DEPARTMENT OF PHARMACY
GURU GHASIDAS VISHWAVIDYALAYA, BILASPUR (C.G.)
(A CENTRAL UNIVERSITY)

M.PHARM. (PHARMACEUTICS)
(W.E.F. SESSION 2023-24)

Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./w k	Marks
Semester I					
MPH101T	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
MPH106P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650
Semester II					
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH 203T	Computer Aided Drug Delivery System	4	4	4	100
MPH204T	Cosmetic and Cosmeceuticals	4	4	4	100

MPH 205P	Pharmaceutics Practical II	12	6	12	150
MPH 206P	Seminar/Assignment	7	4	7	100
	Total	35	26	35	650

Schemes for internal assessments and end semester examinations
(Pharmaceutics- MPH)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester I								
MPH101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MPH102T	Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH103T	Modern Pharmaceutics	10	15	1 Hr	25	75	3 Hrs	100
MPH104T	Regulatory Affair	10	15	1 Hr	25	75	3 Hrs	100
MPH105P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPH106P	Seminar/Assignment	–	–	–	–	–	–	100
							Total	650
Semester II								
MPH 201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	10	15	1 Hr	25	75	3 Hrs	100
MPH 202T	Advanced Biopharmaceutics & Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MPH 203T	Computer Aided Drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MPH204T	Cosmetic and Cosmeceuticals	10	15	1 Hr	25	75	3 Hrs	100
MPH205P	Pharmaceutics Practical I	20	30	6 Hrs	50	100	6 Hrs	150
MPH206P	Seminar/Assignment	–	–	–	–	–	–	100
							Total	650

Course of study for M. Pharm. III Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 301T	Research Methodology and Biostatistics*	4	4
MRM 302P	Journal club	1	1
MRM 303P	Discussion / Presentation (Proposal Presentation)	2	2
MRM 304P	Research Work	28	14
	Total	35	21

**Non University Examination*

Course of study for M. Pharm. IV Semester (Common for All Specializations)

Course Code	Course	Credit Hours	Credit Points
MRM 401P	Journal club	1	1
MRM 402P	Research Work	31	16
MRM 403P	Discussion / Final Presentation	3	3
	Total	35	20

Semester wise credits distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)	Minimum=02 Maximum=07*
Total Credit Points	Minimum=95 Maximum=100*

**Credit Points for Co-curricular Activities*

Schemes for internal assessments and end semester examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
Semester III								
MRM301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3 Hrs	100
MRM 302P	Journal club	–	–	–	25	–	–	25
MRM 303P	Discussion / Presentation (Proposal Presentation)	–	–	–	50	–	–	50
MRM 304P	Research work*	–	–	–	–	350	1 hr	350
							Total	525
Semester IV								
MRM401P	Journal club	–	–	–	25	–	–	25
MRM402P	Discussion / Presentation (Proposal Presentation)	–	–	–	75	–	–	75
MRM403P	Research work and Colloquium	–	–	–	–	400	1 hr	400
							Total	500

*Non University Examination

Programme Outcomes

Post graduates students will be able to:

PO1: **Fundamentals on advanced analytical instrumental techniques**: UV-Visible, IR, Spectroflourimetry, Flame emission and Atomic absorption spectroscopy, NMR spectroscopy, Mass Spectroscopy, Chromatography, Electrophoresis and Immunological assays methods.

PO2: **Advances and development of novel and targeted drug delivery systems**: Sustained Release and Controlled Release, Rate Controlled Drug Delivery Systems, Gastro-Retentive Drug Delivery Systems, Occular Drug Delivery Systems, Occular Drug Delivery Systems, Protein and Peptide Delivery, Vaccine delivery systems. Targeted Drug Delivery Systems, Targeting Methods, Micro Capsules / Micro Spheres, Pulmonary Drug Delivery Systems, Nucleic acid based therapeutic delivery system

PO3: **Advanced knowledge and skills of pharmaceutical industries**: Preformulation Concepts, Optimization techniques in Pharmaceutical Formulation, Validation, cGMP & Industrial Management, Compression and compaction, Study of consolidation parameters.

PO4: **Regulatory filings and different phases of clinical trials**: Documentation in Pharmaceutical industry, Regulatory requirement for product approval, CMC, post approval regulatory affairs, Non clinical drug development, Clinical trials.

PO5: **Knowledge about Research Methodology & Biostatistics**: review of literature, strategies to eliminate errors/bias, values in medical ethics, CPCSEA guidelines for laboratory animal facility, Declaration of Helsinki.

PO6: **Basic and principles of biopharmaceutics and pharmacokinetics**: Drug Absorption from the Gastrointestinal Tract, Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance, Pharmacokinetics, Drug Product Performance, In Vivo: Bioavailability and Bioequivalence, Application of Pharmacokinetics.

PO7: **Computer applications in pharmaceutical drug research and development**: Computers in Pharmaceutical Research and Development, Computational Modeling of Drug Disposition, Computer-aided formulation development, Computer-aided biopharmaceutical characterization, Artificial Intelligence (AI), Robotics and Computational fluid dynamics.

PO8: **Fundamental of cosmetic and cosmeceutical products**: Regulatory on cosmetics, Biological aspects of cosmetics, Formulation Building blocks, Design of cosmeceutical products, Herbal Cosmetics.

First Semester

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH101T	3	1	-	4 hours	25	75	100	4

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know, Chemicals and Excipients

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 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. 11 Hrs

   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.

   c. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

   d. Flame emission spectroscopy and Atomic absorption spectroscopy:Principle,Instrumentation Interference andApplications.

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in 11 Hrs

	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. Applicationsof NMR spectroscopy.	
3.	Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, 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 spectroscopy	11 Hrs
4	Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography	11 Hrs
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, Xray powder technique, Types of crystals and applications of X-ray diffraction.	11 Hrs
6	Immunological assays :RIA (Radio immuno assay), ELISA, Bioluminescence assays.	5Hrs

REFERENCES

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 B – J W Munson, Volume 11, Marcel Dekker Series

Course Outcomes

After completion of course student is able to know

CO1. Recognize, utilize and explain theoretical concepts, instrumentation and applications of Spectroscopic techniques like UV, IR, Fluorimetry, FES and AAS.

CO2. Acknowledge, apply and clarify theoretical ideas, equipment, and uses of spectroscopic methods such as NMR.

CO3. Understand, apply and clarify the theoretical ideas, instrumentation and uses of spectroscopic methods such as Mass Spectroscopy (MS).

CO4. Acknowledge, apply and clarify theoretical ideas, equipment, and uses of chromatographic methods such as gel chromatography, electrophoresis, TLC, HPTLC, lon exchange, column GC, HPLC, affinity and X-ray crystallography.

CO5. Recognize, utilize, and explain theoretical concepts. instrumentation and applications of potentiometry and thermal techniques like DSC, DTA and TGA.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

DRUG DELIVERY SYSTEM (MPH102T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH102T	3	1	-	4 hours	25	75	100	4

SCOPE

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

OBJECTIVES

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

The various approaches for development of noveldrug 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.

THEORY 60 Hrs

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. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 10 Hrs

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 Hrs

3 Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time 10 Hrs

	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.	
4	Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.	06 Hrs
5	Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.	10 Hrs
6	Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.	08 Hrs
7	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	06 Hrs

REFERENCES

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, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. 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) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

Course Outcomes

After completion of course student is able to know

CO1. Understand the Sustained Release (SR) and Controlled Release (CR)

formulations.

CO2. Understand the various approaches for Rate Controlled Drug Delivery Systems.

CO3. To know about the Gastro-Retentive Drug Delivery Systems.

CO4. Understand the formulation and evaluation Occular Drug Delivery Systems andTransdermal Drug Delivery Systems.

CO5. To know about the Protein and Peptide Delivery and Vaccine delivery systems.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

MODERN PHARMACEUTICS (MPH103T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH103T	3	1	-	4 hours	25	75	100	4

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

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

- The elements of preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY 60 HRS

1. a. Preformation Concepts – 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. 10 Hrs

   b. 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

2 Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH 10 Hrs

	& WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.	
3	cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments 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.	10 Hrs
4	Compression and compaction: Physics of tablet compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.	10 Hrs
5	Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel Hrs plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test.	10 Hrs

REFERENCES

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. Encyclopaedia of Pharmaceutical technology, Vol I – III.

Course Outcomes

After completion of course student is able to know

CO1. Understand the elements of pre-formulation studies.

CO2. Understand the kinetics of stability and Stability testing of drugs.

CO3. Understand the optimization techniques in pharmaceutical formulation and processing.

CO4. Understand the Pharmaceutical Validation, policies of current good manufacturing practices and concept of Total Quality Management.

CO5. Understand the Physics of tablet compression, Dissolution parameters and Pharmacokinetic parameter and linearity Concept of significance.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

REGULATORY AFFAIRS (MPH 104T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH104T	3	1	-	4 hours	25	75	100	4

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

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

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's and guidelines for filing and approval process
- reparation 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
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs

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	12 Hrs

	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	
2	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.	12 Hrs
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12 Hrs
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.	

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, 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

Course Outcomes

After completion of course student is able to know

CO1. To understand the Documentation in Pharmaceutical industry and Regulatory requirement for product approval.

CO2. To learn the concept of CMC, post approval regulatory affairs. Guidelines of ICH-Q, S E, M. Regulatory requirements of EU. MERA, TGA and ROW countries.

CO3. To know about the Non clinical drug development.

CO4. To understand the Clinical trials.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

PHARMACEUTICS PRACTICALS – I (MPH 105P)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH10P	–	–	12	12 hours	50	100	150	6

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
7. To perform $I_{n-vitro}$ dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

Course Outcomes

After completion of course student is able to know

CO1. Understand the elements of pre-formulation studies.

CO2. Understand the kinetics of stability and Stability testing of drugs.

CO3. Understand the optimization techniques in pharmaceutical formulation and processing.

CO4. Understand the Pharmaceutical Validation, policies of current good manufacturing practices and concept of Total Quality Management.

CO5. Understand the Physics of tablet compression, Dissolution parameters and Pharmacokinetic parameter and linearity Concept of significance.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH 201T	3	1	-	4 hours	25	75	100	4

Scope

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

Objectives

Upon completion of the course 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.

THEORY 60 Hrs

1.	Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.	12 Hrs
2	Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3	Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	12 Hrs
4	Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.	12 Hrs
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 Hrs

REFERENCES

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, New Delhi, First edition 1997 (reprint in 2001).

Course Outcomes

After completion of course student is able to know

CO1. Understand the basic concepts of Targeting and Targeted Drug Delivery Systems

CO2. Understand the preparation and evaluation of Micro Capsules / Micro Spheres/ Niosomes,Aquasomes.

CO3. Understand the preparation and evaluation of Pulmonary Drug Delivery Systems

CO4. Understand the preparation and evaluation of Nucleic acid based therapeutic deliverysystem

CO5. Understand the therapeutic antisense molecules and aptamers as drugs of future.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH202T	3	1	-	4 hours	25	75	100	4

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.

Objectives

Upon completion of this course, it is expected that students will be able 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.
- 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

THEORY 60 Hrs

1. Drug Absorption from the Gastrointestina Tract: 12 Hrs

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formuulation 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.	
2	Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic 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 Hrs
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 Hrs
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,	12 Hrs

	study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivomethods .generic biologics (biosimilar drug products),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.	
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 antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.	12 Hrs

REFERENCES

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, 2nd edition, 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 MalcolmRowland 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,1 st edition,Sunil S JambhekarandPhilip J Breen,pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

Course Outcomes

After completion of course student is able to know

CO1. To impart knowledge and skills of Drug Absorption from the Gastrointestinal Tract.

CO2. To understand concepts of Biopharmaceutic considerations in drug product design andIn-Vitro Drug Product Performance.

CO3. To learn pharmacokinetic models and compartment modeling.

CO4. To understand bioavailability and bioequivalence

CO5. impart knowledge about applications of pharmacokinetics in targeted drug delivery,biotechnological products

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Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH203T	3	1	-	4 hours	25	75	100	4

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. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

Upon completion of this course it is expected that students will 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)

THEORY 60 Hrs

1. a. Computers in Pharmaceutical Research andDevelopment: 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. 12 Hrs

   b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

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 Hrs
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 Hrs
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 considerations 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	12 Hrs
5	Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.	12 Hrs

REFERENCES

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.

Course Outcomes

After completion of course student is able to know

CO1. Understanding the Utilization of Computers in Pharmaceutical Research andDevelopment.

CO2. Exploring Computational Modeling of Drug Disposition.

CO3. Exploring the Applications of Computers in Pharmaceutical Formulation Development.

CO4. Gaining Insight into Computer-Aided Clinical Methodologies in BiopharmaceuticalStudies and Simulation in ADME.

CO5. Updating Knowledge through Study of Automation in the Pharmaceutical Industry and Applications of Artificial Intelligence

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Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

COSMETICS AND COSMECEUTICALS (MPH 204T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH204T	3	1	-	4 hours	25	75	100	4

Scope

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

Objectives

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

understand

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

THEORY 60 Hrs

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 Hrs
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 Hrs
3. Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: 12 Hrs

	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, formaldehyde liberators, dioxane.	
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.	12 Hrs
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 Hrs

REFERENCES

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
5. H.I. Maibach. 3rd edition
6. Cosmetic and Toiletries recent suppliers catalogue.
7. CTFA directory.

Course Outcomes

After completion of course student is able to know

CO1. To know the key ingredients used in cosmetics and regulatory aspects for manufacturing, labeling, import, export and license of cosmetic products.

CO2. To know key building blocks for various formulations, biological aspects of skin andrelated diseases, hairs and problems, cleansing products and its uses.

CO3. To know current technologies in the market, formulation building blocks of cosmetics and cosmeceuticals and controversial ingredients

CO4. To understand various key ingredients and basic science to develop cosmetics and cosmeccuticals, designing of cosmeceutical products such as sunscreen, dental products etc.

CO5. To know scientific knowledge to develop cosmetics and cosmeceuticals with desired safety, stability, and efficacy, herbal cosmetic products, ingredients, regulatory guidelines and challenges facing with herbal cosmetics and herbal ingredients

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Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

PHARMACEUTICS PRACTICALS – II (MPH 205P)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MPH205P	–	–	12	12 hours	50	100	150	6

1. To study the effect of temperature change, non-solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

Course Outcomes

After completion of course student shall be able to understand-

CO1. To study the effect of temperature change, non-solvent

addition, incompatible polymer addition in microcapsules preparation.

CO2. Preparation and evaluation of Alginate beads. Formulation and evaluation of gelatin/albumin microspheres, liposomes/niosomes and spherules. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.

CO3. Protein binding studies of a highly protein bound drug & poorly protein bound drug.

CO4. DoE Using Design Expert® Software and formulation data analysis Using Design Expert® Software. Computer Simulations in Pharmacokinetics and Pharmacodynamics.

CO5. Development and evaluation of Creams, Shampoo and Toothpaste base. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly

RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

Sub Code	L	T	P	Duration	IA	ESE	Total	Credits
MRM 301T	3	1	–	4 hours	25	75	100	4

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

Course Outcomes

The student will try to learn-

CO1. Describe the General Research Methodology.

CO2. Explain Biostatistics i.e., sample size,, statistical tests of significance, Biostatistics* parametric tests, non-parametric tests, analysis of variance etc.

CO3. To know about the Medical Research i.e., History, values in medical ethics, autonomy,beneficence, non- maleficence etc.

CO4. Describe the CPCSEA guidelines for laboratory animal facility.

CO5. Explain Declaration of Helsinki.

Course Outcomes and their mapping with Programme Outcomes

CO	PO							
	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8
CO-1								
CO-2								
CO-3								
CO-4								
CO-5								

Weightage: 1-Sightly; 2-Moderately; 3-Strongly