Sanjivani Rural Education Society's

Sanjivani College of Pharmaceutical Education and Research,

Kopargaon-Autonomous

(Approved by AICTE, PCI New Delhi and affiliated to Savitribai Phule University of Pune)

NBA and **NAAC 'A' Accredited, CII Platinum & NIRF Rank**

Detailed Syllabus structure and Syllabus for the First Year M Pharm

Choice Based Credit System (CBCS)

Effective for F. Y. M. Pharm from Academic Year 2022-2023

Table – 1: List of M.Pharm. Specializations and their Code

Sr. No.	Specialization	Code
1.	Pharmaceutics	MPH
6.	Pharmaceutical Regulatory Affairs	MRA
7.	Pharmaceutical Biotechnology	MPB
5.	Pharmaceutical Quality Assurance	MQA

Table - 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
SEMESTER II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Development	4	4	4	100
MPH204T	Cosmetic & Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table - 2: Course of study for M. Pharm. (Regulatory Affairs)

Course Code	Course	Credit Hours	Credit Points	Hrs. / wk	Marks
SEMESTER I					
MRA101T	Good Regulatory Practices	4	4	4	100
MRA102T	Documentation and Regulatory Writing	4	4	4	100
MRA103T	Clinical Research Regulations	4	4	4	100
MRA 104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	4	4	100
MRA105P	Regulatory Affairs Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**
SEMESTER II					
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	4	4	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	4	4	100
MRA203T	Regulatory Aspects of Medical Devices	4	4	4	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	4	4	100
MRA205P	Regulatory Affairs Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		**35**	**26**	**35**	**650**

Table - 3: Course of study for M. Pharm. (Pharmaceutical Biotechnology)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPB 102T	Microbial And Cellular Biology	4	4	4	100
MPB 103T	Bioprocess Engineering and Technology	4	4	4	100
MPB 104T	Advanced Pharmaceutical Biotechnology	4	4	4	100
MPB 105P	Pharmaceutical Biotechnology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MPB 201T	Proteins and protein Formulation	4	4	4	100
MPB 202T	Immuno-technology	4	4	4	100
MPB 203T	Bioinformatics and Computer Technology	4	4	4	100
MPB 204T	Biological Evaluation of Drug Therapy	4	4	4	100
MPB 205P	Pharmaceutical Biotechnology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Table - 4: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**
SEMESTER II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
	Total	**35**	**26**	**35**	**650**

Semester I

(Pharmaceutics)

SUBJECT: MPAT101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 03Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks
Name of Faculty: Mrs. Poonam S Aher	

Scope

Scope: This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc. Simple structure elucidation problems may be included based on UV-IR-NMR data.

Course Objectives:

Upon completion of course the students shall able to

1. Analytical techniques for identification, characterization and quantification of drugs
2. Theoretical and practical skills of instrument handling and use.
3. Structural Elucidation of organic compounds using spectroscopic tools

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the theory, instrumentation, principle and application of UV visible spectroscopy, IR spectroscopy, Spectroflourimetry and flame emission and absorption spectroscopy	1,2,3	Remember, Understand, Analyze and Apply
CO 2	The students should be able to understand the theory, instrumentation, principle and application of NMR spectroscopy	1,2,3	Remember, Understand, Analyze and Apply
CO 3	The students should be able to understand the theory, instrumentation, principle and application of Mass spectroscopy and structural elucidation of UV,IR,NMR and mass interpretation problems	1,2,3	Remember, Understand, Analyze and Apply
CO 4	The students should be able to understand the theory, instrumentation, principle and application of HPLC, HPTLC,TLC,UPLC,GC,Ion exchange chromatography, Affinity chgromatography, Gel chromatography, column chromatography	1,2,3	Remember, Understand, Analyze and Apply
CO 5	The students should be able to understand the theory, instrumentation, principle and application of Electrophoresis and X ray chrysatallography, calculation of Braggs law and structure of crystal	1,2,3	Remember, Understand, Analyze and Apply

			and Apply
CO 6	To understand the basic concepts theory, instrumentation, principle and application of Thermal methods TGA, DTA, DSC	1,2,3	Remember and Understand

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	2	3	0	2	0	0	2	0	2
CO2	3	2	2	3	0	2	0	0	2	0	2
CO3	3	2	2	3	0	2	0	0	2	0	2
CO4	3	2	2	3	0	2	0	0	2	0	2
CO5	3	2	2	3	0	2	0	0	2	0	2
CO6	3	2	2	3	0	2	0	0	2	0	2

COURSE CONTENTS

Unit	Details	Hours
1	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy. b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	10
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	10

3	**Mass Spectrometry**: Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry Simple structure elucidation problems based on UV, IR, NMR and• Mass data.	12
4	**Chromatography:** Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) High Performance Liquid chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Gas chromatography e) Ultra High Performance Liquid chromatography f) Affinity chromatography g) Gel Chromatography TLC and Column Chromatography	10
5	**a) Electrophoresis**: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing **b) X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction, calculation of Braggs law and structure of crystal	**10**
6	**Thermal Techniques**: a) Thermogravimetric analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. b) Differential scanning calorimetry (DSC): Principle, thermal	**08**

	transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. c) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).	
	TOTAL	**60 hrs**

Reference Books (Latest Editions to be adopted):

References Book:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series

8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.

9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

SUBJECT: MPH102T. DRUG DELIVERY SYSTEM
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials:	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Course Objectives:

Upon completion of the course a student shall be able to understand -

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the fundamentals/ terminology/definitions, rationale and Physicochemical & biological approaches for Control Release & Sustain Release formulation and its application s in personalized medicine	1,3	Recall facts and basic concept , Apply
CO 2	To explain basic concepts, definition, principles, merit, demerit and learn the formulation and development techniques of Rate Controlled Drug Delivery Systems	1,3	Recall facts and basic concept , Apply
CO 3	To clarify basic principles, rationale, approaches & formulation techniques of Gastro-Retentive Drug Delivery Systems	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 4	The student should be understand the basic terms , definition barrier properties, merits & demerits of Ocular Drug Delivery Systems ,Vaccine delivery systems& and Nasal Drug Delivery System	1	Recall facts and basic concept
CO 5	To explain basic concepts, definition, principles, merit, demerit and learn the formulation and development techniques of Transdermal Drug Delivery Systems	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 6	To clarify basic principles Protein & Peptide, barrier properties, merits, demerits &formulation and development techniques of Protein and Peptide Delivery	2,3	Explain ideas or concept, Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	1	1	-	-	1	-	1	-	1
CO2	3	2	1	1	-	-	1	-	1	-	1
CO3	3	2	2	1	-	-	1	-	1	-	1
CO4	2	-	1	-	-	-	1	-	1	-	1
CO5	3	2	2	1	-	-	1	-	1	-	1
CO6	3	2	2	1	-	-	1	-	1	-	1

COURSE CONTENTS

Unit	Details	Hours
1	**Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction & basic concepts, advantages / disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation, dose calculation, Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, and Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.	10
2	**Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic Activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.	10
3	**Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.	10
4	**Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers **Nasal Drug Delivery System:** Introduction ,Merits Demerits, Formulation and evaluations	06
5	**Transdermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10
6	**Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08
7	**Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. Allen LV, Ansel HC. Pharmaceutical Dosage Forms and Delivery Systems, 10th Ed., Lippincott Williams and Wilkins.
5. Remington JP. Remington: the science and practice of pharmacy.21st ed. USA: Lippincott Williams and Wilkins; 2006:916.

Text Books:

1. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)

SUBJECT: MPH 103T MODERN PHARMACEUTICS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:15 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course has been designed to provide the advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Course Objectives:

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

- The elements of preformulation studies
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Pharmaceutical Validation and essentials of technology transfer
- Industrial management and GMP considerations
- Concept involved in the compression and compaction
- Drug release from the dosage form with various modeling

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand the importance of preformulation study in drug development with respect to prime dosage forms	1	Understand
CO 2	To explain the significance of optimization and quality by design concept in the pharmaceutical formulation	2	Understand
CO 3	To understand and apply the concept of pharmaceutical validation	3	Apply
CO 4	To learn the management involved in the industrial production including material management and total quality management	2	Understand
CO 5	To know and apply the physics involved in the compression of dosage form	3	Apply
CO 6	To understand and explain drug release modeling across various barrier	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	3	3	-	1	2	-	-	-	3
CO2	3	2	2	3	-	1	2	-	-	-	3
CO3	3	2	2	3	-	1	2	-	-	-	3
CO4	3	2	2	3	-	1	2	-	-	1	3
CO5	3	1	2	3	-	1	1	-	-	-	3
CO6	3	1	2	3	-	1	-	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Preformulation Concept** Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability. Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. ICH guidelines of Stability Testing	12
2	**Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation, Introduction of software used for optimization	10
3	**Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, ICH & WHO guidelines for validation of equipment, Validation of cone blender, mixer granulator and tablet compression machine, URS, DQ, IQ, OQ & P.Q. of facilities, Types of process validation. Process validation of any one dosage form. Technology transfer from R & D to pilot plant to plant scale. Documentation involved in technology transfer	12
4	**GMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipment and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management, ISO and ICH as quality management tools	10
5	**Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, Study of consolidation parameters, Heckel plots, Kawakita Plot and its application in compaction	10
6	**Drug Release Kinetics:** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Similarity factors – f2 and f1, Dissolution models including Higuchi, Peppas plot, zero order, first order and Hixson Crowell. Software application for the prediction of drug release kinetics	06
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.

4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.

5. Modern Pharmaceutics; By Gillbert and S. Banker.

6. Remington‟s Pharmaceutical Sciences.

7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.

8. Physical Pharmacy; By Alfred martin

9. Bentley‟s Textbook of Pharmaceutics – by Rawlins.

10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.

11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.

12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.

13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.

14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.

15. Pharmaceutical Preformulations; By J.J. Wells.

16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

17. ICH Quality Guidelines_ An Implementation Guide- Andrew Teasdale (Editor), David Elder (Editor), Raymond W. Nims (Editor) - Wiley (2017)

18. Robert de Levie-How to Use Excel in Analytical Chemistry and in General Scientific Data Analysis -Cambridge University Press (2004)

19.Quality by Design for Biopharmaceuticals Principles and Case Studies (2009)

20.Feroz Jameel, Susan Hershenson, Mansoor A. Khan, Sheryl Martin-Moe (eds.) - Quality by Design for Biopharmaceutical Drug Product Development- AAPS Advances in the Pharmaceutical Sciences Series

SUBJECT: MPH 104T. REGULATORY AFFAIRS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 03Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks
Name of Faculty: Dr. Sunil J Aher	

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

Course Objectives:

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

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

•Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the theory and Documentation in Pharmaceutical industry and Regulatory requirement for product approval	1,2,3	Remember, Understand
CO 2	The students should be able to understand the theory of CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	1,2,3	Remember, Understand , Analyze and Apply
CO 3	The students should be able to understand the theory, Non clinical drug development: Global submission of IND, NDA, ANDA.	1,2,3	Remember, Understand , Analyze

	Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB)		and Apply
CO 4	The students should be able to understand the theory Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures.	1,2,3	Remember, Understand , Analyze
CO 5	The students should be able to understand the theory of HIPAA – new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	1,2,3	Remember, Understand

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	2	0	0	2	0	0	2	0	2
CO2	3	2	2	0	0	2	0	0	2	0	2
CO3	3	2	2	0	0	2	0	0	2	0	2
CO4	3	2	2	0	0	2	0	0	2	0	2
CO5	3	2	2	0	0	2	0	0	2	0	2
CO6	3	2	2	0	0	2	0	0	2	0	2

COURSE CONTENTS

Unit	Details	Hours
1	a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in–vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. b) Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	24
2	CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA	12

	liaison. ICH – Guidelines of ICH–Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB) Regulatory submission process to Europe, USA and other agencies	12
4	**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA – new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. Marketing Authorization Procedures in USA, Europe and other countries	12
	TOTAL	**60 hrs**

Reference Books (Latest Editions to be adopted):
References Book:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations by Richard a Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.

4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley &Sons.Inc.

5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited by Douglas J. Pisano, David Mantus.

6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams

7. www.ich.org/

8. www.fda.gov/

9. europa.eu/index_en.htm

10. https://www.tga.gov.au/tga–basics

SUBJECT: MPH 105P PHARMACEUTICS PRACTICAL I
(PRACTICAL 180 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 00Hr/Week	In SEM Exam:30 Marks
Practical: 12Hr/Week	End SEM Exam:100 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 20 Marks
Credits: 6	Total Marks: 150 Marks

Scope

This practical course has been designed to provide the practical skills in analytical instrument handling, development and characterization of various dosage forms including SR/CR, Floating Mucoadhesive systems etc with exposure to various software.

Course Objectives:

Upon completion of the course a student shall be able to understand -

The fundamentals of sophisticated Analytical instruments
Importance of Preformulation Studies
The various approaches for development of novel drug delivery systems.
The criteria for selection of drugs and polymers for the development of delivering system

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand the fundamentals of sophisticated Analytical instruments UV,HPLC, GC, Flame photometry	3	Knowledge
CO 2	To perform Preformulation studies of tablets	4	Analysis
CO 3	To formulate and evaluate SR,CR, Floating DDS, Mucoadhesive DDS, Transdermal Patches	4	Evaluate
CO 4	To study Micromeritic properties of powders and granulation.	4	Analysis
CO 5	To study the effect of variables on tablets disintegration time and its dissolution	3	Evaluation
CO 6	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors	3	Analysis

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	1	1	-	1	-	-	-	-	3
CO2	3	3	2	2	-	1	-	-	-	-	3
CO3	3	3	3	3	-	1	-	-	-	-	3
CO4	3	3	3	3	-	1	-	-	-	-	3
CO5	3	3	3	3	-	1	-	-	-	-	3
CO6	3	3	3	2	-	1	-	-	-	-	3

COURSE CONTENTS

Practical	Details	Hours
1	Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer	12
2	Simultaneous estimation of multi component containing formulations by UV spectrophotometry	12
3	Experiments based on HPLC	12
4	Experiments based on Gas Chromatography	06
5	Estimation of riboflavin/quinine sulphate by fluorimetry	06
6	Estimation of sodium/potassium by flame photometry	06
7	To perform In-vitro dissolution profile of CR/ SR marketed formulation	12
8	Formulation and evaluation of sustained release matrix tablets	12
9	Formulation and evaluation osmotically controlled DDS	12
10	Preparation and evaluation of Floating DDS– hydro dynamically balanced DDS	12
11	Formulation and evaluation of Muco adhesive tablets	12
12	Formulation and evaluation of Trans dermal patches	12
13	To carry out preformulation studies of tablets	06
14	To study the effect of compressional force on tablets disintegration time	06
15	To study Micromeritic properties of powders and granulation	06
16	To study the effect of particle size on dissolution of a tablet.	12
17	To study the effect of binders on dissolution of a tablet.	12
18	To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.	12

Reference Books (Latest Editions to be adopted):

Reference Books (Latest Editions to be adopted):

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.

3. Modern Pharmaceutics; By Gillbert and S. Banker.

4. Remington‟s Pharmaceutical Sciences.

5. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

6. Instrumental methods of analysis - Willards, 7th edition, CBS publishers.

7. Quantitative analysis of Pharmaceutical formulations by HPTLC – P D Sethi, CBS Publishers, New Delhi.

8. Practical Pharmaceutical chemistry, 4th Ed. Part-1, Beckett, A. H.; Stenlake, J. B. Bloomsbury Academic, 1988

9. Indian Pharmacopoeia, Controller of Publication, Govt. of India, Ministry of Health and Family Welfare, New Delhi, 2007

10. Rowe RC, Shesky PJ, Weller PT. Handbook of pharmaceutical excipients. 4th ed. London: Pharmaceutical Press; 2003. K.M. Varghese Company.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)

Semester II

(Pharmaceutics)

SUBJECT: MPH201T MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)

(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course has been designed to provide the knowledge to the students on the area of advances in novel drug delivery systems.

Course Objectives:

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should able to understand the various approaches for development of novel drug delivery systems.	1	Recall facts and basic concept
CO 2	To learn the criteria for selection of drugs and polymers for the development of NTDS.	2	Explain ideas or concept
CO 3	To understand about the formulation and evaluation aspects of novel drug delivery systems.	3	Apply
CO 4	To know and understand the basic considerations, formulation and evaluation of route specific novel drug delivery systems such as pulmonary route and intranasal route.	3	Apply
CO 5	To learn the concepts and basic considerations of nucleic acid based therapeutic delivery systems.	3	Apply
CO 6	To understand the in vivo fate, pharmacokinetic and biodistribution of novel drug delivery systems.	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	2	-	1	2	1	1	1	-	1
CO2	3	1	-	-	-	1	1	-	1	-	2
CO3	3	1	1	2	2	2	3	2	1	-	2

CO4	3	2	2	2	2	2	2	2	1	-	1
CO5	3	1	1	2	2	2	2	2	2	-	2
CO6	3		-	2	2	2	2	2	2	2	1

COURSE CONTENTS

Unit	Details	Hours
1	**Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12
2	**Targeting Methods:** Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation	12
3	**Micro Capsules / Micro Spheres:** Types, preparation and evaluation, **Monoclonal Antibodies:** Preparation and application, **Preparation and application of:** Niosomes, Aquasomes, Phytosomes, Electrosomes.	12
4	**Pulmonary Drug Delivery Systems:** Aerosols, propellants, Containers Types, preparation and evaluation. **Intra Nasal Route Delivery systems:** Types, preparation and evaluation.	12
5	**Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex–vivo & in–vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12
	TOTAL	**60**

Reference Books:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery – concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

SUBJECT: MPH 202T ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:15 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students to clarify the concepts.

Course Objectives:

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

- The basic concepts in biopharmaceutics and pharmacokinetics
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination
- The critical evaluation of biopharmaceutic studies involving drug product equivalency. Industrial management and GMP considerations
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
  The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand the fundamental concept involved in drug absorption	2	Understand
CO 2	To learn biopharmaceutical consideration in drug dosage form design	2	Understand
CO 3	To understand the pharmacokinetics and compartment modeling concept	3	Understand
CO 4	To know the concept of bioavailability and bioequivalence	2	Understand
CO 5	To understand the application of pharmacokinetics in drug delivery	3	Apply
CO 6	To understand the application of pharmacokinetics in biotechnology	2	Understand

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	-	1	-	-	1	-	-	-	-	3
CO2	3	-	1	-	-	1	-	-	-	-	3
CO3	3	-	2	-	-	1	-	-	-	-	3
CO4	3	-	2	-	-	1	1	-	-	1	3
CO5	3	-	2	-	-	1	-	-	-	-	3
CO6	3	-	2	-	-	1	-	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability–Solubility–Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight–Junction Complex.	12
2	**Biopharmaceutical considerations in drug product design and in Vitro Drug Product Performance:** Introduction, biopharmaceutical factors affecting drug bioavailability, rate–limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product	12
3	**Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartment modeling: one compartment model– IV bolus, IV infusion, extra–vascular. Multi compartment model: two compartment – model in brief, non–linear pharmacokinetics: cause of non–linearity, Michaelis - Menten equation, estimation of K_{max} and V_{max}. Drug interactions: introduction, the effect of protein– binding interactions, the effect of tissue–binding interactions, cytochrome p450–based drug interactions, drug interactions linked to transporters	12
4	**Drug Product Performance, In Vivo:** Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. biopharmaceutics classification system, methods. Permeability: In–vitro, in–situ and In–vivo methods. Generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. Concept of Total Quality Management. Aspects of sample collection in Pharmacokinetics	12
5	**Application of Pharmacokinetics:** Modified–Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal	12

	antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies, Introduction to Pharmacometrics	
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1.Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2ndedition, Connecticut Appleton Century Crofts, 1985

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel,1987.

10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.

11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

12. Basic Pharmacokinetics,1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing,2009.

13. Stephan Schmidt, Hartmut Derendorf (eds.) - Applied Pharmacometrics-Springer-Verlag New York (2014), AAPS Advances in the Pharmaceutical Sciences Series 14

SUBJECT: MPH 203T. COMPUTER AIDED DRUG DEVELOPMENT
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials:	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process.

Course Objectives:

Upon completion of the course a student shall be able to understand - History of Computers in Pharmaceutical Research and Development • Computational Modeling of Drug Disposition • Computers in Preclinical Development • Optimization Techniques in Pharmaceutical Formulation • Computers in Market Analysis • Computers in Clinical Development • Artificial Intelligence (AI) and Robotics • Computational fluid dynamics (CFD)

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To know history of computers and statistical modeling in pharmaceutical research and development	1,3	Recall facts and basic concept , Apply
CO 2	To understand Quality By Design in pharmaceutical development	1,3	Recall facts and basic concept , Apply
CO 3	To understand Computational modeling of drug disposition	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 4	To aware about optimization techniques and Computer aided formulation and development	1	Recall facts and basic concept
CO 5	To understand Computer aided Biopharmaceutical characterization and clinical development	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 6	To know Artificial Intelligence, Robotics and computational fluid dynamics in pharmaceutical formulation	2,3	Explain ideas or concept, Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	3	1	-	1	1	-	2	2	1
CO2	3	2	3	3	-	-	-	-	2	-	1
CO3	3	2	3	3	-	3	1	-	2	2	1
CO4	3	2	3	2	-	1	1	-	2	2	1
CO5	3	2	3	2	-	1	1	-	2	2	1
CO6	3	2	3	2	-	1	1	-	2	2	1

COURSE CONTENTS

Unit	Details	Hours
1	**a) Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling **b) Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD – examples of application.	12
2	**Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P–gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB–Choline Transporter.	12
3	**Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	12
4	**a) Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver	12

	considerations 47 **b) Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **c) Computers in Clinical Development:** Clinical Data Collection and Management, Regulation of Computer Systems	
5	**Artificial Intelligence (AI), Robotics and Computational fluid dynamics:** General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer–Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

Text Books:

Text Book of, Computer Aided Drug Development, Karri VVS Narayana Reddy, K Gowthamarajan, Arun Radhakrishnan, S.Vikas And company, Medical Publishers, Punjab, 2021

SUBJECT: MPH 204T COSMETICS AND COSMECEUTICALS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:15 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Course Objectives:

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

- Regulation involved in the cosmetics
- Key biological factors involved in the skin function
- Key building blocks for various formulations
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy
- Herbal Cosmetics and regulation involved in it

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand the regulation involved in the cosmetics in India	2	Understand
CO 2	To understand and comprehend various biological factors and conditions treated using cosmetics	2	Understand
CO 3	To understand key ingredient and their roles in cosmetic formulation	3	Apply
CO 4	To learn design various cosmetic preparations	3	Apply
CO 5	To know various regulation involved in cosmetics globally	2	Understand
CO 6	To understand the regulation involved herbal cosmetics	2	Understand

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	-	1	-	-	1	1	-	-	-	3
CO2	3	-	1	-	-	1	-	-	-	-	3
CO3	3	2	2	-	-	1	1	-	-	-	3
CO4	3	2	2	1	-	1	1	-	-	1	3
CO5	3	-	2	-	-	1	1	-	-	-	3
CO6	3	-	2	-	-	1	1	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics - Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12
2	**Cosmetics - Biological aspects:** Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under–arm.	12
3	**Formulation Building blocks:** Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants - Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndetbars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formal - ehyde liberators, dioxane, Polymers in cosmetics applications	12
4	**Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun–protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations, Multifunctional cosmetics	12
5	**Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.	12
	TOTAL	**60**

Reference Books:

1. Harry's Cosmeticology. 8th edition.
2. Poucher'sperfumecosmeticsandSoaps,10th edition.
3. Cosmetics – Formulation, Manufacture and quality control, PP.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.
7. E. Desmond Goddard, James V. Gruber - Principles of Polymer Science and Technology in Cosmetics and Personal Care-Marcel Dekker (1999)
8. Randy Schueller, Perry Romanowski - Multifunctional Cosmetics-Informa Healthcare (2002) (Cosmetic Science and Technology)

SUBJECT: MPH 205P PHARMACEUTICS PRACTICAL II
(PRACTICAL 180 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 00Hr/Week	In SEM Exam:30 Marks
Practical: 12Hr/Week	End SEM Exam:100 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 20 Marks
Credits: 6	Total Marks: 150 Marks

Scope

This practical course has been designed to provide the practical skills in novel drug delivery system including vesicular systems with exposure to various software and in vivo animal studies.

Course Objectives:

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

- The fundamentals of microparticulate drug delivery system
- Formulation and evaluation of vesicular drug delivery systems
- IVIVC correlation
- Design of experiment with computational tools to understand QBD concept
- Development and evaluation of cosmetic formulations
- Formulation of herbal cosmetics and its evaluation

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand fundamentals factors involved in microparticulate drug delivery system	3	Apply
CO 2	To formulate and evaluate vesicular drug delivery systems	4	Analysis
CO 3	To understand and apply the concept of in vitro-in vivo correlation	6	Evaluate
CO 4	To design of experiment with computational tools	5	Synthesis
CO 5	To Develop and evaluate cosmetic formulations	6	Evaluation
CO 6	To formulate herbal cosmetics and evaluate it	5	Synthesis

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	1	1	-	1	-	-	-	-	3
CO2	3	3	2	2	-	1	-	-	-	-	3
CO3	3	3	3	3	-	1	-	-	-	-	3
CO4	3	3	3	3	-	1	-	-	-	-	3
CO5	3	3	3	3	-	1	-	-	-	-	3
CO6	3	3	3	2	-	1	-	-	-	-	3

COURSE CONTENTS

Practical	**Details**	**Hours**
1	To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation	12

2	Preparation and evaluation of Alginate beads	06
3	Formulation and evaluation of gelatin /albumin microspheres	12
4	Formulation and evaluation of liposomes/niosomes	12
5	Formulation and evaluation of spherules/microparticles	12
6	Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique	12
7	Comparison of dissolution of two different marketed products /brands	06
8	Protein binding studies of a highly protein bound drug & poorly protein bound drug	12
9	Case studies of Pharmacokinetic and IVIVC data analysis	06
10	Design of Experiment for any formulation using Design Expert® Software (Only formulation DOE is expected)	12
11	Formulation data analysis Using Design Expert® Software (Data analysis and interpretation of the previous experiment is expected)	06
12	Case studies of Computer Simulations in Pharmacokinetics and Pharmacodynamics	06
13	Development and evaluation of Creams	12
14	Development and evaluation of Shampoo and Toothpaste base	12
15	To incorporate herbal and chemical actives to develop products to address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff	12
16	Quality-by-Design in Pharmaceutical Development	12
17	Case studies of Bioavailability studies of Paracetamol in animals	06
18	Case studies of In vitro cell studies for permeability and metabolism	06
19	Case studies of Computational Modeling of Drug Disposition	06

Reference Books (Latest Editions to be adopted):

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington‟s Pharmaceutical Sciences.

Semester I

(Regulatory Affairs)

SUBJECT: MRA101T. GOOD REGULATORY PRACTICES
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Total Marks: 100 Marks
Credits: 4	

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

Course Objectives:

Upon completion of the course a student shall be able to understand –

- The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand cGMP requirements for pharmaceutical manufacturing plant as per US FDA and EU.	2	Recall facts and basic concept
CO 2	The key regulatory and compliance elements related to Good Laboratory Practices.	2	Apply
CO 3	The key regulatory and compliance elements related to Good Automated Laboratory Practices.	3	Apply
CO 4	The key regulatory and compliance elements related to Good Documentation practices and Distribution Practices.	2	Apply
CO 5	To understand quality management system of pharmaceuticals and ICH quality guidelines.	3	Basic concept

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	2	-	-	2	2	-	2	1	3
CO2	3	1	2	-	-	2	2	-	2	1	2
CO3	3	1	2	-	-	2	2	-	2	1	2
CO4	3	1	2	-	-	2	2	-	2	1	2
CO5	3	1	2	-	-	2	2	-	2	1	3

COURSE CONTENTS

Unit	**Details**	**Hours**
1	**Current Good Manufacturing Practices:** Introduction, US cGMP Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force(GHTF) Guidance docs.	12
2	**Good Laboratory Practices:** Introduction, USFDA GLP Regulations	12

	(Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards	
3	**Good Automated Laboratory Practices:** Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.	12
4	**Good Distribution Practices:** Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12
5	**Quality management systems:** Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. 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. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the PharmaceuticalSciences,Vol.168.
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences,Vol.150.
6. Drugs & Cosmetics Act, Rules & Amendments

SUBJECT: MRA102T. DOCUMENTATION AND REGULATORY WRITING
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Total Marks: 100 Marks
Credits: 4	

Scope: This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Course Objectives:

Upon completion of the course a student shall be able to understand –

- Know the various documents pertaining to drugs in pharmaceutical industry.
- Understand the basics of regulatory compilation.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	Know the various documents pertaining to drugs in pharmaceutical industry.	2	Apply
CO 2	Create and assemble the dossier submission as per the regulatory requirements of agencies.	3	Apply
CO 3	To understand the Auditing/Inspection of manufacturing facilities by regulatory agencies.	2	Apply
CO 4	To understand different types of inspections and inspection compliance.	2	Apply
CO 5	To understand about product lifecycle management.	3	Basic concept

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	2	-	-	2	2	-	2	1	2
CO2	3	3	2	-	-	2	2	-	2	1	3
CO3	3	3	2	-	-	2	2	-	2	1	3
CO4	3	3	2	-	-	2	2	-	2	1	3
CO5	3	1	2	-	-	2	2	-	2	1	2

COURSE CONTENTS

Unit	**Details**	**Hours**
1	**Documentation in pharmaceutical industry:** Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files(DMF).	12
2	**Dossier preparation and submission:** Introduction and overview of dossiers, contents and organization of dossier, binders and sections,	12

	compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.	
3	**Audits:** Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third-party audits, auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	12
4	**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, Root cause analysis, Corrective and Preventive action (CAPA).	12
5	**Product life cycle management:** Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard.	12
	TOTAL	**60**

Reference Books:

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A.Hodges, Stephen P. Denyar.CRC Press.2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley,2000
6. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass,2001
8. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
9. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications

11. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12. Root Cause Analysis, the Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications.
13. International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)

SUBJECT: MRA103T. CLINICAL RESEARCH REGULATIONS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:15 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and Medical Devices, phases and conduct of clinical trials and research, regulations and guidance governing the conduct of clinical research in India, USA 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.

Course Objectives:

Upon completion of the course, the student shall be able to (know, do and appreciate)

• History, origin and ethics of clinical and biomedical research and evaluation

• 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

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To study the clinical drug development process. And different types of clinical studies and their phases. To study the concept and evaluation of medical device	3	Apply
CO 2	Explaining the ethics in clinical research, ICH GCP guidelines, to study the historical perspective	2	Explain ideas or concept
CO 3	Regulation governing clinical trials in INDIA, US and EUROPE. NDA and ANDA regulation study	3	Apply
CO 4	Clinical Research related guidelines	3	Apply
CO 5	USA Guidance, CFR 21, good pharmacovigilance practices	3	Apply
CO 6	European Union, EMA guidance, ISO14155	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	2	-	3	3	1	-	1	-	3
CO2	3	1	2	-	3	3	1	-	1	-	3
CO3	3	1	2	-	-	3	1	-	1	-	3
CO4	3	1	2	-	3	3	1	-	1	-	3
CO5	3	1	2	-	-	3	2	-	1	-	3
CO6	2	1	2	-	3	3	2	-	1	-	3

COURSE CONTENTS

Unit	**Details**	**Hours**

1	Clinical Drug Development Process • Different types of Clinical Studies • Phases of clinical trials, Clinical Trial protocol • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug - drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) • Clinical Investigation and Evaluation of Medical Devices & IVDs • Different Types of Studies • Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation	12
2	Ethics in Clinical Research: • Historical Perspectives: Nuremberg Code, Thalidomide study, Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization – Good Clinical Practice (ICH–GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board / Independent Ethics Committee / Ethics Committee-composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data • Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation	12
3	Regulations governing Clinical Trials • India: Clinical Research regulations in India - Schedule Y & Medical Device Guidance • USA: Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry – Acceptance of Foreign Clinical	12

	Studies • FDA Clinical Trials Guidance Document: Good Clinical Practice • EU: Clinical Research regulations in European Union (EMA)	
4	Clinical Research Related Guidelines • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines • GHTF study group 5 guidance documents • Regulatory Guidance on Efficacy and Safety ICH Guidance's • E4 – Dose Response Information to support Drug Registration • E7 - Studies in support of General Population: Geriatrics • E8 - General Considerations of Clinical Trials • E10 - Choice of Control Groups and Related Issues in Clinical Trials • E 11 - Clinical Investigation of Medicinal Products in the Pediatric Population • General biostatics principle applied in clinical research	12
5	USA & EU Guidance USA: FDA Guidance • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post–market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch • Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment	6
6	• European Union: EMA Guidance • EU Directives 2001 • EudraLex (EMEA) Volume 3- Scientific guidelines for medicinal products for human use • EU Annual Safety Report (ASR) • Volume 9A - Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research • ISO 14155	6
	TOTAL	**60**

Reference Books

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. Drugs & Cosmetic s Act & Rules and Amendments

SUBJECT: MRA104T. REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:15 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart fundamental knowledge on regulations and legislation in India w.r.t. Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. It prepares the students for basic regulatory requirements in India of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. For manufacture, import & registration, export, sale, marketing authorization, clinical trials and intellectual property rights

Course Objectives:

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

• Know different Acts and guidelines that regulate Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals industry in India.

• Understand the approval process and regulatory requirements for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To study the Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments), Drug and Cosmetic Act 1940 and Rules 1945	3	Apply
CO 2	Information of other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	2	Explain ideas or concept
CO 3	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities	3	Apply
CO 4	Indian Pharmacopeial Standards, BIS standards and ISO and other relevant standards	3	Apply
CO 5	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR–DBT Guidelines for Stem Cell Research	3	Apply

CO 6	Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	2	-	3	3	-	-	-	-	3
CO2	3	1	2	-	3	3	-	-	-	-	3
CO3	3	1	2	-	3	3	-	-	-	-	3
CO4	3	1	2	-	3	3	-	-	-	-	3
CO5	3	1	2	-	3	3	-	-	-	-	3
CO6	3	1	2	-	3	3	-	-	-	-	3

COURSE CONTENTS

Unit	**Details**	**Hours**
1	Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments): a. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA b. Other relevant provisions (rules schedules and guidelines for approval of Drugs Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India	10
2	Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	10
3	Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities • Rules, regulations, guidelines and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals • Format & contents of Regulatory dossier filing Clinical trial / investigations	10
4	Indian Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	10
5	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines Ethical guidelines for human participants ICMR–DBT Guidelines for Stem Cell Research	10

6	Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs and Geographical Indications, Indian Patent Scenario. IPR vs Regulatory Affairs	10
	TOTAL	**60**

Reference Books

1. Manual of Patent Practice & Procedure, 3rd Edition, by the Patent Office of India
2. Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3. Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4. Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5. CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6. ICH E6 Guideline - Good Clinical Practice" by ICH Harmonised Tripartite
7. Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8. Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO
9. Guidelines for Import and Manufacture of Medical Devices by CDSCO
10. Guidelines from official website of CDSCO

MRA105P. PHARMACEUTICAL REGULATORY AFFAIRS (Practical)
12 Hours / Week

Teaching Scheme	**Examination Scheme:**
Lectures:	In SEM Exam:50 Marks
Practical: 12Hr/Week	End SEM Exam:100 Marks
Tutorials:	Total Marks: 150 Marks
Credits: 6	

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	**Descriptor**
CO 1	To understand good pharmaceutical practices with case studies.	3	Apply
CO 2	To understand documentation for quality control tests for solid, semisolid, liquid and sterile dosage forms.	3	Apply
CO 3	To understand document preparation.	3	Apply
CO 4	To understand product registration requirements of different agencies.	2	Apply
CO 5	To understand regulatory requirements for conducting clinical trial as per different regulatory agencies.	2	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	1	2	-	-	2	2	-	2	1	2
CO2	3	1	2	-	-	2	2	-	2	1	2
CO3	3	1	2	-	-	2	2	-	2	1	2
CO4	3	1	2	-	-	2	2	-	2	1	2
CO5	3	1	2	-	-	2	2	-	2	1	2

COURSE CONTENT

Sr. No.	Practical title	Hrs
1	Case studies (4Nos.) of each of Good Pharmaceutical Practices.	**12**
2	Documentation for in-process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.	**10**
3	Preparation of SOPs, Analytical reports (Stability and validation)	**8**
4	Protocol preparation for documentation of various types of records (BMR, MFR, DR)	**6**
5	Labeling comparison between brand &generics.	**1**
6	Preparation of clinical trial protocol for registering trial in India	**4**
7	Registration for conducting BA/BE studies in India	**4**
8	Import of drugs for research and developmental activities	**4**
9	Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM	**8**
10	Registering for different Intellectual Property Rights in India	**8**

11	GMP Audit Requirements as per CDSCO	**8**
12	Preparation and documentation for Indian Patent application.	**6**
13	Preparation of checklist for registration of IND as per ICH CTD format.	**8**
14	Preparation of checklist for registration of NDA as per ICH CTD format.	**8**
15	Preparation of checklist for registration of ANDA as per ICH CTD format.	**8**
16	Case studies on response with scientific rationale to USFDA Warning Letter	**5**
17	Preparation of submission checklist of IMPD for EU submission.	**6**
18	Comparison study of marketing authorization procedures in EU.	**8**
19	Comparative study of DMF system in US, EU and Japan	**6**
20	Preparation of regulatory submission using eCTD software	**12**
21	Preparation of Clinical Trial Application (CTA) for US submission	**8**
22	Preparation of Clinical Trial Application (CTA) for EU submission	**8**
23	Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.	**6**
24	Regulatory requirements checklist for conducting clinical trials in India.	**6**
25	Regulatory requirements checklist for conducting clinical trials in Europe.	**6**
26	Regulatory requirements checklist for conducting clinical trials in USA.	**6**

Semester II

(Regulatory Affairs)

SUBJECT: MRA201T REGULATORY ASPECTS OF DRUG & COSMETICS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart the fundamental knowledge on the drug development process, regulatory requirements for approval of new drugs, drug products and cosmetics in regulated and semi–regulated countries It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products and cosmetics in regulated and semi–regulated countries

Course Objectives:

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

- Process of drug discovery and development and generic product development
- Regulatory approval process and registration procedures for API and drug products in US, EU
- Cosmetics regulations in regulated and semi–regulated countries
- A comparative study of India with other global regulated markets

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	**USA & CANADA**: Organization structure and functions of FDA. Code of Federal Regulations (CFR), Hatch Waxman act and orange book, purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada	3	Apply
CO 2	**European Union & Australia**: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia.	3	Apply
CO 3	**Japan:** Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan,	3	Apply

	Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan		
CO 4	**Emerging Market**: Introduction, Countries covered, Study of the world map,study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) – General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana).	3	Apply
CO5	**Brazil, ASEAN, CIS and GCC Countries**: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory pre– requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre–requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	1	3	1	3	2	1	3	1	3
CO2	3	1	1	3	1	3	2	2	3	1	3
CO3	2	2	1	2	1	3	2	1	3	1	3
CO4	2	2	1	2	1	3	2	1	3	1	3
CO5	3	2	3	2	1	3	2	2	3	1	3

COURSE CONTENTS

Unit	**Details**	**Hours**
1	USA & CANADA: Organization structure and functions of FDA. Federal register and Code of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drug and Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug Master Files (DMF) system in US, Regulatory Approval Process for Investigational New Drug (IND), New Drug Application(NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA); Regulatory requirements for Orphan drugs and Combination Products, Changes to an approved NDA / ANDA. Regulatory considerations for manufacturing, packaging and labeling of	12

	pharmaceuticals in USA. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in USA and Canada	
2	European Union & Australia: Organization and structure of EMA & EDQM, General guidelines, Active Substance Master Files (ASMF) system in EU, Content and approval process of IMPD, Marketing Authorization procedures in EU (Centralized procedure, Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralex directives for human medicines, Variations & extensions, Compliance of European Pharmacopoeia (CEP)/ Certificate of Suitability (CoS), Marketing Authorization (MA) transfers, Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in European Union & Australia..	12
3	Japan: Organization of the PMDA, Pharmaceutical Laws and regulations, types of registration applications, DMF system in Japan, drug regulatory approval process, regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in Japan, Post marketing surveillance in Japan. Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Japan	12
4	Emerging Market: Introduction, Countries covered, Study of the world map, study of various committees across the globe (ASEAN, APEC, EAC, GCC, PANDRH, SADC) WHO: WHO, GMP, Regulatory Requirements for registration of drugs and post approval requirements in WHO through prequalification programme, Certificate of Pharmaceutical Product (CoPP) – General and Country Specific (South Africa, Egypt, Algeria and Morocco, Nigeria, Kenya and Botswana)	12
5	Brazil, ASEAN, CIS and GCC Countries: ASIAN Countries: Introduction to ACTD, Regulatory Requirements for registration of drugs and post approval requirements in China and South Korea & Association of Southeast Asian Nations (ASEAN) Region i.e. Vietnam, Malaysia, Philippines, Singapore and Thailand. CIS (Commonwealth Independent States): Regulatory pre– requisites related to Marketing authorization requirements for drugs and post approval requirements in CIS countries i.e. Russia, Kazakhstan and Ukraine GCC (Gulf Cooperation Council) for Arab states: Regulatory pre–requisites related to Marketing authorization requirements for drugs and post approval requirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture, distribution and sale of cosmetics in Brazil, ASEAN, CIS and GCC Countries.	12
	TOTAL	**60**

Reference Books:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry Marcel Dekker Series, Vol.144
3. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185 Informa Health care Publishers.

4. New Drug Approval Process: Accelerating Global Registrations by Richard a Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
5. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
6. Drugs: From Discovery to Approval, Second Edition By Rick Ng
7. New Drug Development: A Regulatory Overview, Eighth Edition By Mark Mathieu
8. Pharmaceutical Risk Management by Jeffrey E. Fetterman, Wayne L. Pines and Gary H. Slatko
9. Preparation and Maintenance of the IND Application in eCTD Format by William K. Sietsema
10. Country Specific Guidelines from official websites.
11. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/ListMRAWebsites.pdf
12. Roadmap to an ASEAN economic community Edited by Denis Hew. ISEAS Publications, Singapore 2005, ISBN981–230–347–2
13. ASEAN, Rodolfo C. Severino, ISEAS Publications, Singapore 2005, ISBN 978–981–230–750–7
14. Building a Future with Brics: The Next Decade for Offshoring, Mark Kobayashi–Hillary, Springer
15. Outsourcing to India: The Offshore Advantage, Mark Kobayashi–Hillary, Springer Trade performance and Regional Integration of the CIS Countries, Lev Freinkman,
16. The World Bank, Washington, DC, ISBN: 0–8212–5896–0
17. Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World ByFrederick M. Abbott, Graham Dukes, Maurice Nelson Graham Dukes 139
18. The Gulf Cooperation Council: A Rising Power and Lessons for ASEAN by Linda Low and Lorraine Carlos Salazar (Nov 22, 2010)
19. Doing Business in the Asean Countries, Balbir Bhasin, Business Expert Press ISBN: 13:978–1–60649–108–9
20. Realizing the ASEAN Economic Community: A Comprehensive Assessment, Michael G Plummer (Editor), Chia Siow Yue (Editor), Instute of South East Asian studies, Singapore

SUBJECT: MRA202T REGULATORY ASPECTS OF HERBAL AND BIOLOGICALS (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart fundamental knowledge on Regulatory Requirements, Licensing and Registration, Regulation on Labelling of Biologics in India, USA and Europe It prepares the students to learn in detail on Regulatory Requirements for biologics, Vaccines and Blood Products.

Course Objectives:

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

- Know the regulatory Requirements for Biologics and Vaccines.
- Understand the regulation for newly developed biologics and biosimilars.
- Know the pre-clinical and clinical development considerations of biologics.
- Understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	Students should be able to understand regulatory Requirements for Biologics and Vaccines.	3	Basic ideas and concepts
CO 2	To understand the regulation for newly developed biologics and biosimilars.	3	Apply
CO 3	Students should be able to understand what the pre-clinical and clinical development considerations of biologics are.	3	Apply
CO 4	To understand the Regulatory Requirements of Blood and/or Its Components Including Blood Products and label requirements.	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	1	2	2	2	2	2	2	2	2
CO2	2	2	3	2	3	3	2	2	2	2	2
CO3	2	2	1	2	2	2	2	2	2	2	2
CO4	2	2	1	2	2	2	2	2	2	2	2

COURSE CONTENTS

Unit	**Details**	**Hours**
1	**India:** Introduction, Applicable Regulations and Guidelines , Principles for Development of Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for Clinical Trial Application, Data Requirements for Market Authorization Application, Post-Market Data for Similar Biologics,	12

	Pharmacovigilance.GMP andGDP.	
2	**USA:** Introduction to Biologics; biologics, biological and biosimilars, different biological products, difference between generic drug and biosimilars, laws, regulations and guidance on biologics/ biosimilars, development and approval of biologics and biosimilars (IND,PMA, BLA, NDA,510(k), pre-clinical and clinical development considerations, advertising, labelling and packing of biologics.	12
3	**European Union:** Introduction to Biologics; directives, scientific guidelines and guidance related to biologics in EU, comparability/ biosimilarity assessment, Plasma master file, TSE/ BSE evaluation, development and regulatory approval of biologics (Investigational medicinal products and biosimilars), pre-clinical and clinical development considerations; stability, safety, advertising, labelling and packing of biologics in EU.	12
4	**Vaccine regulations in India, US and European Union:** Clinical evaluation, Marketing authorisation, Registration or licensing, Quality assessment, Pharmacovigilance, Additional requirements Blood and Blood Products Regulations in India, US and European Union: Regulatory Requirements of Blood and/or Its Components Including Blood Products, Label Requirements, ISBT (International Society of Blood Transfusion) and IHN(International Haemovigilence Network)	12
5	**Herbal Products:** Quality, safety and legislation for herbal products in India, USA and European Union.	12
	TOTAL	**60**

Reference Books:

1. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David S. Mantus;Informa,2008
2. Biological Drug Products: Development and Strategies; Wei Wang, Manmohan Singh ;wiley,2013
3. Development of Vaccines: From Discovery to Clinical Testing; Manmohan Singh,IndreshK.Srivastava;Wiley,2011
4. www.who.int/biologicals/en
5. www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInfo rmation/
6. www.ihn-org.com
7. www.isbtweb.org
8. Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India
9. www.cdsco.nic.in
10. www.ema.europa.eu › scientific guidelines › Biologicals.
11. www.fda.gov/biologics blood Vaccines/Guidance Compliance Regulatory Information (Biologics)

Text Books:

12. Drug Regulatory Affairs: Dr. N.S. Vyawahare and Sachin Itkar

SUBJECT: MRA203T REGULATORY ASPECTS OF MEDICAL DEVICES
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart the fundamental knowledge on the medical devices and in vitro diagnostics, basis of classification and product life cycle of medical devices, regulatory requirements for approval of medical devices in regulated countries like US, EU and Asian countries along with WHO regulations. It prepares the students to learn in detail on the harmonization initiatives, quality and ethical considerations, regulatory and documentation requirements for marketing medical devices and IVDs in regulated countries.

Course Objectives:

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

- basics of medical devices and IVDs, process of development, ethical and quality considerations
- harmonization initiatives for approval and marketing of medical devices and IVDs
- regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN
- clinical evaluation and investigation of medical devices and IVDs

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	Students should be able to understand basics of medical devices and IVDs, process of development, ethical and quality considerations.	3	Basic ideas and concepts
CO 2	To learn harmonization initiatives for approval and marketing of medical devices and IVDs	3	Apply
CO 3	To understand regulatory approval process for medical devices and IVDs in India, US, Canada, EU, Japan and ASEAN region.	3	Apply
CO 4	To understand clinical evaluation and investigation of medical devices and IVDs	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	3	1	2	3	3	3	3	2	1	3
CO2	2	2	1	2	2	2	2	2	2	2	2
CO3	2	2	1	2	2	3	2	2	2	2	2
CO4	3	3	3	3	2	2	2	2	2	2	2

COURSE CONTENTS

Unit	Details	Hours
1	**Medical Devices:** Introduction, Definition, Risk based classification and Essential Principles of Medical Devices and IVDs. Differentiating medical devices IVDs and Combination Products from that of pharmaceuticals, History of Medical Device Regulation, Product Lifecycle of Medical Devices and Classification of Medical Devices. IMDRF/GHTF: Introduction, Organizational Structure, Purpose and Functions, Regulatory Guidelines, Working Groups, Summary Technical Document (STED), Global Medical Device Nomenclature (GMDN).	12
2	**Ethics:** Clinical Investigation of Medical Devices, Clinical Investigation Plan for Medical Devices, Good Clinical Practice for Clinical Investigation of medical devices(ISO 14155:2011) Quality: Quality System Regulations of Medical Devices: ISO 13485,Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device, Adverse Event Reporting of Medical device.	12
3	**USA:** Introduction, Classification, Regulatory approval process for Medical Devices (510k) Premarket Notification, Pre-Market Approval (PMA), Investigational Device Exemption (IDE) and In vitro Diagnostics, Quality System Requirements21CFR Part820, Labeling requirements 21 CFR Part 801, Post marketing surveillance of MD and Unique Device Identification (UDI).Basics of In vitro diagnostics, classification and approval process.	12
4	**European Union:** Introduction, Classification, Regulatory approval process for Medical Devices (Medical Device Directive, Active Implantable Medical Device Directive) and In vitro Diagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitro diagnostics, classification and approval process.	12
5	**ASEAN, China & Japan:** Medical Devices and IVDs, Regulatory registration procedures, Quality System requirements and clinical evaluation and investigation. IMDRF study groups and guidance documents.	12
	TOTAL	**60**

Reference Books:

1. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics by Douglas J. Pisano, David Mantus.
2. Medical Device Development: A Regulatory Overview by Jonathan S. Kahan
3. Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
4. Compliance Handbook for Pharmaceuticals, Medical Devices and Biologics by Carmen Medina
5. Country Specific Guidelines from official websites

Text Books:

6. Drug Regulatory Affairs: Dr. N.S. Vyawahare and Sachin Itkar

SUBJECT: MRA204T REGULATORY ASPECTS OF FOOD AND NUTRACEUTICALS (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart the fundamental knowledge on Regulatory Requirements, Registration and Labeling Regulations of Nutraceuticals in India, USA and Europe.
It prepares the students to learn in detail on Regulatory Aspects for Nutraceuticals and food supplements

Course Objectives:

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

• Know the regulatory Requirements for nutraceuticals

• Understand the regulation for registration and labeling of nutraceuticals and food supplements in India, USA and Europe

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market.	3	Basic ideas and concepts
CO 2	WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements & Nutraceuticals Industries, NSF Certification, NSF Standards for Food Dietary Supplements. Good Manufacturing Practices for Nutraceuticals	3	Apply
CO 3	Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India	3	Apply
CO 4	US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	3	Apply
CO5	European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	1	2	1	2	3	1	3	1	2
CO2	3	2	1	3	2	2	3	1	3	1	2
CO3	3	2	1	3	1	3	2	1	3	1	3

CO4	3	2	1	3	1	3	2	1	3	1	3
CO5	3	2	1	3	1	3	2	1	3	1	3

COURSE CONTENTS

Unit	Details	Hours
1	**Nutraceuticals:** Introduction, History of Food and Nutraceutical Regulations, Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods, Scope and Opportunities in Nutraceutical Market	12
2	**Global Aspects**: WHO guidelines on nutrition. NSF International: Its Role in the Dietary Supplements & Nutraceuticals Industries, NSF Certification, NSF Standards for Food Dietary Supplements. Good Manufacturing Practices for Nutraceuticals.	12
3	**India :** Food Safety and Standards Act, Food Safety and Standards Authority of India: Organization and Functions, Regulations for import, manufacture and sale of nutraceutical products in India, Recommended Dietary Allowances (RDA) in India.	12
4	**USA:** US FDA Food Safety Modernization Act, Dietary Supplement Health and Education Act. U.S. regulations for manufacture and sale of nutraceuticals and dietary supplements, Labelling Requirements and Label Claims for Dietary Supplements, Recommended Dietary Allowances (RDA) in the U.S	12
5	**European Union**: European Food Safety Authority (EFSA): Organization and Functions. EU Directives and regulations for manufacture and sale of nutraceuticals and dietary supplements. Nutrition labelling. European Regulation on Novel Foods and Novel Food Ingredients. Recommended Dietary Allowances (RDA) in Europe.	12
	TOTAL	**60**

Reference Books:

1. Regulation of Functional Foods and Nutraceuticals: A Global Perspective by Clare M. Hasler (Wiley Online Library)
2. Nutraceutical and Functional Food Regulations in the United States and Around the World by Debasis Bagchi (Academic Press, Elsevier)
3. http://www.who.int/publications/guidelines/nutrition/en/
4. http://www.europarl.europa.eu/RegData/etudes/STUD/2015/536324/IPOL_ STU (2015) 536324_EN.pdf
5. Handbook of Nutraceuticals by Yashwant Pathak (CRC Press)
6. Food Regulation: Law, Science, Policy and Practice by Neal D. Fortin (Wiley)
7. Country Specific Guidelines from official websites

SUBJECT: MRA205P REGULATOY AFFAIRS PRACTICAL – II
PRACTICAL II – 180 (HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 00Hr/Week	In SEM Exam:50 Marks
Practical: 12Hr/week	End SEM Exam:100 Marks
Tutorials: 00Hr/Week	Continuous Assessment: -
Credits: 6	Total Marks: 150 Marks

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To study change management, corrective and preventive actions, documentations of raw materials and case studies.	3	Apply
CO 2	Preparation of submission to FDA, EMA, MHRA using e CTD software, preparation of audit checklist for various agencies.	3	Apply
CO 3	Preparation of biologics license application and documents required for vaccine product approval, clinical trial application requirements, preparation of checklist for registration of blood and blood products.	3	Apply
CO 4	Registration requirement comparison study in 5 emerging markets (WHO), (BRICS), (China and South Korea), (ASEAN), (GCC) and preparing its checklist.	3	Apply
CO 5	Checklist for 510k and PMA for US market and CE marking, STED application, audit checklist for medical device facility, clinical investigation plan for medical device	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	1	-	-	2	1	-	2	-	3
CO2	3	1	1	-	-	3	1	-	2	-	3
CO3	3	1	1	-	-	3	1	-	2	-	3
CO4	3	1	2	-	-	3	1	-	2	-	3
CO5	3	1	2	-	-	2	1	-	2	-	3

COURSE CONTENTS

Unit	**Practical title**	**Hours**
1	Case studies on	8
2	Change management/ change control deviations	8
3	Corrective and preventive actions (CAPA)	8
4	Documentation of raw materials analysis as per official monograph	8
5	Preparation of audit checklist for various agencies	8
6	Preparation of submission to FDA using eCTD software	**9**
7	Preparation of submission to EMA using eCTD software	**9**
8	Preparation of submission to MHRA using eCTD software	**9**

9	Preparation of Biologics License Applications (BLA	**9**
10	Preparation of documents required for Vaccine Product Approval	**8**
11	Comparison of clinical trial application requirements of US, EU and India of Biologics	**8**
12	Preparation of Checklist for Registration of Blood and Blood Products	**8**
13	Registration requirement comparison study in 5 emerging markets (WHO) and preparing check list for market authorization	**8**
14	Registration requirement comparison study in emerging markets (BRICS) and preparing check list for market authorization	**8**
15	Registration requirement comparison study in emerging markets (China and South Korea) and preparing check list for market authorization	**8**
16	Registration requirement comparison study in emerging markets (ASEAN) and preparing check list for market authorization	**8**
17	Registration requirement comparison study in emerging markets (GCC) and preparing check list for market authorization	**8**
18	Checklists for 510k and PMA for US market	**8**
19	Checklist for CE marking for various classes of devices for EU	**8**
20	STED Application for Class III Devices	**8**
21	Audit Checklist for Medical Device Facility	**8**
22	Clinical Investigation Plan for Medical Devices	**8**

Semester I

(Pharmaceutical Biotechnology)

SUBJECT: MPAT101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 03Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 01Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks
Name of Faculty: Mrs. Poonam S Aher	

Scope

Scope This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc. Simple structure elucidation problems may be included based on UV-IR-NMR data.

Course Objectives:

Upon completion of course the students shall able to

1. Analytical techniques for identification, characterization and quantification of drugs
2. Theoretical and practical skills of instrument handling and use.
3. Structural Elucidation of organic compounds using spectroscopic tools

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the theory, instrumentation, principle and application of UV visible spectroscopy, IR spectroscopy, Spectroflourimetry and flame emission and absorption spectroscopy	1,2,3	Remember, Understand , Analyze and Apply
CO 2	The students should be able to understand the theory, instrumentation, principle and application of NMR spectroscopy	1,2,3	Remember, Understand , Analyze and Apply
CO 3	The students should be able to understand the theory, instrumentation, principle and application of Mass spectroscopy and structural elucidation of UV,IR,NMR and mass interpretation problems	1,2,3	Remember, Understand , Analyze and Apply
CO 4	The students should be able to understand the theory, instrumentation, principle and application of HPLC, HPTLC, TLC,UPLC, GC, Ion exchange chromatography, Affinity chromatography, Gel chromatography, column chromatography	1,2,3	Remember, Understand , Analyze and Apply
CO 5	The students should be able to understand the theory, instrumentation, principle and application of Electrophoresis and X ray crystallography, calculation of Braggs law and structure of crystal	1,2,3	Remember, Understand , Analyze and Apply

			and Apply
CO 6	To understand the basic concepts theory, instrumentation, principle and application of Thermal methods TGA, DTA, DSC	1,2,3	Remember and Understand

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	2	3	0	2	0	0	2	0	2
CO2	3	2	2	3	0	2	0	0	2	0	2
CO3	3	2	2	3	0	2	0	0	2	0	2
CO4	3	2	2	3	0	2	0	0	2	0	2
CO5	3	2	2	3	0	2	0	0	2	0	2
CO6	3	2	2	3	0	2	0	0	2	0	2

COURSE CONTENTS

Unit	Details	Hours
1	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy. b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	10
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of	10

	FT-NMR and 13C NMR. Applications of NMR spectroscopy.	
3	**Mass Spectrometry**: Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry Simple structure elucidation problems based on UV, IR, NMR and Mass data.	12
4	**Chromatography:** Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) High Performance Liquid chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Gas chromatography e) Ultra High Performance Liquid chromatography f) Affinity chromatography g) Gel Chromatography TLC and Column Chromatography	10
5	**a) Electrophoresis**: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing **b) X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction, calculation of Braggs law and structure of crystal	**10**
6	**Thermal Techniques**: a) Thermogravimetric analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. b) Differential scanning calorimetry (DSC): Principle, thermal	**08**

	transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. c) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).	
	TOTAL	**60 hrs**

Reference Books (Latest Editions to be adopted):

References Book:

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series

8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.

9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

SUBJECT: MPB102T MICROBIAL AND CELLULAR BIOLOGY
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This subject is designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced microbiology which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Course Objectives:

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

- Importance of Microorganisms in Industry
- Central dogma of molecular biology
- Structure and function of cell and cell communication
- Cell culture technology and its applications in pharmaceutical industries.
- Microbial pathogenesis and correlating it to rational use of antimicrobial agents.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the importance of Microorganisms in Industry	1	Recall facts and basic concept
CO 2	To learn central dogma of molecular biology	2	Explain ideas or concept
CO 3	To understand and know Structure and function of cell and cell communication	3	Apply
CO 4	To know concept, techniques and components of cell culture technology and its applications in pharmaceutical industries.	3	Apply
CO 5	To learn various microbial pathogenesis and correlating it to rational use of antimicrobial agents.	3	Apply
CO 6	To understand about microbial nutrition growth of animal cells in culture.	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	3	3	-	-	-	-	-	-	3
CO2	3	2	1	3	-	-	-	-	-	-	3
CO3	3	2	2	3	-	-	2	-	-	-	3
CO4	3	2	2	3	-	-	-	-	-	-	3
CO5	3	2	2	3	-	-	-	-	-	-	3
CO6	3	1	3	3	-	-	-	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Microbiology Introduction** Prokaryotes and Eukaryotes. Bacteria, fungi, actionomycetes and virus – structure, chemistry and morphology, cultural, physiological and reproductive features. Methods of isolation, cultivation and maintenance of pure cultures. Industrially important microorganisms – examples and applications	12
2	**Molecular Biology:** Structure of nucleus and chromosome, Nucleic acids and composition, structure and types of DNA and RNA. **Central dogma of molecular biology:** Replication, Transcription and translation. Gene regulation Gene copy number, transcriptional control and translational control. RNA processing Modification & maturation, RNA splicing, RNA editing, RNA amplification. Mutagenesis and repair mechanisms, types of mutants, application of mutagenesis in stain improvement, gene mapping of plasmids types purification and application. Phage genetics, genetic organization, phage mutation and lysogeny**.**	12
3	Cell structure and function Cell organelles, cytoskeleton & cell movements, basic aspects of cell regulation, bioenergetics and fuelling reactions of aerobics and anaerobic, secondary metabolism & its applications. Cell communication, cell cycle and apoptosis, mechanism of cell division. Cell junctions/adhesion and extra cellular matrix, germ cells and fertilization, histology - the life and death of cells in tissues. **Cell Cycle and Cytoskeleton:** Cell Division and its Regulation, G–Protein Coupled Receptors, Kinases, Nuclear receptors, Cytoskeleton & cell movements, Intermediate Filaments. **Apoptosis and Oncogenes:** **Programmed Cell Death, Tumor cells, carcinogens & repair.** **Differentiation and Developmental Biology:** Fertilization, Events of Fertilization, In vitro Fertilization, Embryonic Germ Cells, Stem Cells & its Application	12
4	**Principles of microbial nutrition:** Physical and chemical environment for microbial growth, Stability and degeneration of microbial cultures. **Growth of animal cells in culture:** General procedure for cell culture, Nutrient composition, Primary, established and transformed cell cultures, applications of cell cultures in pharmaceutical industry and research. Growth of viruses in cell culture propagation and enumeration. In-vitro screening techniques– cytotoxicity, anti–tumor, anti–viral assays.	12
5	**Microbial pathology:** Identifying the features of pathogenic bacteria, fungi and viruses. Mechanism of microbial pathogenicity, etiology and pathology of common microbial diseases and currently recommended therapies for common	12

	bacterial, fungal & viral infections. Mechanism of action of antimicrobial agents and possible sites of chemotherapy.	
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn, Industrial Microbiology, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. David Freifelder, Molecular Biology, 2nd edition, Narosa Publishing House.
5. R. Ian Freshney, Culture of animal cells - A manual of Basic techniques, 6th edition, Wileys publication house.
6. David Baltimore, Molecular cell biology, W H Freeman & Co publishers.
7. Cell biology vol–I,II,III by Julio E.Cells
8. Bergeys manual of systematic bacteriology, Williams and Wilkins– A Waverly Company.

Text Books:

Modern Biotechnology: S.B Primrose

SUBJECT: MPB103T BIOPROCESS ENGINEERING AND TECHNOLOGY
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course has been designed to provide the knowledge to the biotechnology students in invaluable areas of bioprocess technology to develop skills to modify, design and operate different types of fermenters, to understand and implement various fermentation procedures, to train students in scale up fermentation operations.

Course Objectives:

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

- Understand basics and design of fermentation technology
- Scale up and scale down processing of fermentation technology
- Bioprocessing of the industrially important microbial metabolites in industries and R & D organizations.
- Regulation governing the manufacturing of biological products
- Understand and conduct fermentation process kinetics.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the fundamentals of basics and design of fermentation technology	1	Recall facts and basic concept
CO 2	To explain scale up and scale down processing of fermentation technology	2	Explain ideas or concept
CO 3	To learn Bioprocessing of the industrially important microbial metabolites in industries and R&D organizations.	3	Apply
CO 4	To know various regulatory norms governing the manufacturing of biological products	3	Apply
CO 5	To understand and conduct fermentation process kinetics	3	Apply
CO 6	To know computer control system in fermentation process	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	1	-	-	-	-	-	-	-	2
CO2	3	1	-	-	-	-	-	-	-	-	3
CO3	3	-	1	2	-	-	-	-	-	-	2
CO4	3	1	1	2	-	-	1	-	-	1	2
CO5	2	1	1	2	-	-	-	-	-	-	2
CO6	2	3	1	2	-	-	-	-	-	-	2

COURSE CONTENTS

Unit	Details	Hours
1	**Introduction to fermentation technology** **Basic principles of fermentation** Study of the design and operation of bioreactor, Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam. **Types of bioreactor** CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application **Computer control of fermentation process** System configuration and application	12
2	**Mass transfer** Theory, diffusional resistance to oxygen requirements of microorganisms, measurement of mass transfer coefficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity. **Rheology** Rheological properties of fermentation system and their importance in bioprocessing.	12
3	**Scale up of fermentation process** Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization. **Cultivation and immobilized culture system** Cultivation system: Batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems. **Introduction to immobilization** Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.	12
4	**Scale down of fermentation process** Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery. **Isolation and screening of Industrially Important Microorganisms** Primary and secondary, maintenance of stock culture, strain improvement for increased yield.	12
5	**Bioprocessing of the industrially important microbial metabolites** a) Organic solvents - Alcohol and Glycerol b) Organic acids – Citric acids, Lactic acids, c) Amino acids – Glutamic acids, Lysine, Cyclic AMP and GMP d) Antibiotics – Penicillin, Streptomycin, Griseofulvin, e) Vitamins – B12, Riboflavin and Vitamin C Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids	12

	Regulation governing the manufacturing of biological products.	
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Peter Stanbury, Allan Whitaker, Stephen Hall, Principles of Fermentation technology, Elsevier stores.
2. L.E. Casida, Industrial Microbiology, John Wiley & sons Inc.
3. F.M. Asubel, Current protocols in molecular biology, volume I and II, John Wiley Publishers.
4. Biotol Board, Bioreactor design and product yield, Butterworth and Helhemann Publishers.

Text Books:

1. H. Patel, Industrial microbiology, Macmillan India Limited.

SUBJECT: MPB104T ADVANCED PHARMACEUTICAL BIOTECHNOLOGY (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course has been designed to provide the knowledge to the students to develop skills of advanced techniques of isolation and purification of enzymes, to enrich students with current status of development of vaccines and economic importance of biotechnology products.

Course Objectives:

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

- Understand about the latest technology development in biotechnology technique, tools and their uses in drug and vaccine development.
- Identify appropriate sources of enzymes.
- Understand and perform genetic engineering techniques in gene manipulation, r–DNA technology and gene amplification.
- Understand the overview of Pharmacogenetics.
- Learn the various Microbial bioprocess like biotransformation and biodegradation
- To understand Biosensors design, components and its various applications.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the fundamentals of latest technology and tools development in biotechnology for vaccine development.	1	Recall facts and basic concept
CO 2	To learn various sources, isolation, purification and clinical applications of various enzymes.	2	Explain ideas or concept
CO 3	To understand and know various genetic engineering techniques in gene manipulation, r-DNA technology and gene amplification.	3	Apply
CO 4	To know concept, techniques and components of Pharmacogenetics	3	Apply
CO 5	To learn various microbial microbial biotransformation and microbial biodegradation process.	3	Apply
CO 6	To understand design, development and applications of Biosensors	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	3	3	-	-	-	-	-	-	3
CO2	3	2	1	3	-	-	-	-	-	-	3
CO3	3	2	2	3	-	-	2	-	-	-	3
CO4	3	2	2	3	-	-	-	-	-	-	3
CO5	3	2	2	3	-	-	-	-	-	-	3
CO6	3	1	3	3	-	-	-	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Enzyme Technology** Classification, general properties of enzymes, dynamics of enzymatic activity, sources of enzymes, extraction and purification, pharmaceutical, therapeutic and clinical application. Production of amyloglucosidase, glucose isomerase, amylase and trypsin.	12
2	**Genetic Engineering** Techniques of gene manipulation, cloning strategies, procedures, cloning vectors expression vectors, recombinant selection and screening, expression in E.coli and yeast. Site directed mutagenesis, polymerase chain reaction, and analysis of DNAsequences. **Gene library and cDNA** **Applications of the above technique in the production of**: • Regulatory proteins – Interferon, Interleukins • Blood products – Erythropoietin • Vaccines – Hepatitis–B • Hormones – Insulin	12
3	**Therapeutic peptides** Study on controlled and site specified delivery of therapeutic peptides and proteins through various routes of administration. **Transgenic animals** Production of useful proteins in transgenic animals and gene therapy. **Human Genome** The human genome project–a brief study, Human chromosome - Structure and classification, chromosomal abnormalities - Syndromes	12
4	**Signal transduction:** Introduction, cell signaling pathways, Ion channels, Sensors and effectors, ON and OFF mechanisms, Spatial and temporal aspects of signaling, cellular process, development, cell cycle and proliferation, neuronal signaling, cell stress, inflammatory responses and cell death, signaling defects and diseases. **Oncogenes:** Introduction, definition, various oncogenes and their proteins.	12
5	**Microbial Biotransformation** Biotransformation for the synthesis of chiral drugs and steroids. **Microbial Biodegradation** Biodegradation of xenobiotics, chemical and industrial wastes, Production of single–cell protein, Applications of microbes in environmental monitoring. **Biosensors** Definition, characteristics of ideal biosensors, types of biosensors, biological recognition elements, transducers, application of biosensors.	12
	TOTAL	**60**

Reference Books:

1. Biotechnology–The biological principles: MD Trevan, S Boffey, KH Goulding and P.F. Stanbury.
2. Immobilization of cells and enzymes: Hosevear Kennadycabral& Bicker staff
3. Principles of Gene Manipulating: RW Old and S.B.Primrose.
4. Molecular Cell Biology: Harvey Lodish, David Baltimore, Arnold Berk, S LawenceZipursky, Paul Matsudaira, James Darnell.
5. Gene transfer and expression protocols–methods in Molecular Biology, vol. VII, Edit E.T. Murray
6. Current protocols in Molecular Biology, Vo1.I & II:F.M. Asubel, John wiley Publishers
7. Current protocols in cellular biology, Vo1.1 & II John wiley publishers.
8. Principles of human genetics; by Curt Stern, published by W.H. Freeman.

Text Books:

1. Modern Biotechnology: S.B Primrose

MPB 105 P. PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL-I (Practical)
12 Hours / Week

Teaching Scheme	**Examination Scheme:**
Lectures: --	In SEM Exam:50 Marks
Practical: 12 Hr/Week	End SEM Exam:100 Marks
Tutorials: --	Continuous Assessment:
Credits: 6	Total Marks: 150 Marks

Scope: This paper has been designed to provide the knowledge to the students to develop skills of analysis of API, microbial contamination, antimicrobial assay, sterility testing of pharmaceuticals, microbial growth kinetics, fermentation production of important substances and molecular biology tools and techniques.

Course Objectives:

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

Understand operation and handling of various analytical equipments for pharmaceuticals
Understand Microbes screening, isolation, production and antimicrobial assay techniques.
Understand microbial growth, kinetics and assay for fermentation process
Understand sterility testing techniques for various pharmaceuticals and biologicals
Understand about the latest technology development in molecular biology techniques

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	Practical application aspects of instrumental analysis and to perform various analysis of official compounds and their estimation by using UV, HPLC, GC, flame photometry, fluorimetry etc.	1	Recall facts and basic concept
CO 2	To study isolation, purification, microbial contamination and MIC assay of various microorganisms.	2	Explain ideas or concept
CO 3	To perform growth kinetics and cytotoxicity assay of various cells.	3	Apply
CO 4	To understand the official process of sterility testing of various pharmaceutical preparation.	3	Apply
CO 5	To know the fermentation process for production of industrially important products like alcohols, vitamins and antibiotics.	3	Apply
CO 6	To understand basics of molecular biology including isolation, characterization of DNA, RNA, Proteins etc.	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	-	2	-	2	-	-	-	-	-	2
CO2	3	-	1	-	-	-	-	-	-	-	2
CO3	3	-	1	2	2	-	-	-	-	-	2
CO4	3	-	2	2	1	-	-	-	-	-	2
CO5	3	-	1	2	2	-	-	-	-	-	2
CO6	3	-	1	2	3	-	-	-	-	-	2

COURSE CONTENT

Unit	Course content	Hours
I	1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer 2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry 3. Experiments based on HPLC 4. Experiments based on Gas Chromatography 5. Estimation of riboflavin/quinine sulphate by fluorimetry 6. Estimation of sodium/potassium by flame photometry	**30**
II	1. Isolation and Purification of microorganism from the soil 2. Microbial contamination of Water and biochemical parameters. 3. Determination of Minimum Inhibitory concentration by gradient plate technique and serial dilution method. 4. UV– survival curve and Dark repair 5. Replica plating 6. Bio–autography	**30**
III	1. Construction of growth curve and determination of specific growth rate and doubling time 2. Thermal death kinetics of bacteria 3. Sub culturing of cells and cytotoxicity assays	**30**
IV	1. Sterility test for pharmaceutical preparations	**25**
V	1. Fermentation process of alcohol and wine production 2. Fermentation of vitamins and antibiotics 3. Whole cell immobilization engineering	**30**
VI	1. Isolation and estimation of DNA 2. Isolation and estimation of RNA 3. Isolation of plasmids 4. Agarose gel electrophoresis. 5. Transformation techniques 6. SDS - polyacrylamide gel electrophoresis for proteins **7.** Polymerase chain reaction technique.	**35**
	TOTAL	**180 Hrs**

Reference Books (Latest Editions to be adopted):

1. Indian Pharmacopoeia
2. A.H. Beckett and J.B. Stenlake, Practical Pharmaceutical Chemistry, Forth Edition, Volume 2, CBS Publication, Page No, 286-288.
3. Chandrakant Kokare, "Pharmaceutical Microbiology – Experiments and Techniques"
4. Published by Career publication, Nashik, Fourth edition- 41 – 43, 83 – 84, 170 – 188.
5. Vivek N. Upasani, Praful D. Bharadia & Parul B. Patel, "Lab Manual in Pharmaceutical

6. Microbiology & Biotechnology - 1" published by Nirav & Roopal Prakashan, First edition 2011, 36 – 38, 48 – 50, 73, 74.
7. European committee for antimicrobial susceptibility testing (EUCAST) of the European society of clinical Microbiology and infectious disease (ESCMID). Volume 6th, Page no – 509-515. https://doi.org/10.1046/j.1469.0691.2000.00142.x.
8. Núñez, M. J., & Lema, J. M. (1987). Cell immobilization: Application to alcohol production.
9. Enzyme and Microbial Technology, 9(11), 642–651. doi:10.1016/0141-0229(87)90121-9
10. The book of industrial microbiology by A. H. Patel Page No. 125 to 127.
11. S. Das, H. R. Dash, Microbial Biotechnology- A laboratory Manual for Bacterial Systems, DOI 10.1007/978-81-322-2095-4_1, © Springer India 2015

Semester II

(Pharmaceutical Biotechnology)

SUBJECT: MPB201T PROTEIN AND PROTEIN FORMULATIONS
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart knowledge and skills necessary for knowing fundamental aspects of proteins and their formulations is a part of drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of information for protein formulation and design are provided to help the students to clarify the various biological concepts of protein.

Course Objectives:

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

- To understand basic concepts and various methods of purification of proteins
- To know various peptides in drug development process
- To understand protein identification and characterization tools
- To understand various methods for sequencing of proteins
- To know preformulation, formulation and stability aspects of Protein based formulations

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the basic concepts and various methods of purification of proteins	1	Recall facts and basic concept
CO 2	To learn various peptides in drug development process.	2	Explain ideas or concept
CO 3	To understand and know various protein identification and characterization tools	3	Apply
CO 4	To know techniques and components of various methods for sequencing of proteins	3	Apply
CO 5	To learn preformulation, formulation and stability aspects of Protein based formulations.	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	-	3	-	-	-	-	-	-	3
CO2	3	1	2	-	-	-	-	-	-	-	3
CO3	3	2	3	3	-	-	2	-	-	-	3
CO4	3	2	3	3	-	-	-	-	-	-	3
CO5	3	1	3	-	-	-	-	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Protein engineering** Concepts for protein engineering. Isolation and purification of proteins, Stability and activity based approaches of protein engineering, Chemical and Physical Considerations in Protein and Peptide Stability, Different methods for protein engineering, gene shuffling, and direct evolution.	12
2	**Peptidomimetics** Introduction, classification, conformationally restricted peptides design, pseudopeptides, peptidomimetics and transition state analogs; Biologically active template; Amino acid replacements; Peptidomimetics and rational drug design; CADD techniques in peptidomimetics; Development of non peptide peptidomimetics.	12
3	**Proteomics** Protein identification and characterization: Methods/strategies, protein identification, de novo protein characterization, Isotope labelling, N– and C–terminal tags, Protein array technology. **Techniques of characterization of proteins:** 2-Dimensional gel electrophoresis Methods including immobilized pH gradients (IPGs), resolution, reproducibility and image analysis, future developments.	12
4	**Protein formulation** Different strategies used in the formulation of DNA and proteins, Analytical and biophysical parameters of proteins and DNA in pre– formulation, Liposomes, Neon–spears, Neon–particulate system, PEGylation, Biological Activity, Biophysical Characterization Techniques, Forced degradation studies of protein.	12
5	**Methods of protein sequencing** Various methods of protein sequencing, characterisation, Edman degradation, Tryptic and/or Chymotryptic Peptide Mapping, Experimental design and quality control in proteomics, Mass spectrometry applications in protein identification and characterization	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

1. H. Lodhishet. Al. Molecular Cell Biology, W. H. Freeman and Company
2. Protein Purification - Hand Book, Amersham pharmacia biotech
3. Engelbert Buxbaum, Fundamentals of Protein Structure and Function, Springer Science
4. Sheldon J. Park, Jennifer R. Cochran, Protein Engineering and Design, CRC press.
5. Robert K. Skopes. Protein purification, principle and practice, springer link.
6. David Whitford, Proteins–Structure and Function, John Wiley & Sons Ltd.
7. James Swarbrick, Protein Formulation and Delivery Informa Healthcare USA, Inc.
8. Rodney Pearlman, Y. John Wang Formulation, Characterization, and Stability of Protein Drugs, Kluwer Academic Publishers.
9. **Introducing Proteomics, from concepts to sample preparation, mass spectrometry and data analysis** by J. Lovric (2011), Wiley-Blackwell Publishers

SUBJECT: MPB202T IMMUNOTECHNOLOGY
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart knowledge on production and engineering of antibodies, the application of antigens, the design of (recombinant) vaccines, strategies for immune intervention, etc. The Immunotechnology – based techniques will be used for therapeutics and diagnostics, industries in the production, quality control and quality assurance, and in R&D..

Course Objectives:

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

To understand basic concepts Immunology

To know various Immune Regulation and Tolerance mechanisms

To understand hypersensitivity types, its reaction and treatment

To understand various vaccines, their types and productions

To understand hybridoma technology, production and applications

To understand the techniques like immunodiagnostic tests

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand basic concepts Immunology	1	Recall facts and basic concept
CO 2	To know various Immune Regulation and Tolerance mechanisms	2	Explain ideas or concept
CO 3	To understand hypersensitivity types, its reaction and treatment	3	Apply
CO 4	To understand various vaccines, their types and productions	2	Explain ideas or concept
CO 5	To understand hybridoma technology, production and applications	3	Apply
CO 6	To understand the techniques like immunodiagnostic tests	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	-	-	-	-	-	-	-	-	3
CO2	3	2	2	-	-	-	-	-	-	-	3
CO3	3	1	3	3	-	-	2	-	-	-	3
CO4	3	2	3	3	-	-	-	-	-	-	3
CO5	3	2	3	3	-	-	-	-	-	-	3
CO6	3	1	3	3	-	-	-	-	-	-	3

COURSE CONTENTS

Unit	Details	Hours
1	**Fundamental aspects of immunology** Introduction, cells and organs of the immune system, cellular basis of Immune response, primary and secondary lymphoid organs, antigen antibody and their structure. Types of immune responses, anatomy of immune response. Overview of innate and adaptive Immunity. **Humoral Immunity** B-Lymphocytes and their activation. Structure and function of immunoglobulins, idiotypes and anti idiotypic antibodies. **Cell mediated Immunity** Thymus derived lymphocytes (T cells)-their ontogeny and types, MHC complex, antigen presenting cells (APC), mechanisms of T cell activation, macrophages, dendritic cells, langerhans cells, mechanism of phagocytosis.	12
2	**Immune Regulation and Tolerance** Complement activation and types and their biological functions, cytokines and their role in immune response. **Hypersensitivity** Hypersensitivity Types I–IV, Hypersensitivity reactions and treatment Autoimmune diseases.	12
3	**Vaccine technology** Vaccine and their types, conventional vaccines, novel methods for vaccine production, antiidiotype vaccine, DNA vaccine, genetically engineered vaccine, iscoms, synthetic peptides, and immunodiagnostics. Stabilization and Formulation of Vaccines, Lyophilization in vaccine process **Stem cell technology** Stem cell technology and applications to immunology	12
4	**Hybridoma Technology** Hybridoma techniques - fusion methods for myeloma cells and B–Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in Pharmaceutical industry.	12
5	**Immunological Disorder** Autoimmune disorders and types, pathogenic mechanisms, treatment, experimental models of auto immune diseases, primary and secondary immunodeficiency disorders. **Immunodiagnosis:** Antigen antibody interaction-Precipitation reaction, Agglutination reactions, Principles and applications of ELISA, Radio Immuno Assay, western blot analysis, immune-electrophoresis, immuno fluorescence, chemiluminescence assay, complement fixation reaction.	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. J. Kubey, Immunology - an Introduction.
2. S.C. Rastogi, Immunodiagonstics, New Age International.
3. Ashim Chakravarthy, Immunology and Immunotechnology, Oxford University Press.
4. E. Benjamini, Molecular Immunology.
5. EMILY P. WEN RONALD ELLIS NARAHARI S. PUJAR; VACCINE DEVELOPMENT AND MANUFACTURING; Wiley Series in Biotechnology and Bioengineering

Link for web recourses:

file:///C:/Users/DELL/Downloads/Vaccine%20Development%20and%20Manufacturing%20(%20PDFDrive%20).pdf

SUBJECT: MPB-203T-BIOINFORMATICS AND COMPUTATIONAL BIOTECHNOLOGY
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This paper has been designed to provide the advanced knowledge to the biotechnology students in invaluable areas of advanced bioinformatics which plays a crucial role in determining its future use and applications in medicine, drug discovery and in pharmaceutical industry.

Course Objectives:

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

- Use of computers in developing a new drug
- Biological concepts for bioinformatics
- Proteins and their diversity
- Various gene finding methods
- Searching the biological databases
- Target searching
- Various methods of drug designing

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	Introduction to bioinformatics and (protein and nucleic acid) databases	1	Recall facts and basic concept
CO 2	Introduction to sequence analysis	2	Explain ideas or concept
CO 3	Introduction to protein informatics and protein structure prediction	2	Explain ideas or concept
CO 4	Introduction to docking	2	Explain ideas or concept
CO 5	Study of diversity of Genomes	2	Explain ideas or concept
CO 6	Study of target searching and drug designing	2	Explain ideas or concept

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	-	-	3	-	2	-	-	2	-	3
CO2	3	-	2	2	-	1	-	-	1	-	3
CO3	3	-	2	2	-	1	-	-	-	-	2
CO4	3	-	-	3	-	1	-	-	-	-	1
CO5	3	-	-	1	-	1	-	-	1	2	3
CO6	3	-	-	3	-	3	-	-	2	1	3

COURSE CONTENTS

Unit	Details	Hours
1	**Introduction to Bioinformatics:** Definition and History of Bioinformatics, Internet and Bioinformatics, Introduction to Data Mining, Applications of Data Mining to Bioinformatics, Biological Database Protein and nucleic acid databases. Structural data bases. Collecting and storing the sequence and Applications of Bioinformatics.	12
2	**Sequence analysis:** Sequence alignment, pair wise alignment techniques, multiple sequence analysis, multiple sequence alignment; Flexible sequence similarity searching with the FAST3 program package, the use of CLUSTALW and CLUSTALX for the multiple sequence alignment. Tools used for sequence analysis.	12
3	**Protein informatics:** Introduction; Force field methods; Energy, buried and exposed residues, side chains and neighbours; Fixed regions, hydrogen bonds, mapping properties onto surfaces; Fitting monomers, R & S fit of conformers, assigning secondary structures; Sequence alignment–methods, evaluation, scoring; Protein completion, backbone construction and side chain addition; Small peptide methodology, software accessibility, building peptides; Protein displays; Substructure manipulations, annealing. **Protein structure prediction:** Protein folding and model generation; Secondary structure prediction, analyzing secondary structures; Protein loop searching, loop generating methods, loop analysis; Homology modeling, concepts of homology modeling, potential applications, description, methodology, homologous sequence identification; Align structures, align model sequence; Construction of variable and conserved regions, threading techniques, Topology fingerprint approach for prediction, evaluation of alternate models; Structure prediction on a mystery sequence, structure aided sequence techniques of structure prediction, structural profiles, alignment algorithms, mutation tables, prediction, validation, sequence based methods of structure prediction, prediction using inverse folding, fold prediction; Significance analysis, scoring techniques, sequence– sequence scoring. **Docking:** Docking problems, methods for protein– ligand docking, validation studies and applications; Screening small molecule databases, docking of combinatorial libraries, input data, analyzing docking results.	12
4	**Diversity of Genomes:** Prokaryotic and Eukaryotic Gene Families. Genome Analysis: Introduction, Gene prediction methods, Gene mapping and applications– Genetic and Physical Mapping, Integrated map, Sequence assembly and gene expression. Completed Genomes Bacterium, Nematode, Plant and Human Evolution of Genomes Lateral or Horizontal Transfer among Genomes, Transcriptome and Proteome– General Account Phylogenetic analysis Evolutionary Change in Nucleotide Sequences, Rates and Patterns of Nucleotide Substitution, Models for Nucleotide Substitution, Construction of Phylogenetic Tree, Genome Annotation technique.	12
5	**Target searching and Drug Designing:** Target and lead, timeline for drug development, target discovery, target modulators, In-silico gene expression,	12

	microarray, and lead discovery, libraries of ligands, active site analysis, and prediction of drug quality.	
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. David W. Mount, Bioinformatics Sequence and Genome Analysis, CBS Publishers and Distributors
2. S. C. Rastogiet. al. Bioinformatics– Concepts Skill and Applications, CBS Publishers and Distributors
3. T.E.Creighton, Protein Structure and Molecular Properties, W.H.Freeman and Company
4. Andreas D. Baxevanis, B. F. Francis Ouellette, Bioinformatics; A Practical Guide to the Analysis of Genes and Proteins, John Wiley & Sons, Inc.
5. Arthur M. Lesk, Introduction to Bioinformatics, Oxford University Press.
6. Shui Qing Ye. Bioinformatics: A Practical Approach, Chapman & Hall/CRC.
7. David Posada, Bioinformatics for DNA Sequence Analysis, Humana press.
8. Lesk, A.M. Introduction to Bioinformatics. Oxford University Press.
9. Letovsky, S.I. Bioinformatics. Kluwer Academic Publishers.
10. Baldi, P. and Brunak, S. Bioinformatics. The MIT Press.

SUBJECT: BIOLOGICAL EVALUATION OF DRUG THERAPY-MPB 204T (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

SCOPE

This paper has been designed to provide the knowledge to the biotechnology students to understand the importance of biological and evaluation of drug therapy of biological medicines.

Objectives

Upon completion of this course the student should be able to

- Understand about the general concept of standardization of biological.
- Understand the importance of transgenic animals and knockout animals.
- Understand the biological medicines in development of various diseases.
- Learn the biological evaluation of drugs in vitro and in vivo

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand the general idea of biological standardisation	2	Recall facts and basic concept
CO 2	To understand about pyrogens and biological evaluation of drugs.	2	Explain ideas or concept
CO 3	To understand the role of biologic medicines	3	Apply
CO 4	To know about various regulatory consideration for pre-clinical testing and clinical testing	3	Apply
CO 5	To have a better understanding of NDA for global pharmaceutical product approvals	3	Explain ideas or concept
CO 6	To learn about the role of bioavailability and bioequivalence studies	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	1	3	-	-	-	-	-	-	-	3
CO2	3	-	-	-	-	-	-	-	-	-	2
CO3	3	-	-	-	-	2	-	-	-	-	-
CO4	3	2	2	2	-	-	-	-	-	-	2
CO5	2	1	2	-	-	-	-	-	-	-	-
CO6	3	1	1	-	-	2	-	-	2	-	1

COURSE CONTENTS

Unit	Details	Hours
1	**Biological Standardization** General principles, Scope and limitation of bio-assay, bioassay of some official drugs. **Preclinical drug evaluation** Preclinical drug evaluation of its biological activity, potency and toxicity-Toxicity test in animals including acute, sub-acute and chronic toxicity, ED50 and LD50 determination, special toxicity test like teratogenecity and mutagenecity. **Guidelines for toxicity studies** Various guidelines for toxicity studies. Animal experiments assessing safety of packaging materials.	12
2	**Pyrogens** Pyrogens: Sources, Chemistry and properties of bacterial pyrogens and endotoxins, Official pyrogen tests. **Microbiological assay** Assay of antibiotics and vitamins. **Biological evaluation of drugs** Screening and evaluation (including principles of screening, development of models for diseases: In vivo models / In vitro models / cell line study).	12
3	**Biologic Medicines in Development for various diseases -** By Therapeutic Category • Genetic Disorders • Eye related Disorders • Digestive Disorders • Diabetes/Related Conditions • Cardiovascular Disease • Cancer/Related Conditions • Blood Disorders • Autoimmune Disorders • Infectious Diseases • Neurologic Disorders • Skin Diseases • Organ Transplantation **Biologic Medicines in Development for various diseases –by Product Category** • Antisense • Vaccines • Recombinant Hormones/Proteins • Monoclonal Antibodies (mAb) • Interferons • Growth Factors	12

	• Gene Therapy • RNA Interference	
4	**Regulatory aspects :** Drugs, biologics and medical devices **An introduction to the regulations and documents necessary for approval of a medical product.** Regulatory consideration: Regulatory consideration for pre-clinical testing and clinical testing of drugs, biologics and medical devices. New Drug Applications for Global Pharmaceutical Product Approvals	12
5	**Bioavailability** Objectives and consideration in bio-availability studies of Biopharmaceuticals, Concept of equivalents, Measurements of bio-availability. Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems of Biopharmaceuticals. **Pharmacokinetics** Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development of Biopharmaceuticals and designing of dosage forms and Novel drug delivery systems of Biopharmaceuticals.	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Biological Drug Products-Developments and Strategies: Wei Wang and Manmohan singh
2. Handbook of Bioequivalence Testing: Sararaz K. Niazi

Text Books:

1. Produced by Recombinant DNA Technology, International Association of Biological Standardization
2. J.H. Burn., Biological Standardization, Oxford University Press
3. Drug Discovery and Evaluation in Pharmacology assay: Vogel
4. Chow, Shein, Ching, Design and analysis of animal studies in pharmaceutical development,
5. Nodine and Siegler, Animal and Clinical pharmacologic Techniques in Drug Evaluation.
1. 6. Screening methods in pharmacology (vol I & II), R.A. Turner.

SUBJECT: MPB205P PHARMACEUTICAL BIOTECHNOLOGY PRACTICAL-II (Practical)
12 Hours / Week
(PRACTICAL 180 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: --	In SEM Exam:50 Marks
Practical: 12 Hr/Week	End SEM Exam:100 Marks
Tutorials: --	Continuous Assessment:
Credits: 6	Total Marks: 150 Marks

Scope: This paper has been designed to provide the knowledge to the students to develop skills of identification, characterization of proteins, various tools and techniques for protein expression, data base searching of biologicals, sequence methods and some techniques of isolation and purification of DNA, RNA and recombinant DNA methods for biotechnology products.

Course Objectives:

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

Understand identification, characterization and expression of proteins.
Understand isolation, purification and characterization of DNA, RNA.
Understand computational biology tools for protein expression and database search tools operation.
Understand recombinant DNA techniques and tools
Understand characterization techniques of DNA and RNA in molecular Biology.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To learn practical aspects of identification, characterization & expression of proteins	1	Recall facts and basic concept
CO 2	To learn isolation, purification and characterization of DNA	1	Recall facts and basic concept
CO 3	To perform various tools and techniques for protein expression and database searching	3	Explain ideas or concept
CO 4	To perform various tools and techniques for r-DNA technology	3	Apply
CO 5	To perform database searching of DNA and proteins by using various search engine	3	Apply
CO 6	To learn techniques for study of protein, DNA and RNA in molecular biology	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	-	3	3	-	-	-	-	-	-	2
CO2	3	-	3	3	-	-	-	-	-	-	2
CO3	3	2	3	3	-	-	-	-	-	-	2
CO4	3	2	3	3	-	-	2	-	-	-	2
CO5	3	1	3	3	-	-	-	-	-	-	2
CO6	3	2	3	3	-	-	-	-	-	-	2

COURSE CONTENT

UNIT	Course content	Hours
I	1. Protein identification 2. Protein characterization 3. Protein biochemistry and protein formulation 4. Protein expression 5. Protein structure prediction 6. Protein, DNA binding studies	40
II	7. Preparation of DNA for PCR applications 8. Isolation, Purity and Quantification 9. Introduction to PCR - working of PCR, Programming. 10. Introduction to RT–PCR - working, programming. 11. Primer design using softwares. 12. Gene DNA amplification by random / specific primers.	60
III	13. Database searching 14. Sequence analysis methods	10
IV	15. Recombinant DNA Technology 16. Gene annotation methods	20
V	17. PDB search engine 18. To learn how to use Entrez search engine to retrieve nucleotide/protein sequence data.	20
VI	19. Southern Hybridization 20. Western Blotting 21. Gene transformation	30
	TOTAL	**180 Hrs**

Reference Books (Latest Editions to be adopted):

1.Gasteiger E., Hoogland C., Gattiker A., Duvaud S., Wilkins M.R., Appel R.D., Bairoch A.; Protein Identification and Analysis Tools on the ExPASy Server; (In) John M. Walker (ed): The Proteomics Protocols Handbook, Humana Press (2005). Pp. 571-607

2.P, Jonnalagedda M, Arnold K, Baratin D, Csardi G, de Castro E, Duvaud S, Flegel V, Fortier A, Gasteiger E, Grosdidier A, Hernandez C, Ioannidis V, Kuznetsov D, Liechti R, Moretti S, Mostaguir K, Redaschi N, Rossier G, Xenarios I, and Stockinger H. ExPASy: SIB bioinformatics resource portal, Nucleic Acids Res, 40(W1):W597-W603, 2012.

3.Primrose B. Sandy, Twyman M. Richard, Old W. Robert, Principles of Gene Manipulation, sixth edition

4.Maniatis Tom, Fritsch F.E, Sambrook Joeseph, Molecular cloning-a laboratory manual 7th edition, Cold Spring Harbor Laboratory, 1982

5. https://vlab.amrita.edu/index.php?sub=3&brch=273&sim=1437&cnt=1
6. T K Attwood & D J Parry-Smith “Introduction to bioinformatics”. Sixth edition , 2003, ISBN 817808-507-0, published by Pearson education(Singapore) Pte.Ltd., Indian branch, Delhi.
7. Paul G. Higgs and Teresa K. Attwood, “Bioinformatics and Molecular Evolution” , First indian Reprint , 2005, ISBN 1-4051-3802-5, published by BLACK WELL PUBLISHING, Australia.
8. Jin Xiong, "Essential Bioinformatics" , First edition, 2006, ISBN: 0521600820, published by Cambridge University Press.
9. Jeremy M. Berg, John L Tymoczko and Lubert Stryer. “Biochemistry” 5th edition, 2002, ISBN 978-0716730514, published by W.H. Freeman.
10. David L. Nelson and Michael M. Cox, “Lehninger Principles of biochemistry” 4th edition,2004, ISBN 978-0716743392, published by W.H. Freeman.
11. T K Attwood & D J Parry-Smith “Introduction to bioinformatics”. Sixth edition , 2003, ISBN 81-7808-507-0, published by Pearson education(Singapore) Pte.Ltd., Indian branch, Delhi.
12. Arthur M.Lesk ,Introduction to Bioinformatics (Second Edition) ,published by Oxford University Press, 2002, ISBN 0199251967.
13. Bustin SA 2004 A to Z of Quantitative PCR. LaJolla, California: International University Line.
14. Harris E 1998 A Low-Cost Approach to PCR. Oxford: Oxford University Press.
15. Innis MA, DH Gelfand, JJ Sninsky, and TJ White (eds.) 1990 PCR Protocols: A Guide to Methods and Applications. San Diego, California: Academic Press.
16. McPherson MJ, SG Moller, R Beynon, and C Howe 2000 PCR: Basics from Background to Bench. Heidelberg: Springer-Verlag.
17. U. Satyanarayana and U. Chakrapani : Essential of Biochemistry second edition, page no. 320-322.
18. An introduction to practical biotechnology by S. Harisha, Laxmi Publications, 2006.
19. Modern Experimental Biochemistry, third edition. Robert Boyer, 2007, Dorling Kindersley (India) Pvt. Ltd.

Webliography:

1. blast.ncbi.nlm.nih.gov/Blast.cg
2. www.ncbi.nlm.nih.gov/blast/blastcgihelp.shtml
3. www.genebee.msu.su/blast/blast_help.html
4. www-bimas.cit.nih.gov/blast info/blastexample.html
5. https://vlab.amrita.edu/index.php?sub=3&brch=273&sim=1437&cnt=1

Semester I

(Quality Assurance Techniques)

SUBJECT: MPAT101T. MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 0Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

Scope This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are UV, IR, NMR, Mass spectrometer, HPLC, GC etc. Simple structure elucidation problems may be included based on UV-IR-NMR data.

Course Objectives:

1. Upon completion of course the students shall able to
2. Analytical techniques for identification, characterization and quantification of drugs
3. Theoretical and practical skills of instrument handling and use.
4. Structural Elucidation of organic compounds using spectroscopic tools

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the theory, instrumentation, principle and application of UV visible spectroscopy, IR spectroscopy, Spectroflourimetry and flame emission and absorption spectroscopy	1,2,3	Remember, Understand , Analyze and Apply
CO 2	The students should be able to understand the theory, instrumentation, principle and application of NMR spectroscopy	1,2,3	Remember, Understand , Analyze and Apply
CO 3	The students should be able to understand the theory, instrumentation, principle and application of Mass spectroscopy and structural elucidation of UV,IR,NMR and mass interpretation problems	1,2,3	Remember, Understand , Analyze and Apply
CO 4	The students should be able to understand the theory, instrumentation, principle and application of HPLC, HPTLC, TLC, UPLC, GC, Ion exchange chromatography, Affinity chromatography, Gel chromatography, column chromatography	1,2,3	Remember, Understand , Analyze and Apply
CO 5	The students should be able to understand the theory,	1,2,3	Remember,

	instrumentation, principle and application of Electrophoresis and X ray crystallography, calculation of Braggs law and structure of crystal		Understand , Analyze and Apply and Apply
CO 6	To understand the basic concepts theory, instrumentation, principle and application of Thermal methods TGA, DTA, DSC	1,2,3	Remember and Understand

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	**3**	**2**	**2**	**3**	**0**	**2**	**0**	**0**	**2**	**0**	**2**
CO2	**3**	**2**	**2**	**3**	**0**	**2**	**0**	**0**	**2**	**0**	**2**
CO3	**3**	**2**	**2**	**3**	**0**	**2**	**0**	**0**	**2**	**0**	**2**
CO4	**3**	**2**	**2**	**3**	**0**	**2**	**0**	**0**	**2**	**0**	**2**
CO5	**3**	**2**	**2**	**3**	**0**	**2**	**0**	**0**	**2**	**0**	**2**
CO6	**3**	**2**	**2**	**3**	**0**	**2**	**0**	**0**	**2**	**0**	**2**

COURSE CONTENTS

Unit	**Details**	**Hours**
1	a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy. b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. c) Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectroscopy. d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications	10
2	**NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of	10

	principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.	
3	**Mass Spectrometry**: Principle, Theory, Instrumentation of Mass Spectrometry, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectrometry Simple structure elucidation problems based on UV, IR, NMR and• Mass data.	12
4	**Chromatography:** Principle, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) High Performance Liquid chromatography b) High Performance Thin Layer Chromatography c) Ion exchange chromatography d) Gas chromatography e) Ultra High Performance Liquid chromatography f) Affinity chromatography g) Gel Chromatography TLC and Column Chromatography	10
5	**a) Electrophoresis**: Principle, Instrumentation, working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing **b) X ray Crystallography:** Production of X rays, Different X ray diffraction methods, Bragg,,s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction, calculation of Braggs law and structure of crystal	**10**
6	**Thermal Techniques**: a) Thermogravimetric analysis (TGA): Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. b) Differential scanning calorimetry (DSC): Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their	**08**

	influence, advantage and disadvantages, pharmaceutical applications. c) Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).	
	TOTAL	**60 hrs**

Reference Books (Latest Editions to be adopted):

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.

2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part A and B - J W Munson, Volume 11, Marcel Dekker Series

8. Introduction to Spectroscopy, Donald L. Pavia, Gary M. Lampman, George S. Kriz, James A. Vyvyan, Cengage Learning, 2008.

9. Solving spectroscopy problems: A basic approach by Nazma Inamdar (Career publications).

SUBJECT: MQA 102T. QUALITY MANAGEMENT SYSTEMS

(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the Pharmaceutical industries.

Course Objectives:

Upon completion of the course a student shall be able to understand -

Upon completion of the course the student shall be able to

1) The importance of quality 2) Tools for quality improvement 3) Analysis of issues in quality 4) Quality evaluation of pharmaceuticals 5) Stability testing of drug and drug substances 6) Statistical approaches for quality

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand the fundamentals/ terminology/definitions, rationale of quality control	1,3	Recall facts and basic concept , Apply
CO 2	To explain basic concepts, definition, principles, merit, demerit and learn the basics of quality control and quality assurance	1,3	Recall facts and basic concept , Apply
CO 3	To clarify basic principles, rationale, approaches & guidelines of regulatory authorities	1,2,3	Recall facts, understand basic concept, Apply
CO 4	The student should be able to understand the basic terms in different guidelines, laws for quality control	1,6	Recall facts ,basic concept and create
CO 5	To explain basic concepts in stability studies and quality control of different formulations	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 6	To clarify basic principles in statistical approaches	3,4,5	Apply ideas or concept, analyse and evaluate

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	3	3	2	-	-	1	-	1	-	3
CO2	3	3	3	2	-	-	1	-	1	-	3
CO3	3	3	3	3	-	-	1	-	1	-	3
CO4	3	1	2	2	-	-	2	-	1	-	2
CO5	3	2	2	2	-	-	1	-	1	-	2
CO6	3	2	2	3	-	-	2	-	1	-	3

COURSE CONTENTS

Unit	Details	Hours
1	Introduction to Quality: Evolution of Quality Definition of Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality • Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies. • Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality	08
2	• Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements	12
3	• Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self inspection. • Quality systems: Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), • Complaints - evaluation and handling, Investigation and determination 117 of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	16
4	• Drug Stability: ICH guidelines for stability testing of drug substances and drug products. • Study of ICH Q8, Quality by Design and Process development report • Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines.	12

5	• Statistical Process control (SPC): Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.	8
6	• Regulatory Compliance through Quality Management and development of Quality Culture Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking	4
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Al Endres, Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, Wiley, 2000.

2. Jiju Antony; David Preece, Routledge, Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, 2002.

3. Edward E. Lawler, Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report, 2001.

4. James W. Fairfield-Sonn, Corporate Culture and the Quality Organization, Quorum Books, 2001.

5. Christine Avery; Diane Zabel, Routledge, the Quality Management Sourcebook: An International Guide to Materials and Resources 1997.

6. Nancy R. Tague, the Quality Toolbox, Second Edition, ASQ Publications.

7. Joseph M. Juran and Joseph A., De Feo, Juran's Quality Handbook, Sixth Edition, ASQ Publications.

8. Duke Okes, Root Cause Analysis, the Core of Problem Solving and Corrective Action, 2009, ASQ Publications.

MQA 103T QUALITY CONTROL AND QUALITY ASSURANCE (QCQA)
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

Scope This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Objectives:

Upon completion of this course the student should be able to

1) Understand the cGMP aspects in a pharmaceutical industry 2) To appreciate the importance of documentation 3)To understand the scope of quality certifications applicable to Pharmaceutical industries 4)To understand the responsibilities of QA & QC departments.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To know aspects of quality control and quality assurance of pharmaceutical industries.	1	Recall facts and basic concept
CO 2	To know aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs	2,3	Explain ideas or concept and apply
CO 3	To know the cGMP aspects in a pharmaceutical industry	1,3	Recall facts ,basic concept and Apply
CO 4	To know the importance of documentation	1,3	Recall facts ,basic concept and Apply
CO 5	To understand the scope of quality	2	Understand concept
CO 6	To understand the scope of quality certifications applicable to Pharmaceutical industries	2	Understand concept

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	3	3	-	3	3	-	3	-	3
CO2	3	2	3	3	-	3	3	-	3	-	3
CO3	3	2	3	3	-	3	3	-	3	-	3
CO4	3	2	3	3	-	3	3	-	3	-	3
CO5	3	2	3	3	-	3	3	-	3	-	3
CO6	3	2	3	3	-	3	3	-	3	-	3

COURSE CONTENTS

Unit	Details	Hours
1	Concept and Evolution of Quality Control and Quality Assurance Good Laboratory Practice, GMP, Overview of ICH Guidelines – QSEM, with special emphasis on Q– series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.	12
2	cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.	12
3	Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials.	12
4	Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles– How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports.Distributionrecords.Electronicdata	12
5	Manufacturing operations and controls: Sanitation of manufacturing premises, mix–ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge–in 112 of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.

2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker

Series, 1995.

3. Quality Assurance of Pharmaceuticals– A compedium of Guide lines and related materials Vol I & II, 2nd edition, WHO Publications, 1999.

4. How to Practice GMP's - P P Sharma, Vandana Publications, Agra, 1991.

5. The International Pharmacopoeia - vol I, II, III, IV & V – General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations - Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.

7. ICH guidelines

8. ISO 9000 and total quality management

9. The drugs and cosmetics act 1940 - Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006. 10. QA Manual - D.H. Shah, 1st edition, Business Horizons, 2000.

11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control - Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.

12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 – With Checklists and Software Package). Taylor & Francis; 2003.

13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008

SUBJECT: MQA104T PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
Practical:	End SEM Exam:75 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and 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.

Course Objectives:

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

- To understand the new product development process
- 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

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand the new product development process.	1	Recall facts and basic concept
CO 2	To understand the basic concepts of pre formulation studies.	2	Explain ideas or concept
CO 3	To learn the basic concepts, significance and manufacturing techniques and pilot plant scale up of different dosage forms.	3	Apply
CO 4	To know about the pharmaceutical packaging concepts, requirements, packaging materials and different quality control tests involve in the testing of packaging materials.	3	Apply
CO 5	To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D	3	Apply
CO 6	To elucidate necessary information to transfer technology of existing products between various manufacturing places	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	1	2	1	1	2	1	1	1	-	1
CO2	3	2	2	2	1	1	1	1	1	-	2
CO3	3	1	1	2	2	2	3	-	-	-	2
CO4	3	2	2	2	2	2	2	2	1	-	1
CO5	3	-	3	1	-	2	1	-	2	2	1
CO6	3	-	3	1	-	2	1	-	2	2	1

COURSE CONTENTS

Unit	Details	Hours
1	**UNIT-I** • **Principles of Drug discovery and development**: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), 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, Product registration guidelines – CDSCO, USFDA.	12
2	**UNIT-II** • **Pre-formulation studies**: Introduction / concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. • **Solubility, Methods to improve solubility of Drugs**: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	12
3	**UNIT-III** • **Pilot plant scale up** : Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.	12
4	**UNIT-IV** • **Pharmaceutical packaging**: Pharmaceutical dosage form and their packaging requirments, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.	12
5	**UNIT-V** • **Technology transfer**: Development of technology by R & D,	12

	Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. • **Documentation in technology transfer**: Development report, technology transfer plan and Exhibit.	
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

Reference Books:

1. Charles G. Smith, James T and O. Donnell, The process of new drug discovery and development. I and II Edition (2006) CRC Press, Group of Taylor and Francis.

2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd E/d Bhalani publishing house Mumbai.

4. Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, Tablets Vol. I, II, III, 2nd E/d. (1989), Marcel Dekker Inc. New York.

5. Milo Gibaldi, Text book of Bio- Pharmaceutics and clinical Pharmacokinetics 3rd E/d Lea & Febriger, Philadelphia.

6. Vandana V. Patrevale. John I. Disouza. Maharukh T.Rustomji, Pharmaceutical product development. CRC Press, Group of Taylor and Francis.

7. Abdou H.M, Dissolution, Bioavailability and Bio-Equivalence, Mack Publishing company, Eastern Pennsylvania.

8. Alfonso & Gennaro, Remingtons Pharmaceutical Sciences, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.

9. D. A Sawant, The Pharmaceutical Sciences; the Pharma Path way Pure and applied Pharmacy, Pragathi Books Pvt. Ltd.

10. D.A. Dean. E.R. Evans, Pharmaceutical Packaging technology, I.H. Hall. 1st E/d (Reprint 2006). Taylor and Francis. London and New York. 130

SUBJECT: MQA105 P PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL (THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures:	In SEM Exam:30 Marks
Practical: 12 Hr/Week	End SEM Exam:100 Marks
Tutorials: 00Hr/Week	Continuous Assessment: 20 Marks
Credits: 4	Total Marks: 150 Marks

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like QC tests, qualification and validation of analytical and testing equipments, documentation, quality certifications and concepts of QbD and PAT.

Course Objectives:

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

- Understand the 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 QA & QC departments.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To understand Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer and Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry	1,2,3	Recall facts and basic concept, Apply and Analyze
CO 2	Determination of Drugs by HPLC, Gas chromatography and AAS, Flourimetry	1,2,3	Recall facts & basic concept, Apply & Analyze
CO 3	To Understand Case studies on – Total Quality Management • Six Sigma • Change Management/ Change control. Deviations • Out of Specifications (OOS) • Out of Trend (OOT) • Corrective & Preventive Actions (CAPA) Deviations	1,2,3	Recall facts and basic concept, Apply and Analyze
CO 4	Describe the concept of validation with its need, types, and benefits along with the validation procedure of drugs with Assay	1,2,3	Recall facts & basic concept, Apply & Analyze
CO 5	The principles and implementation of Stability and solubility studies	1,2,3	Recall facts & basic concept, Apply & Analyze
CO 6	The principles and implementation of IPQC study	1,2,3	Recall facts & basic concept, Apply &Analyze

CO 7	To understand principles and implementation of pre formulation study for tablets, parenteral	1,2,3	Recall facts & basic concept, Apply & Analyze

Mapping of Course Outcomes to Program Outcomes:

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	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	2	-	-	1	2	1	1	1	-	2
CO2	3	2	-	2	-	2	2	-	1	-	2
CO3	3	2	-	2	-	2	2	-	1	-	2
CO4	3	2	2	-	-	2	2	1	1	-	2
CO5	3	2	3	1	-	2	1	-	2	-	2
CO6	3	2	3	1	-	2	1	-	2	-	2

List of practical

Sr. No	**List of Practicals**
1	Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet / capsules / semisolids) by UV Vis spectrophotometer
2	Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3	Experiments based on HPLC
4	Experiments based on Gas Chromatography
5	Estimation of riboflavin/quinine sulphate by fluorimetry
6	Estimation of sodium/potassium by flame photometry or AAS
7	Case studies on – Total Quality Management
8	• Six Sigma
9	• Change Management/ Change control. Deviations
10	• Out of Specifications (OOS)
11	• Out of Trend (OOT)
12	• Corrective & Preventive Actions (CAPA) Deviations

13	Development of Stability study protocol
14	Estimation of process capability
15	In process and finished product quality control tests for tablets, capsules, parenteral and semisolid dosage forms.
16	Assay of raw materials as per official monographs
17	Testing of related and foreign substances in drugs and raw materials
18	To carry out pre formulation study for tablets, parenteral (2 experiment).
19	To study the effect of pH on the solubility of drugs, (1 experiment)
20	Quality control tests for Primary and secondary packaging materials
21	Accelerated stability studies (1 experiment).
22	Improved solubility of drugs using surfactant systems (1 experiment)
23	Improved solubility of drugs using co-solvency method (1 experiment)
24	Determination of Pka and Log p of drugs

Reference Books (Latest Editions to be adopted):

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
5. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
6. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
7. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

Wagh Kaveri Raman, Rageeb Md. Usman, Sufiyan Ahmad Raees Ahmad, Shakeeb Akhtar, A practical book on Pharmaceutical Quality Assurance I, Edition 2021. S. Vikas and company (Medical Publishers). Punjab, 2021.

Semester II

(Quality Assurance Techniques)

SUBJECT: MQA201T HAZARDS AND SAFETY MANAGEMENT
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 0Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

COURSE OBJECTIVE:

At completion of this course it is expected that students will be able to Understand about environmental problems among learners

.• Impart basic knowledge about the environment and its allied problems

.• Develop an attitude of concern for the industry environment

.• 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 Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	The students should be able to understand theory of enviornmental studies and Ecosystems	1,2,3	Recall facts & basic concept, understand & apply
CO 2	To learn the importance and learning about Air based sources and hazards	1,2,3	Recall facts and basic concept, understand & apply
CO 3	To learn the importance and learning about Chemical based sources and hazards	1,2,3	Recall facts & basic concept, understand & apply

CO 4	To learn the importance and learning about Fire based sources and hazards	1,2,3	Recall facts & basic concept, understand & apply
CO 5	To learn the importance and learning about Fire based explosion and Fire protection systems	1,2,3	Explain ideas or concept
CO 6	To learn the importance and learning about Hazards and safety management	1,2,3	Recall facts & basic concept, understand & apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	3	-	1	3	-	-	-	-	3	3	3
CO2	3	-	1	3	-	-	-	-	3	3	3
CO3	3	-	1	2	-	-	-	-	3	3	3
CO4	3	-	1	3	-	-	-	-	3	3	3
CO5	2	-	1	2	-	-	-	-	3	3	3
CO6	3	-	1	3	-	-	-	-	3	3	3

COURSE CONTENTS

Unit	**Details**	**Hours**
1	Multidisciplinary nature of environmental studies Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources Ecosystems: Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.	12
2	Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.	12
3	Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard. Control measures for chemical hazards. Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, MSDS, Labelling guidelines, Management of over Exposure to chemicals	12

	and TLV concept, Disposal of hazardous material.	
4	Fire and Explosion: Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions. Safety and hazards regulations Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers.	12
5	Hazard and risk management: Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools, Preliminary hazard analysis Factory act and rules, fundamentals of accident prevention, elements of• safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services.	12

List of references:

Sr.No	**Reference book**
1	Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2	Quantitative Risk Assessment in Chemical Process Industries, American Institute of Chemical Industries, Centre for Chemical Process safety.
3	T.S.S. Dikshith, Hazardous Chemicals: Safety Management and Global Regulations, CRC press.
4	M. N. Vyas, Safety and hazard management in chemical industries, Atlantic Publisher
5	Daniel A. Crowl, Joseph F. Louvar, Chemical Process Safety: Fundamentals with Applications, 3rd Edition, Prentice Hall, 2011
6	H. H. Fawcett and W.S. Wood, Safety and Accident Prevention in Chemical Operations, 2nd E/d, John Wiley & Sons, New York 1982.
7	C.S.Rao, Environmental Pollution Control Engineering, New Age international publisher
8	Phillip Carson, Clive Mumford, Butterworth-Heinemann, Hazardous Chemicals Handbook, Second edition, An imprint of Elsevier Science

SUBJECT: MQA202T PHARMACEUTICAL VALIDATION
(THEORY 60 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 04Hr/Week	In SEM Exam:25 Marks
	End SEM Exam:75 Marks
Tutorials: 0Hr/Week	Continuous Assessment: 10 Marks
Credits: 4	Total Marks: 100 Marks

Scope

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

COURSE OBJECTIVE:

At completion of this course, it is expected that students will be able to understand The concepts of calibration, qualification and validation

- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	The students should be able to understand theory of validation and Qualification	1,2,3	Recall facts & basic concept, understand & apply
CO 2	To learn the importance and learning about theory, principle of Qualification of manufacturing equipment and Analytical Instruments	1,2,3	Recall facts and basic concept, understand and apply
CO 3	To learn the importance and learning about theory, principle of Qualification of laboratory equipment and validation of utility systems	1,2,3	Recall facts and basic concept, understand and apply
CO 4	To learn the importance and learning about theory, principle of Process validation and Analytical method validation	1,2,3	Recall facts & basic concept, understand and apply
CO 5	To learn the importance and learning about theory, principle of cleaning validation and Computerized System validation	1,2,3	Explain ideas or concept
CO 6	To learn the importance and learning about IPR and patent types, and its filling	1,2,3	Recall facts and basic concept, understand and apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	3	3	3	-	-	-	2	-	2
CO2	3	2	3	3	3	-	-	-	2	-	2
CO3	3	2	3	2	3	-	-	-	2	-	2
CO4	3	2	3	3	3	-	-	-	2	-	2
CO5	2	2	3	2	3	-	-	-	2	-	2
CO6	3	2	3	3	3	-	-	-	2	-	2

COURSE CONTENTS

Unit	Details	Hours
1	Introduction to validation: Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan. Qualification: User requirement specification, Design qualification,• Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).	10
2	Qualification of manufacturing equipment: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization / Tunnels, Autoclaves, Membrane filtration, Capsule filling machine. Qualification of analytical instruments: UV-Visible• spectrophotometer, FTIR, GC, HPLC, HPTLC.	10
3	Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceutical water system• & pure steam, HVAC system, Compressed air and nitrogen.	10
4	Process Validation: Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re	10

	validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.	
5	Cleaning Validation: Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant. Computerized system validation: Electronic records and digital• signature - 21 CFR Part 11 and GAMP	10
6	General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property–patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent application; patent application forms and guidelines. Types patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	10

List of references:

Sr.No	**Reference book**
1	B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2	Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, The Theory & Practice of Industrial Pharmacy, 3rd edition, Varghese Publishing House, Bombay.
3	Terveeks , Validation Master plan Davis Harwood International publishing.

4	Carleton & Agalloco, Validation of Aseptic Pharmaceutical Processes, 2nd Edition,
5	Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6	Syed Imtiaz Haider.Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries
7	Phillip A. Cloud, Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, , Interpharm Press
8	Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Validation of Pharmaceutical Processes: Sterile Products, Marcel Dekker
9	Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Analytical Method validation and Instrument Performance Verification, Wiley Interscience
10	Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11	Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press

MQA203T AUDITS AND REGULATORY COMPLIANCE
(THEORY 60 HOURS)

SCOPE

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

- 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

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	The students should be able to understand the importance of auditing	2	Recall facts and basic concept
CO 2	To learn the importance of auditing	2	Explain ideas or concept
CO 3	To understand the methods followed for auditing	3	Apply
CO 4	To know how to prepare the auditing report	3	Apply
CO 5	To learn about how carry out the audit process in various departments	3	Explain ideas or concept
CO 6	To learn how prepare the check list for auditing	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	3	3	3	-	-	-	-	-	-	3
CO2	3	2	1	3	-	-	-	-	-	-	2
CO3	3	2	1	2	-	2	1	-	-	-	2
CO4	3	2	2	3	-	-	-	-	-	-	2
CO5	2	3	2	2	-	-	-	-	-	-	3
CO6	3	1	3	3	-	-	-	-	-	-	1

COURSE CONTENTS

Unit	Details	Hours
1	**INTRODUCTION**: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	12
2	**Role of quality systems and audits in pharmaceutical manufacturing environment**:	12

	cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, transitioning to quality system approach, Audit checklist for drug industries.	
3	**Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12
4	**Auditing of Microbiological laboratory**: Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.	12
5	**Auditing of Quality Assurance and engineering department**: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.	12
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

6. Shayne Cox Gad, Pharmaceutical Manufacturing Handbook, Regulations and Quality, Wiley-Interscience, A John Wiley and sons, Inc. Publications.
7. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. Handbook of microbiological Quality control,CRC Press. 2000.
8. C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden, Laboratory auditing for quality and regulatory compliance. Donald Taylor and Francis (2005).

Text Books:

1.Karen Ginsbury and Gil Bismuth,Compliance auditing for Pharmaceutical Manufacturers. Interpharm/CRC, Boca Raton, London New York, Washington D.C

MQA204T PHARMACEUTICAL MANUFACTURING TECHNOLOGY
(THEORY 60 HOURS)

Scope

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

Course Objectives:

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

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	The common practices in the pharmaceutical industry developments, plant layout and production planning.	1	Recall facts and basic concept
CO 2	The principles and practices of aseptic process technology.	2	Explain ideas or concept
CO 3	The principles and practices of non sterile manufacturing technology.	3	Apply
CO 4	The principles and practices of packaging technology.	3	Apply
CO 5	The principles and implementation of Quality by design (QbD) in pharmaceutical manufacturing	3	Apply
CO 6	The principles and implementation of process analytical technology (PAT) in pharmaceutical manufacturing	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	1	2	1	1	2	1	1	1	-	1
CO2	3	2	2	2	1	1	1	1	1	-	2
CO3	3	1	1	2	2	2	3	-	-	-	2
CO4	3	2	2	2	2	2	2	2	1	-	1
CO5	3	-	3	1	-	2	1	-	2	2	1
CO6	3	-	3	1	-	2	1	-	2	2	1

COURSE CONTENTS

Unit	Details	Hours
1	• **Pharmaceutical industry developments**: Legal requirements and Licenses for API and formulation industry, Plant location- Factors	12

	influencing. • **Plant layout**: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. • **Production planning**: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.	
2	• **Aseptic process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). • **Advanced sterile product manufacturing technology** : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance. • **Process Automation in Pharmaceutical Industry**: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals& Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.	12
3	• **Non sterile manufacturing process technology**: Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft). • Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, • **Improved Tablet Production**: Tablet production process, granulation and Pelletization equipment, continuous and batch mixing, rapid mixing granulators, Rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. • **Problems encountered. Coating technology**: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.	12
4	• **Containers and closures for pharmaceuticals**: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.	12
5	• **Quality by design (QbD) and process analytical technology (PAT)**: Current approach and its limitations. Why QbD is required, Advantages, • **Elements of QbD, Terminology**: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation / minimization. Quality by Design, Formulations by Design, QbD for drug	12

	products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. • **FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs**: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.	
	TOTAL	**60**

Reference Books (Latest Editions to be adopted):

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.
9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

MQA205PQUALITY ASSURANCE PRACTICAL II
(Practical 60 HOURS)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like QC tests, qualification and validation of analytical and testing equipments, documentation, quality certifications and concepts of QbD and PAT.

Course Objectives:

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

- The common practices in the pharmaceutical industry developments, plant layout and production planning.
- The calibration and qualification of analytical instruments.
- The qualification of various testing equipments.
- The concept of validation with its need, types, and benefits along with the validation procedure of some equipment.
- The principles and implementation of Quality by design (QbD) and process analytical technology (PAT)in pharmaceutical manufacturing

Course Outcomes:

CO's	Course Outcomes	Bloom Taxonomy	
		Level	Descriptor
CO 1	Explain the common practices in the pharmaceutical industry developments, plant layout and production planning.	1	Recall facts and basic concept
CO 2	Explain the calibration and qualification of various analytical instruments.	2	Explain ideas or concept
CO 3	Explain the qualification of various testing equipments.	3	Apply
CO 4	Describe the concept of validation with its need, types, and benefits along with the validation procedure of some equipment.	3	Apply
CO 5	The principles and implementation of Quality by design (QbD) in pharmaceutical manufacturing	3	Apply
CO 6	The principles and implementation of process analytical technology (PAT) in pharmaceutical manufacturing	3	Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11
CO1	3	2	-	-	1	2	1	1	1	-	1
CO2	3	2	-	2	-	2	2	-	1	-	2
CO3	3	2	-	2	-	2	2	-	1	-	2
CO4	3	2	2	-	-	2	2	1	1	-	1
CO5	3	-	3	1	-	2	1	-	2	2	1
CO6	3	-	3	1	-	2	1	-	2	2	1

List of practical

Sr. No.	Practical
1	Organic contaminants residue analysis by HPLC

2	Identification of antibiotic residue by TLC
3	Estimation of Chlorine in Work Environment.
4	Sampling and analysis of SO_2 using Colorimetric method
5	Qualification of following Pharma equipment a) Autoclave b) Hot air oven c) Powder Mixer (Dry) d) Tablet Compression Machine.
6	Validation of an analytical method for a drug
7	Process validation of any non-sterile or sterile dosage form
8	Validation of a processing area
9	Qualification of at least two analytical instruments
10	Cleaning validation of one equipment
11	Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, friability Apparatus, Disintegration Tester)
12	Check list for Bulk Pharmaceutical Chemicals vendors
13	Check list for tableting production.
14	Check list for sterile production area
15	Design of plant layout: Sterile and non-sterile
16	Case study on application of QbD
17	Case study on application of PAT

Reference Books (Latest Editions to be adopted):

8. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.

9. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.

10. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.

11. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.

12. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.

13. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

14. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

Wagh Kaveri Raman, Rageeb Md. Usman, Sufiyan Ahmad Raees Ahmad, Shakeeb Akhtar, A practical book on Pharmaceutical Quality Assurance I, Edition 2021. S. Vikas and company (Medical Publishers). Punjab, 2021.

MANDATORY LEARNING COURSE FOR ALL SPECIALIZATIONS (SEM-I)

SUBJECT: APPLICATION OF EXCEL IN ADVANCED PHARMACY (THEORY 25 HOURS)

Teaching Scheme	**Examination Scheme:**
Lectures: 02Hr/Week	End SEM Exam: 20Marks
Practical:	Continuous Assessment including attendance Marks: 20
Tutorials: 0Hr/Week	Total Marks: 40 Marks
Credits: No credit	

Scope

This course will prepare the young pharmacy student to understand how to manage data with the use of Excel, and how to process information into useful data.

Course Objectives:

Upon completion of the course a student shall be able to understand -

1. How to organize the gathered data
2. How to analyze the data
3. How to interpret and present the data in an easily understandable form.
4. Understand the application of Excel in pharmacy.

Course Outcomes:

CO's	**Course Outcomes**	**Bloom Taxonomy**	
		Level	**Descriptor**
CO 1	To explain Excel and basic terms,	1	Recall facts and basic concept
CO 2	To understand Basic formulas of excels- Addition, subtraction, multiplication, division	1, 2	Recall facts and basic concept, Explain ideas or concept
CO 3	To explain IF and NESTEDIF Formula, IF, OR Formula	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 4	To understand Concatenate, SUMIF formula	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 5	Different File Types Data Preparation Sorting data Filtering data Basic elements of charts in excel create basic chart types Introduction of Macros in Excel	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 6	To understand INDEX Formula, PIVOT Table	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 7	WHATIF analysis and Worksheet formulas	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply
CO 8	Introduction to named ranges and EXCEL tables	1,2,3	Recall facts and basic concept, Explain ideas or concept, Apply

Mapping of Course Outcomes to Program Outcomes:

	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**
CO1	-	1	1	3	-	1	-	-	-	-	3

CO2	-	2	1	3	-	2	-	-	-	-	3
CO3	-	3	3	3	-	3	-	-	-	-	3
CO4	-	3	3	3	-	2	-	-	-	-	3
CO5	-	3	3	3	-	2	-	-	-	-	3
CO6	-	3	3	3	-	1	-	-	-	-	3
CO7		3	3	3		-	-	-	-	-	-
CO8		3	3	3		-	-	-	-	-	-

COURSE CONTENTS

Unit	Details	Hours
1	To explain Excel and basic terms,	3
2	To understand Basic formulas of excels- Addition, subtraction, multiplication, division	3
3	To explain IF and NESTEDIF Formula, IF, OR Formula	4
4	To understand Concatenate, SUMIF formula	3
5	Different File Types Data Preparation Sorting data Filtering data Basic elements of charts in excel create basic chart types Introduction of Macros in Excel	3
6	To understand INDEX Formula, PIVOT Table, PIVOT Charts	4
7	WHATIF analysis and Worksheet formulas	4
8	Introduction to named ranges and EXCEL tables	1
	Total	**25**

References:

1. Guerrero, H. (2010). Excel Data Analysis. In *Excel Data Analysis*.
2. Guerrero, H. (2019). Excel Data Analysis. In *Excel Data Analysis*.
3. Harvey, G. (2013). Excel 2013 all-in-one for dummies. In *Katalog BPS: Vol. XXXIII* (Issue 2).
4. Walkenbach, J. (2007). Excel 2007 Bible. In *Ebook*.
5. Zhou, H. (2020). Learn Data Mining Through Excel. In *Learn Data Mining Through Excel*.