Central University of Rajasthan
Department of Pharmacy

Semester-wise structure for the
M. Pharm. in Pharmaceutics (MPH) programme
Semester I

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/E/S		L	I.L	P	T	P	ST	IA	
1.	MPH 101	Modern Pharmaceutical Analytical Techniques	C	4	3	1	-	3	-	40	10	50
2.	MPH 102	Modified Release Drug Delivery Systems	C	4	3	1	-	3	-	40	10	50
3.	MPH 103	Modern Pharmaceutics	C	4	3	1	-	3	-	40	10	50
4.	MPH 104	Cosmetics and Cosmeceuticals	C	4	3	1	-	3	-	40	10	50
5.	MPH 105P	Pharmaceutics Lab.-I	C	3	-	-	6	-	6	-	20	80
6.	MPH 106P	Pharmaceutics Lab.-II	C	3	-	-	6	-	6	-	20	80
7.	MPH 151	Research Seminar-I/Assignment	C	2	-	2	-	1	-	-	-	100

Total Credits: Semester I–24 Credits

CIE Continuous Internal Evaluation; **ESE** End Semester Examination; **ST** Sessional Tests; **IA** Internal Assessment, **L** Lectures, **I.L**. Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; **P** Practicals, Lab. work, Project, **C** Core, **E** Elective.

The guide will be chosen based on mutual consent of the student and faculty member. After selection of the research guide the student will formulate his/her Seminar topic (MPH 151).

Semester II

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/E/S		L	I.L	P	T	P	ST	IA	
1	MPH 201	Advanced Pharmacokinetics and Biopharmaceutics	C	4	3	1	-	3	-	40	10	50
2	MPH 202	Computer-aided Drug Delivery Systems	C	4	3	1	-	3	-	40	10	50
3	MPH 203	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	C	4	3	1	-	3	-	40	10	50
4	MPH 204	Basic Molecular Biology	C	4	3	1	-	3	-	40	10	50
5	MPH 205 MPH 206 MPH 207 MPH 208	Elective Subject Advanced Spectral Analysis or Advances in Drug Metabolism and Pharmacokinetics or Drug Evaluation Techniques or Pharmaceutical Unit Operations	E	2	1	1	-	3	-	40	10	50
6	MPH 209 P	Pharmaceutics Lab-III	C	3	-	-	6	-	6	-	20	80
7	MPH 210 P	Pharmaceutics Lab-IV	C	3	-	-	6	-	6	-	20	80

Total Credits: Semester II –24

Semester III

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/E/S		L	I.L	P	T	P	ST	IA	
1	MPH 300	Research Methodology	C	2	1	1	-	3	-	40	10	50
2	MPH 301	Drug Regulatory Affairs	C	2	1	1	-	3	-	40	10	50
3	MPH 351	Research Seminar-II/Journal Club	C	2	-	2	-	1	-	-	-	100
4	MPH 303	Research Project	C	18	-	-	-	1	-	-	-	100

Total Credits: Semester III –24

The research work will commence from this Semester. The students will submit progress report and present seminar(s) based on the progress of his research work that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The student will be evaluated by all faculty members. The final marks will be the average of the marks given by the faculty. The progress report should be handed in by the student the next day after the delivery of the seminar.

*The student is free to opt one audit course of his/her interest, offered by any department of the University, however, the subject will appear in the Marks Sheet (if examination is qualified), but credits will not be accumulated.

Semester IV

No.	Sub. Code	Title of the Course	Type of Course	Credits	Contact hours/week			ESE (hour)		Weightage (%)		
										CIE		ESE
			C/E/S		L	I.L	P	T	P	ST	IA	
1	MPH 451	Research Seminar-III/Journal Club	C	2	-	2	-	1	-	-	-	100
2	MPH 403	Research Project	C	22	-	-	-	1	-	-	-	100*

Total Credits: Semester IV –24

This Semester is devoted totally to research which will culminate in the submission of a thesis. The student will deliver a pre-submission seminar before submission of his/her thesis at a date and time fixed by the department, that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The Seminar will be followed by a discussion.

*The theses of the students will be evaluated by all faculty members (for Max. Marks of 70). The final marks will be the average of the marks given by the faculty (for Max. Marks of 70). The viva-voce will be conducted by an external examiner (for Max. Marks of 30).

Strong emphasis should be placed on the novelty/IPR aspects of the plagiarism free research work, beside publications in peer reviewed journals of good impact factors. Students should be encouraged to attend conferences, seminars where they will present their research work.

Detailed Syllabus
Semester I

Course No MPH 101 Title of the Course: Modern Pharmaceutical Analytical Techniques Credits 4

Unit	Course Content (Topics)	Contact Hours
1.0	**Ultraviolet / Visible Spectroscopy and Fluorimetry**	5
	Energy level and selection rules, effect of substituents, effect of conjugation, conformation and geometry, the Woodward-Fisher rules, the Fisher-Kuhn rules, applications of UV with reference to different electronic systems. Derivative spectroscopy and its applications. Fluorescence and chemical structure, fluorescence intensity, factors affecting fluorescence, instrumentation, comparison of fluorometry with spectrophotometry, applications of fluorimetry in pharmaceutical analysis.	
2.0	**Infrared Spectroscopy**	6
	The Hook's law and calculation of stretching frequencies for different types of bonds and their bond strengths, coupled interactions, hydrogen bonding, examination of infrared spectrum, survey of important functional groups with examples, radiation source, detectors used, sample handling, quantitative applications, qualitative applications with special reference to stereochemical aspects and hydrogen bonding, absorption and reflectance spectroscopy Near-IR spectroscopy, instrumentation, applications, Far Infrared spectroscopy. Introduction to FTIR, instrumentation and its applications.	
3.0	**Raman spectroscopy**	2
	Introduction, theory and polarization measurement, rules of selection and polarization, instrumentation, applications in pharmaceutical sciences. Comparison of Infrared and Raman spectra.	
4.0	Nuclear Magnetic Resonance Spectroscopy	15
	^{1}H-NMR spectroscopy: Magnetic equivalence, failure of the N+1 rule, chemical shifts, local diamagnetic shielding, hybridization effects, magnetic anisotropy, mechanism of spin-spin coupling, the origin of spin-spin splitting, Pascal's triangle, the coupling constant, protons on oxygen, nitrogen and sulphur, diastereomeric protons, chemical shift reagents, long range coupling, spin decoupling methods, nuclear over Hauser effect. Correlation NMR spectrometry: introduction to 1H -1H cosy and 1H - 13C cosy and its applications. Introduction and applications of 2D NMR; solid state NMR. 13C-NMR spectroscopy: Introduction, peak assignments, off resonance decoupling, selective proton decoupling; chemical shift equivalence; chemical shifts; spin coupling. Spectrometry of other important nuclei: Introduction to 15N, 19F, 31P, basic concepts.	
5.0	**Electron Spin Resonance Spectroscopy:** Introduction, derivative curves, g values, hyperfine splitting, ESR instrumentation, ESR spectra of free radicals, applications.	1
6.0	**Mass Spectrometry**	6

	Basic principle and theory involved; instrumentation, various ion sources, electron impact source, chemical ionization sources, field ionization sources, desorption sources, mass analysers, double focusing, quadripole, time of flight, ion trap analyzer, ionization, fragmentation, rearrangements, mass spectra of representative compounds, recognition of molecular ion peak, metastable peak, isotopic peaks, applications.	
7.0	**X-Ray Spectroscopy**	4
	Introduction, production and properties of the X-ray, X-ray emission, X-ray absorption, principles of X-ray diffraction, powder diffraction, X-ray diffraction methods, application of X-ray diffraction technique in pharmaceutical sciences.	
8.0	**Thermal Analysis**	3
	Pharmaceutical applications of thermo gravimetric analysis (TGA), differential thermal analysis (DTA), differential scanning calorimetry (DSC) and microcalorimetry, different types of calorimeters and micro calorimeters, advantages of microcalorimetry over DSC.	
9.0	**Chromatography**	12
	Gas Chromatography: Gas liquid chromatography, gas solid chromatography, instrumentation and applications (GC-MS and GC-FTIR). Derivatization as a means of sampling of thermosensitive compounds. High Performance Liquid Chromatography: Partition, adsorption, ion exchange, size exclusion; pharmaceutical applications of HPLC and LC-MS. Super critical fluid chromatography; brief introduction to HPTLC.	
10.0	**Optical Rotatory dispersion and Circular Dichroism:** Definition, cotton effect and stereochemistry, octet rule and applications.	2
11.0	Electrophoresis (paper, gel, capillary, zone, moving boundary, isoelectric) and Immunological assays (RIA, ELISA and bioluminescence assays)	4
	Total	**60**

Books

1. Spectroscopy, Pavia D. L., Lapman G. M., Kritz G. S., Vyvyan J. R., Brooks/Cole Indian Reprint.
2. Modern NMR Techniques for Chemistry Research, Derome A. E., Pergamon Press.
3. Spectroscopic Methods in Organic Chemistry, Williams D. H., Fleming I., Tata McGraw Hill.
4. Spectrometric Identification of Organic Compounds, Silverstein R. M., Bassler G. C., Morrill T. C., John Wiley.
5. Instrumental Methods of Analysis, Willards, 7th edn., CBS publishers.
6. Pharmaceutical Analysis-Modern Methods-Part B-JW Munson, Volume 11, Marcel Dekker Series

Course No MPH 102 Title of the Course: Modified Release Drug Delivery Systems Credits 4

Unit	Course Content (Topics)	Contact Hours
1	Fundamentals of controlled release (CR)/sustained release (SR) drug delivery: Rationale of sustained/controlled drug delivery, physicochemical and biological factors influencing design and performance of CR products, therapeutic status of CRDDS. Concept of temporal and spatial drug delivery.	5
2	Strategies and approaches for designing oral controlled release/gastroretentive delivery systems modified and delayed formulations, buccoadhesive/ mucoadhesive systems. Osmotic controlled oral drug delivery.	6
3	Parenteral systems, biopharmaceutical considerations, design and development, polymeric microspheres, dispersed drug delivery systems.	5
4	Subdermal implantable therapeutic systems: Rational, classification and approaches, blood and tissue compatibility; Intrauterine and intravaginal devices.	5
5	Transdermal therapeutic systems (TTS): Drug absorption through skin, permeation enhancers, basic components of TTS, approaches to development and kinetic evaluation, testing of transdermal patches, pressure sensitive adhesives; Iontophoresis, sonophoresis and electroporation.	6
6	Novel ocular drug delivery systems: Ocular therapeutics and constraints to effective delivery, formulation considerations to improve the ocular bioavailability, ocular inserts including insoluble and soluble inserts, non-corneal routes and their use for systemic drug delivery.	5
7	Nasal/pulmonary drug delivery systems including MDI, DPI and nebulizers.	5
8	Protein and peptide delivery: Barriers, Formulation approaches, delivery of macromolecules.	8
9	Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.	5
10	Polymers employed in CR/SR formulations: Introduction, classification, properties and applications.	5
11	Dosage forms for personalized medicine: Customized drug delivery systems, bioelectronic medicines, 3D printing of pharmaceuticals, telepharmacy.	5
	Total	**60**

Books

1. Robinson JR and Lee VHL. Controlled Drug Delivery - Fundamentals and Applications. Vol. 29 and Vol. 31, Marcel Dekker, New York. Latest Edition.
2. Chien YW. Transdermal Controlled Systemic Medications, Marcel Dekker, New York. Latest Edition.
3. Bruck SD. Controlled Drug Delivery. Vol. I (Basic Concepts), CRC Press, Florida. Latest Edition.
4. Bruck SD. Controlled Drug Delivery. Vol. II (Clinical Applications), CRC Press, Florida. Latest Edition.
5. Tyle P and Ram B. Targeted Therapeutic Systems, Marcel Dekker, New York. Latest Edition.
6. Prescott LF and Nimmo WS. Novel Drug and its Therapeutic Applications, John Wiley and Sons. Chichester. Latest Edition.
7. N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers and Distributors, Latest edition/reprint.
8. S. P. Vyas and R. K. Khar, Controlled Drug Delivery-Concepts and Advances, Vallabh Prakashan, New Delhi, Latest edition.

Course No MPH 103. Title of the Course: Modern Pharmaceutics Credits 4

Unit	Course Content (Topics)	Contact Hours
1.	Preformulation Studies: Introduction, goals of preformulation, physicochemical properties, criteria for selection of drug and excipients, compatibility tests.	3
2.	Solubility and Solubilization: Development of theoretical relationships of prognostic relevance, techniques of solubilization of drugs including surfactant systems, co-solvents, solid state manipulations, complexation and chemical modifications.	3
3.	Partition Coefficient: Pharmaceutical significance of partition coefficient, correlation with in-vivo performance, techniques to estimate log P values, shake flask method, choice of solvent systems, chromatographic determination, theoretical computation using Hansch& Leo/Rekker principle, effect of various variants like temperature, pH, etc. on partition coefficient.	3
4.	Solid State Pharmaceutics: Crystallinity, crystal habit, polymorphism, amorphous state, solvates hydrates and analytical techniques for characterization.	4
5.	Complexation: Metal and organic molecular complexes, inclusion complexes with reference to cyclodextrins, types of cyclodextrins, their pharmaceutical applications.	4
6.	Rheology: Concepts of rheology, viscoelastic analysis of semisolids, applications and practice of rheology, viscometers.	5
7.	Stability Testing: Stress testing and stability assessment protocols, photostability, post approval changes (SUPAC), packing influence on stability, NDSS specific stability issues and general approaches for the improvement of stability of finished products.	5
8.	Systematic Optimization of Pharmaceutical Formulations: Pitfalls of traditional OVAT approach, Design of Experiments (DoE) using experimental designs, terminology, response surface methodology, basics of factorial, composite and mixture designs with merits and limitations, strategy for DoE optimization, applications of systematic optimization techniques.	5
9.	Recent Advances in tablet and capsule technology.	5
10.	cGMP and Industrial Management: GMP-WHO and US FDA guidelines, concepts of quality control and quality assurance, manufacturing facilities for tablets, capsule, liquid orals, semisolids and parenterals as per schedule M, cGMP. Pharmaceutical plant location, layout, utility services including HVAC. Certification for pharmaceutical industries, technology transfer guidelines, salient features of ISO 9000 series, total quality management (TQM).	8
11.	Validation: ICH and WHO guidelines for calibration and validation of instruments. Types of validation	5
12.	Consolidation parameters: Diffusion parameters, dissolution parameters, pharmacokinetic parameters, Heckal plots, similarity factors (f1 and f2), Higuchi, Weibull, Korsmeyer-Peppas plots	10
	Total	**60**

Books

1. Wells JI. Pharmaceutical Prefomulation: The Physicochemical Properties of Drug Substances. Ellis Horwood, Chiechester, U. K. Latest Edition.
2. Yalkowsky SH. Techniques of Solubilization of Drugs. Marcel Dekker, New York. Latest Edition.
3. Doornbos C and Hann P. Optimization Techniques in Formulation and Processing. In Encyclopedia of Pharmaceutical Technology. Swarbrick J and Boylan JC, Eds., Vol. II, Marcel Dekker, New York. 1995.
4. Lewis GA. Optimization Methods. In Encyclopedia of Pharmaceutical Technology. Vol. IV, Informa Healthcare, New York. 2007
5. Swarbrick J and Boylan JC, Eds., Encyclopedia of Pharmaceutical Technology. Vol. I, Marcel Dekker, New York. Latest Edition.
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6. Singh B. and Ahuja A. Response Surface Optimization of Drug Delivery Systems. In Controlled and Novel Drug Delivery Systems, Jain NK, Ed., CBS, New Delhi. Latest Edition.
7. Carstensen JT. Drug Stability: Principles and Practices. Marcel Dekker, New York. Latest Edition
8. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, 5th edition, revised and expanded by Sidney H. Willig, Marcel and Dekker. USFDA Guidelines
9. How to practice GMPs, P. P. Sharma, Vandhana Publications, Agra.
10. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann

Course No MPH 104 Title of the Course: Cosmetics and Cosmeceuticals Credits 4

Unit	Course Content (Topics)	Contact Hours
1.	Formulations approaches and Requirements: Definition of cosmetic products as per Indian and EU regulations. Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odour. 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-arms. Formulation requirements for ethnic needs.	10
2.	Commonly used cosmetics raw materials: 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 cream, shampoo and toothpaste. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.	10
3.	Design of special purpose cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, and body odour. Dandruff, dental cavities, bleeding gums, mouth odour and sensitive teeth.	10
4.	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.	10
5.	Hair colorants, and labelling and safety requirements of cosmeceuticals: Chemistry and formulation of paraphylene diamine based hair colorants. Soaps and syndet bars, labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men's range of the products in the market and conduct comparative study of the formulations.	10
6.	Regulatory aspects: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labelling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious	10

	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.	
	Total	**60**

Books

1. Cosmetics: Science and Technology. Edited by Edward Sagarin, Interscience Publishers, New York, Latest Edition.
2. Technology of Herbal Cosmetics and Toiletries Products with Formulae, by EIRI Board (Author), Engineers India Research Institute (2008), New Delhi.
3. Cosmetics - Formulation, manufacture and quality control P. P. Sharma, 4th edition
4. Harry's Cosmeticology. 8th edition.
5. Poucher's perfume cosmetics and Soaps,10th edition.
6. Handbook of cosmetic science and Technology A. O. Barel, M. Paye and H.I. Maibach. 3rd edition

Course No MPH 105P. Pharmaceutics Lab-I Credits 3

A number of experiments based on the theory syllabus **such as:**

Unit	Course Content (Topics)	Contact Hours
1.	Analysis of APIs by UV-visible spectrophotometry	
2.	Simultaneous estimation of two APIs in a single dosage form	
3.	Experiments based on fluorimetry	
4.	Formulation of calcium alginate beads and characterization	
5.	Formulation and evaluation of mucoadhesive patches	
6.	Formulation and evaluation of transdermal patches	
7.	Experiments based on Hausner's ratio, Carr's indices and factors affecting the flow of powders	
8.	Micromeritic experiments	
9.	Comparison of the marketed sustained release products of metformin on various pharmacopoeial parameters	
10.	Validation of Noyes Whitney's equation for sparingly soluble drugs	
11.	Effect of complexation on release of antacids	
12.	Demonstration of HPLC and calculations based on it	
13.	Formulation and evaluation of multiple emulsions	
14.	Study of degradation kinetics of established drug(s) using UV-visible spectrophotometry	
	Total	**90**

Course No MPH 106P. Pharmaceutics Lab-II Credits 3

A number of experiments based on the theory syllabus **such as:**

Unit	Course Content (Topics)	Contact Hours
1.	Preparation and evaluation of microparticles	
2.	*In-vitro* drug release/dissolution studies of marketed SR formulations	
3.	Application of correction factors with or without replacement of samples during diffusion studies	
4.	Preparation and evaluation of cyclodextrin complexes.	
5.	Formulation and evaluation of nail lacquers.	
6.	Demi exercises based on Higuchi, Weibull, Zero-order, First-order and Korsmeyer-Peppas models	
7.	Compatibility studies of drugs and excipients	
8.	Determination of shelf-life of drugs using Arrhenius equation	
9.	Dissolution and solubility enhancement by means of solid dispersions	
10.	Study the complexation process of copper and glycine.	
11.	Study the effect of solid state on the dissolution of the drugs.	
12.	Interpretation of data from formulation optimization techniques.	
13.	Experiments based on similarity factors and resigno analysis	
14.	Experiments on enzyme assays	
	Total	**90**

Course No MPH 151 Title of the Course: Research Seminar-I/Assignment Credits 2

The student in consultation with his/her research guide will choose a topic related to his/her area of research and will deliver a Seminar at a date and time fixed by the department, that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The Seminar will be of 25 minutes duration, followed by a discussion. The student will be evaluated by all faculty members under the following parameters: coverage of literature, presentation skills, defence and the seminar report (the report should be handed in by the student the next day after the delivery of the seminar and a copy of the seminar report should be housed in the department). The final marks will be the average of the marks given by the faculty.

Semester II

Course No. MPH 201 Title of the Course: Advanced Pharmacokinetics and Biopharmaceutics Credits 4

1.	**Compartmental Pharmacokinetics:** Review of fundamentals of compartmental approach, basics of kinetics following single dose administration through instantaneous and non-instantaneous routes (like *i.v.* bolus, *i.v.* infusion and peroral) using serum and urine levels, one- and two-compartmental kinetics, method of residuals, multiple-dose administration, superposition rule, problem solving.	12 Lectures
2.	**Noncompartmental Pharmacokinetic Modelling Approach:** Limitations of compartmental approaches, advantages of noncompartmental approaches, definition and significance of stochastic approach, statistical moments (AUC and AUMC) determination of moments using numeric approaches like trapezoidal, log-trapezoidal, etc., computation of statistical moments from plasma and urine data, MRT and its significance, MDT, MIT, MAT, problem solving.	5 Lectures
3.	**Nonlinear Pharmacokinetics:** Significance and applications with literature examples, recognition and cause(s) of nonlinearity, computation of non-linear pharmacokinetic parameters (Vm, Km, AUC, etc.) from the time course and AUC of a drug in body being eliminated by single Michaelis Menten kinetics, problem solving.	4 Lectures
4.	**Biopharmaceutical Considerations in Drug Product Design:** Review of physicochemical, pharmaceutical and physiological variables affecting absorption. Bioavailability and bioequivalence concepts, protocol and assessment of bioequivalence from serum and urine level data as per federal perspectives. Pharmacokinetic drug interactions, role of cytochrome P450 and drug transporters in drug interactions. Pharmacokinetics of drug-loaded and naive nanocarriers. ***In Vitro*/*In Vivo* Correlations (IVIVC):** Biopharmaceutical classification scheme (BCS), basics of IVIVC in the light of BCS perspectives, levels of IVIVC, validation, federal perspectives. Dissolution profile comparison, f_1 and f_2 factors, problem solving.	13 Lectures
5.	**Clinical Pharmacokinetics:** Introduction, pharmacokinetic relationships, duration of response, kinetics of pharmacological response, explanation of clinical response via pharmacokinetics, monitoring of plasma concentrations of drugs during clinical use including problems encountered in clinical investigations, analysis of clinical relevance of kinetic studies, turnover concepts, individualization of dosage and dosage regimen, variability, genetics, age, weight, disease, interacting drugs, use of creatinine clearance, problem solving. Hysteresis of pharmacodynamic response.	7 Lectures
6.	**Protein Binding:** Theory of plasma protein binding and implications, elements of Scatchard, Klotz and Rosenthal analyses for computation of binding parameters, experimental techniques to determine protein binding with their merits and limitations, factors influencing protein binding, effect of binding on drug pharmacokinetics.	3 Lectures
7.	**Advanced Topics in Pharmacokinetics**:	
7.1	**Physiologically-Based Pharmacokinetic (PBPK) Models:** Basic concepts of PBPK models, development of a PBPK model, merits and limitations with respect to classical compartmental approaches, permeation-limited *versus* diffusion-limited models, interspecies scaling, applications.	3 Lectures
7.2	**Pharmacokinetic and Pharmacodynamic (PK/PD) Models:** Basic concepts of PK/PD modelling, methodology including linear, log-linear, E_{max}, non-steady state and time-dependant models, biophase distribution model, biomarkers, nonlinear mixed effect modelling, naïve pool approach, applications.	4 Lectures
7.3	**Allied Advanced Pharmacokinetic Approaches:** Fundamentals and	5 Lectures

	applications of chronopharmacokinetics, toxicokinetics, population pharmacokinetics and dermatokinetics.	
7.4	**Computer-based Pharmacokinetic Modelling:** Strategy for building pharmacokinetic, statistical and variance models, function minimization for goodness of fit, iterative and non-iterative techniques, weighting schemes for nonlinear regression, AIC, SC, MSC, computer-based pharmacokinetic simulations.	4 Lectures

Books (Latest Editions):

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition,Philadelphia, Lea and Febiger.
2. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land Yu ABC.
3. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi
4. Handbook of basic pharmacokinetics including clinical applications, Ritschel WA and Kearns GL, Amer Pharmaceutical Assn.
5. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Leaand Febiger, Philadelphia.
6. Clinical Pharmacokinetics, Concepts and Applications, Malcolm Rowland and Thom- N. Tozer, Lea and Febiger, Philadelphia.
7. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania.
8. Pharmacokinetics, M. Gibaldi and D. Perrier, Wiley-Interscience.
9. Biopharmaceutics and Clinical Pharmacokinetics - An Introduction, Robert. E. Notari, Marcel Dekker Inc, New York and Basel.
10. Biopharmaceutics and Pharmacokinetics - A Treatise, D.M. Brahmankar and Sunil B. Jaiswal., Vallab Prakashan, Pitampura, Delhi.
11. Biopharmaceutics and Pharmacokinetics, V. Venkateswarlu, PharmaMed Press/BSP Books, Hyderabad.

Course No: MPH 202. Title of the Course: Computer-aided Drug Delivery Systems Credits 4

Unit	Course Content (Topics)	Contact Hours
1.	**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 **Quality-by-Design In Pharmaceutical Development:** Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD -examples of application	10
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	9
3.	**Computer-aided formulation development:** Concept of optimization, Optimization parameters, Optimization technology & Screening designs including Factorial designs. Use of these designs in the development of pharmaceutical carriers like liposomes, emulsomes, SLNs, emulsions, microemulsions and other drug delivery carriers, Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis	25
4.	**Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation: Introduction, theoretical background, model construction, parameter sensitivity analysis, virtual trial, Fed vs. fasted state,	10

	in vitro dissolution and in vitro-in vivo correlation, biowaiver considerations **Computer Simulations in Pharmacokinetics and Pharmacodynamics:** Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes. **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.	6
	Total	**60**

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.

4. Singh B. and Ahuja A. Response Surface Optimization of Drug Delivery Systems. In Controlled and Novel Drug Delivery Systems, Jain NK, Ed., CBS, New Delhi. Latest Edition.

Course No. MPH 203 Title of the Course: Molecular Pharmaceutics (Nano Tech and Targeted DDS)

Credits 4

Unit	Course Content (Topics)	Contact Hours
1.	**Novel Drug Delivery Systems:** History, evolution, advantages, need of "nano-based" pharmaceuticals and classification. Need of such systems with some marketed products available in India, USA, EU and Japan.	4
2.	**Vesicular carrier systems:** Raw materials, methods of preparation, characterization, evaluation, advantages/disadvantages and marketed products of liposomes, niosomes, ethosomes, flexible vesicles/Transfersomes, bilosomes and aquasomes.	9
3.	**Particulate carrier systems:** Raw materials, methods of preparation, characterization, evaluation, advantages/disadvantages and marketed products of SLNs, NLCs, polymeric nanoparticles, dendrimers and BSA-based NPs.	9
4.	**Micellar and emulsified colloidal carriers:** Raw materials, methods of preparation, characterization, evaluation, advantages/disadvantages and marketed products of micelles (polymeric/mixed), nano/microemulsions, SEDDs, SMEDDs, SNEDDs, organogels and lipid emulsions. Importance of ternary phase diagram in co-solvent based systems.	6
5.	Regulatory requirements for NDDS (CDSCO and US-FDA) Triggered Pulsed and Programmed Drug Delivery Systems	3
6.	**Targeted drug delivery systems**: Types of targeting, use of ligands and other approaches to target the drug-loaded carriers to brain, lungs, immune system and tumors. EPR effect and MPS effect and the implications on drug targeting.	5

7.	Microcapsules/ microspheres: Types, preparation and evaluation.	3
8.	An introduction to the composition and promises of phytosomes, aquasomes, hybrid nanoparticles, CNTs/fullerenes/graphenes/silica nanoparticles for drug delivery.	3
9.	Safety concerns related to drug delivery at "nano scale".	2
10.	Characterization and evaluation of NDDS: Principle, methodology and equipment employed for characterization techniques like micromeritics, morphology, drug loading and entrapment, drug release, stability (physical and chemical), phase transition and physical state. Biocompatibility, pharmacokinetic and pharmacodynamics assessment of NDDS.	6
11.	Mechanisms of assimilation and absorption of NDDS in biological systems	5
12.	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. Introduction to therapeutic antisense molecules and aptamers as drugs of future.	5
	Total	60

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, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).
4. Tyle P and Ram B. Targeted Therapeutic Systems, Marcel Dekker, New York. Latest Edition.

Course No. MPH 204 **Title of the Course: Basic Molecular Biology** Credits 4

Unit	Course Content (Topics)	Contact Hours
1.0	Introduction: Historical perspective, composition and comparison of RNA and DNA, types of N-bases, Chargaff's rule, structure of DNA and RNA, types of RNA and functions, concept of central dogma, isolation and purification of RNA and DNA.	6
2.0	DNA-antiparallel nature: Analysis of nearest neighbour base frequency, semiconservative nature of DNA replication, basics of Messelson and Stahl experiment, direction of replication, discontinuous replication, Okazaki fragments, roles of DNA polymerase I, II and III, DNA ligase and DNA topoisomerases in DNA replication, fidelity of replication, replication in viruses, rolling circle model, single stranded DNA virus, applications of mitochondrial DNA, Trombon model, translesion synthesis (DNA pol IV and V).	10
3.0	Transcription: Colinerity of genes and proteins, introduction to RNA polymerase I, II and III and their respective roles, biosynthesis of RNA in prokaryotes and eukaryotes; initiation, elongation and termination, RNA dependent RNA synthesis, processing of eukaryotic RNA, cap addition, poly A tail addition, RNA editing and processing of tRNA and mRNA transcripts.	10

4.0	Translation: Genetic code, triplet codon, universality features of the genetic code, assignment of codons, studies of Khorana, Nirenberg, triplet binding techniques, degeneracy, wobble hypothesis, evolution of genetic code and codon usage, variation in the codon usage, structure of prokaryotic and eukaryotic ribosomes, ribosomal protein synthesis: initiation elongation and termination with an elaboration of the roles of mRNA and tRNA, post translation modification of proteins, signal cleavage, disulphide bond formation, O and N-glycosylation, folding of nascent protein, role of chaperones, attachment of glycosyl anchor and other modifications.	18
5.0	Enzymes in DNA and RNA degradation: Nucleases, ribonucleases, classification and role.	3
6.0	Recombinant DNA technology, molecular cloning, & some tools for analyzing gene expression.Genome analysis: DNA typing; Genomics and beyond; Medical molecular biology: applications in Cancer and Gene therapy; Genes and behaviour.Gene Therapy: Introduction and need, barriers to gene delivery, novel approaches based on viral and non viral vectors for site specific gene delivery, their advantages and limitations, siRNA delivery. Genetically modified organisms: Transgenic animals and plants use in basic and applied research with special attention to recombinant proteins.	10
7.0	Introduction to the basics of plant tissue culture and animal cell culture	3
	Total	**60**

Books

1. Genes IX, Ed Benjamin Lewin. Oxford University Press. Latest Edition
2. Molecular Cell Biology, Lodish H, Berk A, Zipursky S L, Matsudaira P., Baltimore D, Darnell J, Publisher W. H. Freeman. Latest Edition
3. Molecular Biology of the Cell, Alberts Publisher Garland Science. Latest Edition
4. Watson, J. D. Tania A. Baker, Stephen P. Bell, Alexander Gann, Michael Levine, Richard Losick, Molecular Biology of the Gene, Benjamin Cummings; 6th Edition, 2007.
1. Molecular Biology in Medicinal Chemistry, Dingemann Th, Steinhilber D and Folkers G, Wiley-VCH, Germany. Latest Edition
5. Basic Principles of Gene Manipulation, Primrose SB, Twyman RM and Old RW, Blackwell. Latest Edition
6. Molecular Biology and biotechnology, Walker JM and Rapley R, Royal Society of Chemistry. Latest Edition
7. Understanding Gene Therapy, N. R. Lemoine, Garland Science, Latest Edition. Latest Edition

Course No. MPH 209P Title of the Course: **Pharmaceutics Lab III** Credits 3

Unit	Course Content (Topics)	Contact Hours
1.	Basic experiments pertinent to molecular biology like DNA extraction, enzyme kinetics, electrophoresis and cell culture.	
2.	Graphical, gravimetric and trapezoidal methods of AUC determination and projection of AUC till infinity	
3.	Demi exercises based on pharmacokinetic principles of 1 CBM IV push/infusion, 1 CBM per-oral, Urinary studies, superposition principle, non-compartmental pharmacokinetics, W-N method/modified W-N method	
4.	Salivary secretion studies in healthy human subjects and subsequent analysis of samples and pharmacokinetic data.	
	Total	**60**

Course No. MPH 210P Title of the Course: **Pharmaceutics Lab IV** Credits 3

Unit	Course Content (Topics)	Contact Hours
1.	Preparation and characterization of blank and drug loaded liposomes by various techniques.	
2.	Preparation and characterization of blank and drug loaded niosomes by various techniques.	
3.	Development of ternary phase diagram for the selection of microemulsion region.	
4.	Preparation and characterization of blank and drug loaded microemulsions by dispersion technique.	
5.	Preparation and characterization of blank and drug loaded elastic membrane vesicles.	
6.	Preparation and characterization of blank and drug loaded chitosan nanoparticles.	
7.	Preparation and characterization of blank and drug loaded BSA-nanoparticles.	
8.	Preparation and characterization of blank and drug loaded solid lipid nanoparticles.	
9.	Preparation and characterization of blank and drug loaded nanolipidic carriers.	
10.	Preparation and characterization of blank and drug loaded **ethosomes.**	
11.	Preparation and characterization of blank and drug loaded organogels.	
12.	Experiments based on other nanocolloidal carriers like silica nanoparticles, CNTs, fullerenes, dendrimers and PLGA nanoparticles.	
	Total	**60**

ELECTIVE SUBJECTS

Course No. MPH 205 Title of the Course: Advanced Spectral Analysis Credits 2

Unit	Course Content (Topics)	Contact Hours
1.0	Molecular Formulae, Elemental Analysis and calculation, Determination of molecular mass, Index of Hydrogen Deficiency, Rule of thirteen, Isotope detection, Nitrogen rule	2
2.0	Analysis of IR spectrum of Organic compounds	3
3.0	UV spectroscopy: Wood ward – Fieser rule for 1,3- butadienes, cyclic dienes and α, β-carbonyl compounds and interpretation compounds of enones. Calcualtion of λ_{max} values by applying these rules	4
4.0	NMR spectroscopy	
4.1	Spin Spin coupling: Coupling constants, one bond couplings, two bond couplings, three bond couplings, long range couplings. Magnetic equivalence, Nonequivalence within a group, measuring coupling constants from first order spectra, mechanisms of coupling in alkenes; allylic coupling, second order spectra: strong coupling, coupling in aromatic and heteroaromatic systems, Homotopic, enantiotopic and diastereotopic systems. Intrepretation of diastereotopic systems.	4
4.2	Other topics in 1-D NMR: Protons on oxygen, exchange in water and D_2O, other types of exchange. Protons on nitrogen, effect of solvent on chemical shifts, Chemical shift reagents, chiral resolving agents, spin decoupling methods	2
4.3	Advanced NMR techniques: DEPT, NOESY, COSY and HETCOR, INADEQUATE techniques, MRI.	2
5.1	Mass Spectroscopy Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.	3
6.0	Problems involving structure determination based on UV, IR, NMR and Mass spectra.	10
	Total	**30**

Books:

1. Silverstein RM and Webster FX. Spectrometric Identification of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
2. Chatten LG. Pharmaceutical Chemistry, Vol I & II. Marcel Dekker, New York. Latest Edition.
3. James WD and Kenneth HT. Analytical Chemistry by Oipen Learning: Thermal Methods. John Wiley and Sons, New York. Latest Edition.
4. Abraham RJ, Fisher J and Bftus P. Introduction to NMR Spectroscopy. John Wiley and Sons, New York. Latest Edition.
5. Pavia DL, Lampman GM and Kriz GS. Introduction to Spectroscopy. Harcourt College Publishers, Orlando. Latest Edition.
6. Skoog DA, Holler FJ and Nieman TA. Principles of Instrumental Analysis. Harcourt College Publishers, Harcourt Asia. Latest Edition

Course No. MPH 206 Title of the Course: Advances in Drug Metabolism and Pharmacokinetics

Credits 2

Unit	Course Content (Topics)	Contact Hours
1.0	**Drug Metabolism**	5
1.1	Introduction	
1.2	Pathways for drug deactivation and metabolism	
2.0	**Metabolism, Pharmacokinetics and Toxicity of Functional Groups**	
2.1	Drugs and their structural mofits	1
2.2	ADMET for drugs	2
2.3	Amines and their isosters	3
2.4	Carboxylic cids and their bioisosters	5
2.5	Sulphonamide as essential functional group in drug design	5
2.6	Influence of aromatic and heteroaromatic rings on ADME properties	9
	Total	**30**

Books

1. Comprehensive Medicinal Chemistry, Series Ed., Hansch C., Pergamon Press.
2. Wilson and Gisvold's, Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott-Raven
3. Foye's Principles of Medicinal Chemistry, Lippincott Williams and Wilkins.
4. Drug Metabolizing Enzymes-Cytochrome P450 and Other Drug Metabolizing Enzymes in Drug Discovery and Development, Lee JS, Obach SR and Fisher MB, Marcel Dekker, Fontis India, 2003
5. Pharmaceutical Profiling in Drug Discovery for Lead Selection, Borchardt RT, Kerns EH, Lipinski CA, Thakker DR and Wang B, AAPS Press, 2004
6. Drug Metabolism – Current Concepts, Ionescu C and Caira MR, Springer International Edition
7. Handbook of Drug Metabolism, Woolf TF, Marcel Dekker, 1999.
8. Metabolism, Pharmacokinetics and Toxicity of Functional Groups-Impact of Chemical Building Blocks on ADMET, Dennis A. Smith, RSC Publishing, Latest Edn.

Course No. MPH 207 Title of the Course: Drug Evaluation Techniques Credits 2

Unit	Course Content (Topics)	Contact Hours
1.0	Pharmacodynamic models for evaluation of drugs/DDS containing drugs of various categories such as Cardiovascular agents; Antidiabetic; Antiinflammatory; Antiepileptic; Anticancer; Hepatoprotectives; Analgesics; Antistress; Antiasthmatic, CNS active agents and Analgesics.	6
2.0	In vitro cell culture techniques for evaluation of drug permeation from drugs/DDS including isolation maintenance of cell lines, culturing monolayers, evaluation of drug transport.	6
3.0	In vitro / ex vivo models for evaluation of Drug absorption	3
4.0	In vitro cytotoxicity evaluation using cell cultures and techniques such as MTT assay, Dye uptake etc.	6
5.0	Toxicity testing: In vitro: In vitro toxicity testing and its application to safety evaluation, General perspectives, in vitro toxicity trends and issue, Ocular and cutaneous irritation, Validation of In vitro toxicity tests. Acute, sub acute and chronic toxicity testing – Biochemical basis of toxicity, Design of toxicological studies, Quality assurance in	9

	toxicology studies, Toxicity by routes – Parental, oral, percutaneous and inhalation, Target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity. Regulatory status- Ethical, moral and professional issues.	
	Total	**30**

Books:

1. Bioassay Techniques for drug Development, Atta Ur Rahman, M. Iqbal Choudhary, William J. Thomsen
2. In vitro Methods in Pharmacuetical Research, Edited by J. V. Casterll, M. J. Gomer, Lechon, Academic Press.
3. In Vitro Toxicity Testing by John M. Fraizer
4. General and Applied Toxicology by Bryan Ballantyne, T. Marrs & P. Turner.

Course No. MPH208 Title of the Course: Pharmaceutical Unit Operations Credits 2

Unit	Course Content (Topics)	Contact Hours
1.0	Mass transfer and Unit Operations: Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities	6
2.0	a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration, c) Distillation: azeotropic and steam distillation d) Evaporation: Types of evaporators, factors affecting evaporation. e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs	15
5.0	Industrial Safety a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Effluents and its management	9
	Total	**30**

Books

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an EverChanging Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)

9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House 14. J.K. Stille: Industrial Organic Chemistry (PH)

Semester III

Course No MPH 300. Title of the Course: Research Methodology Credits 2

Unit	Course Content (Topics)	Contact Hours
1.0	Objectives and purposes of research, types of research (educational, clinical, experimental, basic , applied, patent oriented research) Literature survey: Methods, Objectives and Tools Data Collection and Data Analysis: Types and methods, Application of statistical tools like variance, standard deviation, standard error, mean, t-test, ANOVA, coefficient of correlation and coefficient of determination. Methods and tools of documentation with a special emphasis on computer applications. Report/Thesis and manuscript preparation, contents of report/thesis/manuscript, kinds of abstracts, IMRAD concept, authorship and ethics in medical writing, introduction of plagiarism. Introduction to impact factor, citation analysis, h-index and other metrics.	10
2.0	Laboratory and Biological Safety: Historical background, laboratory protective equipments, primary contaminants of biohazards, biosafety levels for laboratories, regulations and guidelines related to biosafety. Disposal of chemical and carcinogenic waste.	10
3.0	Intellectual Property Rights: Introduction to various kinds of IPRs, need of IPR in pharmaceutical research, introduction to history of important IPR treaties like GATT, WTO, WIPO and TRIPS, introduction to Indian Patent Act 1970, patent filing process in India with a special emphasis on PCT, product patent, process patent, requirements and preparation of patent proposals, registration of patents in foreign countries.	10
	Total	**30**

Books

1. Pharmaceutical Statistics – Practical and Clinical Applications, Bolton S., Marcel Dekker, Inc. N. Y. USA
2. Biostatistics: A Foundation for Analysis in Health Sciences, Wayne W Daniel, John Wiley & Sons, Inc.
3. Research in Education, Best J. W., Khan J. V., Prentice Hall of India Pvt. Ltd.
4. Thesis and Assignment Writing, Jonathan A., Berry H D., Wiley Eastern Ltd., Bangalore.
5. Writing a Technical Paper, Menzel D. H., McGraw Hill Book Co., Inc.
6. Research Methodology-A step-by-step guide for beginners, Ranjit Kumar, SAGE Publications, UK.
7. CRC Handbook of Laboratory Safety by Furr A. K.; CRC Press.

Course No MPH 301. Title of the Course: Drug Regulatory Affairs Credits 2

1.	**Harmonization**: Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.	8
2.	**Documentation:** Master formula record, Drug master file, distribution records, BoMs. General documentation procedures followed during various stages of formulation developments including the storage of control samples.	7
3.	**Post Approval Regulatory Affairs:** CMC post approval changes, CTD, eCTD,	8

	industry and FDA liaison. A comparison between regulatory requirements of CDSCO, EU, MHRA, TGA and ROW countries. Introduction to SUPAC.	
4.	**Clinical Trials:** Ethics committee (as per ICMR), Types of trials, Clinical trials protocols, Sample size determination, Evaluation of trials, Pharmacovigilance. Stand of CDSCO on clinical trials.	7

Recommended Readings:

1. The Pharmaceutical Regulatory Process, Second Edition, edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185, Informa Healthcare Publishers.
2. New Drug Approval Process: Accelerating Global Registrations, Richard A Guarino, 5th edn., Drugs and the Pharmaceutical Sciences, Vol. 190, Informa Healthcare Publishers.
3. http://www.ich.org/products/guidelines.html
4. https://clinicaltrials.gov/

Course No: MPH 351 Title of the Course: Research Seminar II/Journal Club Credits: 2

The students will do a literature survey for the research work that is to be carried out in Semesters III and IV and present a Seminar which should cover aspects of literature report, plan of research work, methodology timelines, and expected outcome of the work before a committee that will constitute the Research guide, Head of the Department and the other faculty of the Department. The final marks will be the average of the marks given by the faculty. All the students in the department should attend seminar.

Course No. MPH 303 Title of the Course: Research Project Credit: 18

The full time research work will commence from this Semester. The students will submit progress report and present seminar(s) based on the progress of his research work that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The student will be evaluated by all faculty members. The final marks will be the average of the marks given by the faculty. The progress report should be handed in by the student the next day after the delivery of the seminar.

Semester IV

Course No: MPH451 Title of the Course: Research Seminar III/Journal Club Credits: 2

This Semester is devoted totally to research which will culminate in the submission of a thesis. The student will deliver a pre-submission seminar before submission of his/her thesis at a date and time fixed by the department, that should be attended by all students in the department, the research guide, the HOD and other faculty of the Department. The Seminar will be followed by a discussion.

Course No: MPH 403 Title of the Course: Research Project Credits: 22

Strong emphasis should be placed on the novelty/IPR aspects of the research work, beside publications in peer reviewed journals of good impact factors. Students should be encouraged to attend conferences, seminars where they will present their research work.

*The theses of the students will be evaluated by all faculty members (for Max. Marks of 70). The final marks will be the average of the marks given by the faculty (for Max. Marks of 70). The viva-voce will be conducted by an external examiner (for Max. Marks of 30).