human Blood Products and large volume parenterals.

Unit-IV

a. Packaging and labeling controls, line clearance and other packaging materials.
b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities – finished products release: quality review, quality audits and batch release document.

Unit- V

a. Distribution and Distribution records: Handling of returned goods recovered materials and reprocessing.
b. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.
c. Quality risk management in production area, data integrity management.
d. Introduction to concepts of QbD, PAT and continuous manufacturing

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.1 and Vol.2, WHO (1999)
3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash

REFERENCE BOOKS:

1. Basic tests for Pharmaceutical substances – WHO (1988)
2. Basic tests for Pharmaceutical substances – WHO (1991)
3. How to practice GMP's – P.P.Sharma
4. The Drugs and Cosmetic Act 1940 – Vijay Malik
5. Q.A. Manual - D.H. Shah
6. SOP Guide lines - D.H. Shah
7. Quality Assurance Guide – OPP
8. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by John Sharp
9. Handbook of Pharmaceutical Quality Assurance by Dr. Premnath Shenoy

2.2 PHARMACEUTICAL ANALYSIS – II 4 hrs/week

Objective: The objective of this course is to impart the knowledge on the in the field of Pharmaceutical

Analysis of a pharmaceutical industry.

- The various modern analytical techniques like UV-Visible, LC-MS, HPTLC, GC, HPLC, different chromatographic methods and other important topics are taught to enable the students to understand and apply the principles involved in the determination of different bulk drugs and their formulation.
- The students will acquire the Technical knowledge about the various aspects of X-Ray diffraction methods, all types of IR methods, particle sizing methods, also DSC, DTA, TGA etc

Outcome:

- By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR and ORD etc.
- Which help them in further research project works and also industrial opportunities

Unit I

An advanced study of the principles and procedures and applications of instrumental methods in the development of medicines (GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS)

Unit II

a) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,
b) X-ray spectroscopy: x-ray diffraction, principle, instrumentation , method and application for the analysis of pharmaceuticals

C) Optical rotator dispersion technique for the analysis of chiral compounds

D) Structure elucidation: Examples from alkaloids, flavaonoids, and sterols.

Unit III

An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame Photometry, Fluorimetry, Nephelo - Turbidimetry and Refractrometry, Study of general principles and methods for the determination of Proteins, Carbohydrates, Fats, Crude fibre, Moisture and Nitrogen

Unit IV

Thermal method of analysis, theory, instrumentation and applications of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA) and DSC.

Unit V

Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation

Methodology involved

a. Moisture content determination in dosage forms
b. Alcohol determination
c. Essential oil determination
d. Surfactant analysis

REFERENCES:

1. Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2. Pharmaceutical Chemistry – Becket and Stanlake
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
4. Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5. Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6. Indian Pharmacopoeia – 1996
7. Instrumental Methods of Chemical Analysis – B.K. Sharma
8. A Text Book of Pharmaceutical – Kenneth A. Conners
9. Spectral Data for Structure Elucidation

Pharmaceutical Analysis – II. The experiments should be conducted based on theory.

2.3. ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

Objective:

The main objective of this course is to impart the knowledge on the current scenario of an analytical laboratory of a pharmaceutical industry.

- To produce competent experts in the field of analytical research through practical training in analytical instrumental techniques, calibration of common laboratory equipments and glass ware.
- The purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products.
- The subject covers the complete information about validation, types, methodology and application.
- Students are given hands-on training on method development, and validation requirements within pharmaceutical industry.

Outcome:

Upon completion of the subject student shall be able to;

- Explain the aspect of method optimization, development and validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation and Calibration to instruments and Glassware

Unit-I

Analytical method development: Introduction, quantification of calibration of various analytical instruments for drug analysis and maintenance of Instruments

Unit-II

Analytical methods development, optimization and validation using the instruments such as UV/Vis spectrometer, FT-IR spectrometer for pharmaceutical dosage forms, active pharmaceutical ingredients (API) and pharmaceutical aids.

Unit-III

a) Development of analytical method, optimization and validation using Paper and Thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.
b) HPLC method development by using different stationary phases, mechanism of interactions, HPLC preventive maintenance and troubleshooting, case studies.
c) Calibration methods: external, internal and standard addition methods.

Unit-IV

Drug analysis from biological samples, extraction using various extraction techniquesand Development, optimization and validation of bioanalytical method.

Unit V

Validations

Concept, Type of Validations, Master plan, Protocol for process, cleaning, equipment and facilities including sterile and non-sterile areas, analytical method validations, vendor validation and audit, sample testing and trade analysis.

Prevalidation activities: Protocol preparations, protocol executions, Deviations and Change Controls, Summary and Certification, Revalidations.

Recommended books:

1. Analytical Method Development and Validation, Michael Swartz, Swartz Swartz, Michael Swartz, CRC press.1997
2. Modern HPLC for practicing scientists, Michael W.Dong (google.com)
3. Practical HPLC method development 2nd edition , Llyod R.synder (google.com)
4. Pharmaceutical process validation, NashRA and Watcher AH, CBS publishers and Distributors, Newdelhi
5. Modern Pharmaceutical analysis, Volume1-4, Satish Ahuja, CBS publishers and Distributors, Newdelhi

Analytical method development and validation: The experiments should be conducted based on theory

2. 4. REGULATORY AFFAIRS-4 hrs/week

Course Objective:

- The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.
- Students would be trained in troubleshooting, analytical instrument failure in compliance with regulatory requirements.

Course Outcome:

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application(MAA) and Medicines and Health Care Products Regulatory Agency (MHRA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

Unit-I New Drug Application: Steps involved in the development of a new drug. Procedure for submission of new drug application (NDA) and abbreviated NDA. Requirements and guidelines on clinical trials for import and manufacture of drug products as per Drugs andCosmetics act. Clinical trials, study design, documentation and interpretation.

Unit-II

Documentation: Importance of documentation, statutory requirement and procedure for documentation, description of documents generated in manufacture of pharmaceutical dosage form.

Unit-III

Current good manufacturing practices (CGMP) as per WHO.

Unit-IV

Regulation of Good Laboratory Practices:

FDA GLP regulations, Indian, and International (OECD) regulation, Regulation of Computer systems, Implementing GLPS in non- GLP analytical Laboratory, Controlling the good laboratory practices inspection process.

Unit-V

A detailed study of the following laws, including latest amendments in India

ISO 9000 series, GATT, TQM, Intellectual property rights and Patent laws in India

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New

Delhi.
5. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013

M. PHARM (PHARMACEUTICS)

I SEMESTER

1. Bio Pharmaceutics & Pharmacokinetics
2. Pharmaceutical Formulation Technology } *
3. Physical Pharmaceutics
4. Quality Assurance
5. Seminars/Assignments

II SEMESTER

1. Novel drug delivery systems-I } *
2. Nano based drug delivery systems
3. Pharmaceutical equipment
4. Cosmetic technology
5. Seminars/Assignments

* **Practicals for both papers**

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar on Dissertation (Results)
Dissertation

M.Pharm I Year Semester - I							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1	MBPPK.T	Bio Pharmaceutics & Pharmacokinetics	4	4	30	70	100
2	MPFT.T	Pharmaceutical Formulation Technology	4	4	30	70	100
3	MPP.T	Physical Pharmacy	4	4	30	70	100
4	MQA.T	Quality Assurance	4	4	30	70	100
5	MBPPK.P	Bio Pharmaceutics & Pharmacokinetics	9	9	30	70	100
6	MPFT.P	Pharmaceutical Formulation Technology	9	9	30	70	100
7		Seminar					50
8		Assignment					50
		TOTAL	32	**32**	180	420	**700**

M.Pharm I Year Semester - II							
S. No	**Paper Code**	**Title of the paper**	**HPW**	**Credits**	**Marks**		**Total marks**
					Internal	**External**	
1	MNDDS.T	Novel Drug Delivery Systems-I	4	3	30	70	100
2	MNBDDS.T	Nano Based Drug Delivery Systems	4	3	30	70	100
3	MPE.T	Pharmaceutical Equipment	4	3	30	70	100
4	MCT.T	Cosmetic Technology	4	3	30	70	100
5	MNDDS-I	Novel Drug Delivery Systems-I	9	9	30	70	100
6	MNBDDS.P	Nano Based Drug Delivery Systems	9	9	30	70	100
7		Seminar					50
8		Assignment					50
		TOTAL	32	**32**	180	420	**700**

MBPPK- BIO PHARMACEUTICS & PHARMACOKINETICS - 4 hrs/week

Objectives: The student shall know about bioavailability, bioequivalence and factor affecting bioavailability. They also know the pharmacokinetic parameter like drug disposition, absorption, nonlinear and time dependant pharmacokinetics. They also know about the drug interactions & problems associated in pharmacokinetic parameters calculations.

Outcomes: students will be able to tell factors affecting the bioavailability and stability of dosage form; they also know the bioequivalence studies and protocols for bioequivalent studies. They also know the parameters for the disposition, absorption and Michaelis-Menton constants for nonlinear kinetics.

Unit-I

a. Bio-availability, Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Tests of significance, t-Test, ANOVA.

b. Physico-Chemical properties affecting bioavailability, pH-partition theory, dissolution, surface area, adsorption, complexation, polymorphism etc., and techniques used to enhance dissolution rate.

c. Formulation factors affecting bioavailability of drug in dosage forms of tablets, capsules, Parenterals, liquid orals and topical dosage forms.

Unit-II

Basic concepts of Pharmacokinetics: Compartmental models: one, two and non compartmental approaches to pharmacokinetics. Merits and demerits of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

i. Absorption: Absorption rate constant. Absorption half life, lag time and extent of absorption, AUC.

ii. Distribution: Apparent volume of distribution and its determination.

iii. Metabolism: Metabolic rate constant and its determination.

iv. Elimination: Over all apparent elimination rate constant and half life.

Under the following conditions:

a) Intra venous bolus injection

b) Intra venous infusion

c) Single dose oral administration

d) Multiple dose injections

e) Multiple dosage oral administration

v. Concept of clearance: Organ clearance, total clearance, hepatic clearance, guts wall clearance, lung clearance and renal clearance.

Unit-III

a.Non-linear Pharmacokinetics: concepts of linear and non linear pharmacokinetics, Michaelis-Menten kinetic characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological response.

b.Non compartmental Pharmacokinetics.

Unit-IV

a. **Clinical Pharmacokinetics**: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver and renal disease states.

b. Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chrono pharmacokinetics - principles, drugs– (amino glycosides, NSAIDS, antihypertensive drug) chemically induced dependency.

Unit-V

Drug Interactions: Kinetics of drug interaction, study of drug-drug interaction mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence.

REFERENCE BOOKS

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. 2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and Pharmacokinetics
3. 3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh
4. Prakashan.2010.
5. 4. Basic biopharmaceutics, Sunil S. Jambhekar and Philip J Brean.
6. 5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by NiaziSarfaraz
7. . Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.
8. Pharmacokinetics, Biopharmaceutics and Clinical pharmacy by Robert E. Notari.
9. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction by Robert E. Notari.
10. Drug drug interactions, scientific and regulatory perspectives by Albert P. G.

MPFT.T- PHARMACEUTICAL FORMULATION TECHNOLOGY 4hrs/week

Objective: The students shall understand about the pilot plant and their scale up techniques for manufacturing of tablets capsules, suspensions, emulsions and semisolids. The students also learn the filling of capsules, compression machines, and sterilizers for formulation of parenterals and also understand the properties of propellants, DPI, MDI and their quality control.

Outcomes: students will understand the planning of pilot plant techniques used for all pharmaceutical dosage forms such as tablets, capsules, parenterals, and aerosols.

Unit-I

Preformulation studies:

a) Goals of preformulation, preformulation parameters, Methodology, Solid state properties Solubility and Partition coefficient, Drug excipient compatibility by DSC &FTIR.,

b) Various excipients used in pharmaceutical dosage forms.

c) Properties and selection criteria for various excipients like surfactants, viscosity promoters, diluents, coating materials, plasticizers, preservatives, and colours.

Unit-II

a.Solid dosage forms: Improved production techniques for tablets: New materials process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

b.Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalations dosage forms.

Unit-III

Liquid and Semi-solid dosage forms: Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation and evaluation of suspensions, dry syrups and semi- solid dosage forms.

Unit-IV

Aerosols: Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

Unit-V

a. Parenteral dosage forms: Advances in materials and production techniques, filling machines, sterilizers.Manufacturing of small and large volume parenterals and quality control.

b. Aseptic processing operation: Introduction, contamination control, microbial environmental monitoring, microbiological testing of water and air, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

RECOMMENDED BOOKS:

1. The Theory and Practice of industrial Pharmacy by Leon Lachman, Herbert A. Lieberman.
2. Remington's Science and Practice of Pharmacy by A. Gennaro.
3. Ansel's Pharmaceutical Dosage form and Drug delivery system by Loyd V. Allen, Jr. Nicholas G. Popovich, Howard C. Ansel.
4. Generic Drug Product Development by Leon Shargel and Isadore Kanfer.
5. Dispensing for Pharmaceutical Students by SJ Carter.
6. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi – 2013.

MPP.T PHYSICAL PHARMACEUTICS 4hrs/week

Course Objectives: the students shall know about particle science, polymer science and its use in pharmaceutical dosage forms. They also know the compression and consolidation parameters for powders and granules. Students also know about the rheology, disperse systems, dissolution and solubility parameters for dosage forms.

Course Outcomes: The students will know particle size analysis method, solid dispersion, physics of tablets, polymer classification and its applications, student will also know the stability calculations, shelf life calculations and accelerated stability studies. They also know the rheology, absorption related to liquids and semi-solid dosage forms. They also know the factors affecting the dissolution and solubility in related to invitro/invivo correlations.

Unit-I

a. Theory of Solubilization and Solubilization Techniques: Solubility and solubilization of non electrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation.

b. Theories of Dispersion: Solid-liquid dispersion: adsorption, wetting, crystal growth mechanisms and prevention of crystal growth.

Unit-II

a. Emulsion: Formation and stability of emulsion with special emphasis on electrical theory, HLB theory and dielectric properties. Preparation, evaluation and applications of multiple and micro emulsions.

b. Solid State Properties: Crystal properties and polymorphism, Techniques for study of Crystal properties, solid state stability, flow properties of powders, segregation and its importance.

c. Theories of Compaction and Compression: Compression, consolidation strength of granules, compression and consolidation under high loads, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.

Unit-III

Polymer Science: Polymer structure, classification and Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state. Applications of polymers in pharmaceutical formulations.

Unit-IV

Diffusion and Dissolution: Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, Thermodynamics of diffusion. Dissolution: Basic theories of dissolution, models. Sink conditions in dissolution and its importance. In-vitro-in-vivo- correlations. Dissolution testing for Novel drug delivery systems.

Unit-V

Kinetics and Drugs stability: Stability calculations, rate equation, kinetics of decomposition, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms. Freeze-thaw methods, centrifugal methods, temperature and humidity control.

REFERENCE BOOKS

1. Physical Pharmacy, 4th Edition by Alfred Martin.
2. Theory and Practice of Tablets – Lachman, Vol.4
3. Pharmaceutical Dosage forms – Disperse systems Vol. I & II
4. Cartenson "Drug Stability, Marcel Decker Solid state properties, Marcel Dekker.
5. Industrial Pharmacy - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh
   Prakashan Delhi – 2013
6. Dispersive systems I, II, and III
7. Robinson. Controlled Drug Delivery Systems.

MQA.T-QUALITY ASSURANCE 4hrs/week

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

Course Outcomes:

On completion of this course it is expected that students will be able to;

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards

Unit-I

Plant Design: Design of manufacturing facility as per current good manufacturing practices for the bulk production of different pharmaceutical dosage forms.

Unit-II

a. Equipment Validation: Installation, validation and maintenance of typical equipment used in bulk manufacture of pharmaceutical dosage forms with reference to GMP requirement.

b.Process Validation: Regulatory basis, validation of solid dosage forms, liquid dosage forms, and sterile products, Process validation of raw materials, validation of analytical methods.

Unit-III

a. Quality Control: Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and its applications in process control. Testing programme and methods for testing quality of pharmaceutical dosage forms. Adulteration and misbranding.

b. Stability studies: ICH guidelines and stability protocols for different pharmaceutical dosage forms.

Unit-IV

Industrial Safety: Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals.Monitoring and prevention systems.

Unit-V

Applications of optimization techniques: Optimization parameters, statistical design and techniques in product development and evaluation. Product optimization and its importance.

REFERENCES:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T. Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Delhi.

II – SEMESTER

MNDDS.T- NOVEL DRUG DELIVERY SYSTEMS – I
4 hrs/week

Objectives

Novel drug delivery system is to provide a therapeutic amount of drug to the appropriate site in the body to accomplish promptlan and maintained desired drug concentration.

Novel drug delivery system should deliver drug at a rate control by the necessarily of the body

Over a specified term of treatment

Outcomes

- Novel drug delivery systems referrers to the approaches, formulations, technologies and systems for transporting a pharmaceutical compound in the body as needed to safely achieve it's desired therapeutic effects.
- Novelist a system for delivery of drugs other than conventional drug delivery system
- Novelist a combination of advanced technique and new dosage forms which are far better than conventional dosage forms
- Novel drug delivery systems are optimum dose at the right time and right location, efficient
  use of expensive drugs and reduction in production cost beneficial to patients, better therapy improved comfort and standard of living.

Unit-I

Review of Fundamentals of controlled drug delivery systems:
Fundamentals, rationale of sustained/controlled drug delivery, factors influencing the design and performance of sustained/controlled release products, Pharmacokinetic/ Pharmacodynamic basis of controlled drug delivery. Types and structure of polymers, Use of polymers and biocompatible polymers in controlled release of active agents.
Unit-II
Transdermal drug delivery systems, Iontophoresis, Electro oration and Micro needles, Gastro Retentive Drug Delivery System, oro dispersible tablets, Dendrimers.

Unit-III

Design and fabrication of controlled release drug delivery system:

Principle involved and formulation of**:** Oral dosage forms – Diffusion system, Reservoir devices, Osmotic systems, Systems utilizing dissolution and ion exchange resins, prodrugs, Multiple Emulsions.

Unit-IV

Parenteral dosage forms, intramuscular injections, implantable therapeutic systems, Transmucosal systems and mucoadhesive systems, Nasal delivery, intravaginal and intrauterine systems, Lung delivery systems. Ocular drug delivery.

Unit-V

Carrier Based Delivery Systems: Principle involved and formulation of Micro particulate drug carriers, Liposomes, Niosomes,Microspheres,Magnetic microspheres, Nanoparticles. Resealed erythrocytes.

Reference Books

1. Novel Drug Delivery System by Yie W. Chien.
2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Kha
5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes.
6. Advances in Drug Delivery, Vol 1, 2, 3 by Y. Madhusudan Rao, A.V. Jithan
7. Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

Practicals: Based on theory

MNBDDS.T-- NANO BASED DRUG DELIVERY SYSTEMS 4hrs/week

Objective : To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Outcomes : The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT - I – Introduction to Nanotechnology a. Definition of nanotechnology b. History of nanotechnology c. Unique properties and classification of nanomaterials d. Role of size and size distribution of nanoparticles properties. e. Marketed formulations based on nanotechnology and science behind them

UNIT - II – Synthesis of Nanomaterials Physical, chemical and biological Methods Methods for synthesis of Gold nanoparticles• Magnetic nanoparticles• Polymeric nanoparticles• Self – assembly structures such as liposomes, Niosomes, transferasomes, micelles,• aquasomes and nanoemulsions

UNIT - III - Biomedical applications of Nanotechnology a. Nanotechnology products used for in vitro diagnostics b. Improvements to medical or molecular imaging using nanotechnology c. Targeted nanomaterials for diagnostic and therapeutic purpose

UNIT - IV Design of nanomaterials for drug delivery, pulmonary and nasal drug delivery, nanomaterials for cancer therapy and cardiovascular diseases. Localized drug delivery systems.

UNIT - V Characterization including the principles, size reduction, analysis of nanoparticles, size, PDI, size separation, stability, methods of analysis regarding integrity and release of drugs

REFERENCE BOOKS:

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanoscience and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P. J. Thomas and G.U. Kulkarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)
6. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)

7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley - VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons,2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016

MPE.T- PHARMACEUTICAL EQUIPMENT **4hrs/week**

Course Objective:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Course Outcome: Upon completion of the subject student shall be able to

- ❖ Explain the aspect of validation
- ❖ Carryout validation of manufacturing processes
- ❖ Apply the knowledge of validation to instruments and equipments

Installation, Validation, Maintenance and working of the following:

Unit-I

Tablet Machines: Rotary tablet, Multi punch

Coating Equipment: Pans, fluidized bed dryer.

Unit-II

Dryers: Freeze, spray, fluidized bed and tray dryer

Granulators: Rapid mixer, extruder-spheronizer

Unit-III

Mixers/Milling: Planetary, double cone, triple roller mill, colloidal mill

Filters: Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room.

Unit-IV

Sterilization: Autoclave

Homogenizers and High Pressure Homogenizer

REFERENCES:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam.

MCT.T COSMETIC TECHNOLOGY 4hrs/week

Course Objectives: Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability and efficacy.

Course Outcomes: Upon completion of the subject student shall able to know Regulatory biological aspects of cosmetics, excipients used for various formulations, designing of cosmeceuticals and herbal products.

Unit-I

Preformulations studies: Preformulation studies and stability testing of Cosmetic products – Shelf–life determination of Cosmetic products, Effects of environmental factors like light, temperatures etc., on product stability.

Raw materials used for Cosmetic preparation: Detailed knowledge of various raw materials used in cosmetic industry, like surfactants, humectants, perfumes and colours.

Unit-II

Hair Care Products: Introduction, Hair structure, Antidandruff shampoos, setting lotion, Hair dyes.

Skin Care Products: Introduction, anatomy and physiology of skin, formulation of skin cleaners, moisturizers, sunscreen products, anti acne products, anti-ageing creams.

Unit-III

Colour cosmetics: Introduction lip sticks, nail polish, face make-up and eye make- up.

Herbal Cosmetics: Introduction, use of plants and plant materials in formulation of cosmetics with emphasis on dentifrices, skin care products and personal hygiene products.

Unit-IV

Personal Hygiene Products: Shaving creams and after shave products, Antiperspirants and deodorants.

Unit-V

Safety testing of Cosmetic Products: Microbiology in Cosmetics. Knowledge of the various microbial contaminants in cosmetic products. Knowledge of various preservative systems for cosmetic products. Selection criteria for preservatives. Efficacy and safety testing of Preservatives in cosmetic products.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfume cosmetics and Soaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, P. P. Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O. Barel, M. Paye and H.I. Maibach. 3 rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.