First Year

Semester I

MPH 101 Title of the Course: Modern Pharmaceutical Analytical Techniques

UV-visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

Infra-red 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.

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

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

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

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

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

X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg‘s law, Rotating crystal technique, X-ray powder technique, Types of crystals and applications of X-ray diffraction.

Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

Potentiometry: Principle, working, Ion selective electrodes and application of potentiometry.

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.

Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). **TGA:** Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

Books recommended:

1. Silverstein, R.M. (2004). Spectrometric Identification of Organic compounds. 6th Ed., New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
2. Skoog, D.A., Holler, F.J., Nieman, T.A. (1998). Principles of Instrumental Analysis. 5th Ed., Bangalore: Eastern press.
3. Beckett, A.H., Stenlake, J.B. (1987). Practical Pharmaceutical Chemistry. 4th Ed., vol 2. New Delhi: CBS Publishers & Distributers.
4. Kemp, W. (1991). Organic Spectroscopy, 3rd Ed., London: Red Globe Press.
5. Sethi, P.D. (1987). Quantitative Analysis of Drugs in Pharmaceutical formulation. 3rd Ed., New Delhi: CBS Publishers & Distributers.
6. Munson, J.W. (2008). Pharmaceutical Analysis- Modern methods – Part B. vol 11. New York: Marcel Dekker, Inc.

MPH 102 Title of the Course: Drug Delivery Systems

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.

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.

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Occular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

Books recommended:

1. Chien, Y.W. (1992). Novel drug delivery systems. 2nd Ed., New York: Marcel Dekker, Inc.
2. Robinson, J.R., Lee, V.H.L. (1992). Controlled drug delivery systems. New York: Marcel Dekker, Inc.
3. Mathiowitz, E. (1999). Encyclopedia of controlled delivery. New York: Wiley Interscience Publication, John Wiley and Sons, Inc.
4. Jain, N.K. (1997). Controlled and novel drug delivery. 1st Ed., New Delhi: CBS Publishers & Distributers.
5. Vyas, S.P., Khar, R.K. (2002). Controlled drug delivery-concepts and advances. 1st Ed., New Delhi: VallabhPrakashan.

MPH 103 Title of the Course: Modern Pharmaceutics

Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.

Dissolution parameter: Similarity factors – f2 and f1, Higuchi and Peppas plot.

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.

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles, Heckel plots.

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & 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 & PQ of facilities.

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.

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

Linearity, Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

Books Recommended:

1. Lachmann, L., Libermann, H.A., Kanig, J.L. (2013). Theory and practice of industrial pharmacy. 4th Ed., Bombay: Varghese Publishing House.
2. Lachmann, L., Libermann, H.A., Joseph, B. (1989). Pharmaceutical dosage forms: Tablets. 2nd Ed.,vol. I-III. New York: Marcel Dekker.
3. Lachmann, L., Libermann, H.A., Martin, M.R., Banker, G.S. (1996). Pharmaceutical dosage forms: disperse systems. vol. I-II, CRC press.
4. Avis, K.E., Lachmann, L., Libermann, H.A. (1984). Pharmaceutical dosage forms: parentral medications. vol.1. New York: Marcel Dekker.
5. Gillbert, S.B., Christopher, T.R. (1996). Modern Pharmaceutics.4th Ed., CRC press.
6. Remington, J.P. (2005). Remington: The science and practice of pharmacy. 21st Ed., Lippincott Williams and Wilkins.
7. Bean, H.S., Beckett, A.H., Carless, J.E. (1964). Advances in pharmaceutical sciences.vol. I-V, London, Berkeley: Academic press.
8. Sinko, P.J. (2011). Martin's physical pharmacy and pharmaceutical sciences.6th Ed., Lippincott Williams and Wilkins.
9. Rawlins, E.A. (2012). Bentley's textbook of pharmaceutics. 8th Ed., Elsevier.
10. Willing, S.H. (2001). Good manufacturing practices for pharmaceuticals: a plan for total quality control. 5th Ed., New York: Marcel Dekker, Inc.
11. Quality Assurance Guide, By Organization of Pharmaceutical producers of India.
12. Kohli, D.P.S., Shah, D.H. (2008). Drug formulation manual. New Delhi: Eastern publishers.
13. Sharma, P.P. (2015). How to practice GMPs. 7 th Ed., Agra: Vandhana publications.
14. Nash, R.A., Watcher, A.H. (2003). Pharmaceutical process validation.3rd Ed., vol. 129. New York: Marcel Dekker Inc.
15. Wells, J.I. (1990). Pharmaceutical preformulation: The physiochemical properties of drug substances. vol. 79.Chichester: Ellis Horwood.

16. Evans, J.R., Anderson, D.R., Sweeny, D.J., Williams, T.A. (1990). Applied production and operations management. 3rd Ed

17. Swarbrick, J. (2006). Encyclopaedia of pharmaceutical technology.3rd Ed., CRC press.

MPH 104 Title of the Course: Regulatory affairs

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 FEDERALREGULATION) ,drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO.

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

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.

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

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.

Books recommended:

1. Shargel, L, Kaufer, I. (2005). Generic Drug Product Development, Solid Oral Dosage forms. Vol.143. New York: Marcel Dekker Inc.

2. Berry, I.R., Martin, R.P. (2008). The Pharmaceutical Regulatory Process.2nd Ed., vol. 185.Drugs and the Pharmaceutical Sciences. New York: CRC press.

3. Guarino, R.A. (2004). New Drug Approval Process: Accelerating Global Registrations. 5th Ed., vol. 190, New York: Marcel Dekker Inc.

4. Weinberg, S. (2009). Guidebook for drug regulatory submissions.1st Ed., John Wiley & Sons Inc.

5. Pisano, D.J., Mantus, D. (2005). FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. 2nd Ed., New York: CRC press.

6. Rozovsky, F.A., Adams, R.K. (2003). Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance. 1st Ed., Washington: John Wiley and Sons.

MPH 105P Pharmaceutics Lab-I

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-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.

MPH 106 Title of the Course: Research Seminar-I/Assignment

The student in discussion 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 given by the faculty.

Semester II

MPH 201 Title of the Course: Advanced Pharmacokinetics and Biopharmaceutics

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors. Physiological factors related to drug absorption.

Biopharmaceutic considerations in drug product design and in vitro drug product performance: Introduction, 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.

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 kmax and Vmax.

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.

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. Biopharmaceutics classification systems.In-vitro, in-situ and In-vivo permeability methods. Clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies.

Introduction to Pharmacokinetics and pharmacodynamic (PK-PD)

Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

Books recommended:

1. Gibaldi, M. (1991). Biopharmaceutics and Clinical Pharmacokinetics. 4th Ed. Philadelphia: Lea and Febiger.

2. Treatise, A., Brahmankar, D.M., Jaiswal, S.B. (2015). Biopharmaceutics and Pharmacokinetics. Delhi: VallabhPrakashan.
3. Shargel, L., Yu, A., Pong, S.W. (2012). Applied Biopharmaceutics and Pharmacokinetics.6th Ed. New York: Mcgraw Hill Publication.
4. Rani, S., Hiremath R. (2012). Textbook of Biopharmaceutics and Pharmacokinetics. 2nd Ed. Delhi: Prism Publications.
5. Gibaldi, M., Perrier, D. (1982). Pharmacokinetics.2nd Ed. Revised and expanded. New York: CRC press.
6. Swarbrick, J. (1970). Current Concepts in Pharmaceutical Sciences: Biopharmaceutics. Philadelphia: Lea and Febiger.
7. Rowland, M. Tozer, T.N.(1995). Clinical Pharmacokinetics, Concepts and Application, 3rd edition, Philadelphia: Lippincott Williams and Wilkins.
8. Mack, H.M. (1989). Dissolution, Bioavailability and Bioequivalence, Pennsylvania: Mack Publishing Company.
9. Notari, R.E. (1987). Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded, New York: Marcel Dekker.
10. Wagner, J.G. Pemarowski, M.(1971). Biopharmaceutics and Relevant Pharmacokinetics, 1st edition, Illinois: Drug Intelligence Publications.
11. Swarbrick, J. Boylan, J.G. (1996). Encyclopedia of Pharmaceutical Technology, New York: Marcel Dekker.
12. Jambhekar, S.S. Breen, P.J. (2009). Basic Pharmacokinetics, 1st edition, Pharmaceutical press.
13. Avdeef, A. (2003).Absorption and Drug Development- Solubility, Permeability, and Charge State, New York: John Wiley & Sons Inc.

MPH 202 Title of the Course: Computer-aided Drug Development

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.

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.

Computer-aided Formulation Development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro-emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

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

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

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

Books recommended:

1. Ekins, S. (2006). Computer Applications in Pharmaceutical Research and Development, John Wiley & Sons.
2. Djuris, J. (2013). Computer-Aided Applications in Pharmaceutical Technology, 1st Ed. Cambridge: Woodhead Publishing.
3. Swarbrick, J., Boylan, J.G. (1996). Encyclopedia of Pharmaceutical Technology.vol 13. New York: Marcel Dekker Inc.
4. Bolton, S., Bon, C. (2010). Pharmaceutical Statistics.5th Ed.,vol 203. New York: Informa

MPH 203 Title of the Course: Molecular Pharmaceutics

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting.Tumor targeting and Brain specific delivery.

Targeting Methods: Introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.

Micro Capsules / Micro Spheres:Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Pulmonary Drug Delivery Systems : Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

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.

Books recommended:

1. Chien, Y.W. (1992). Novel Drug Delivery Systems. 2nd Ed. revised and expanded. New York: Marcel Dekker.
2. Vyas, S.P., Khar R.K. (2002). Controlled Drug Delivery - concepts and advances. New Delhi: VallabhPrakashan.
3. Jain, N.K. (2001). Controlled and Novel Drug Delivery.1st Ed. New Delhi: CBS Publishers & Distributors.

MPH204 Title of the Course: Cosmetics and Cosmeceuticals

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.

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.

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants – Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy.Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste.Soaps and syndetbars.

Perfumes: Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

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.

Herbal Cosmetics: Herbal ingredients used in Hair care, skincare 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.

Books recommended:

1. Harry, R.G., Reiger, M.M. (2000). Harry's Cosmeticology.8th Ed. New York: Chemical publishing company.
2. Butler, H. (2000). Poucher's perfume cosmetics and Soaps, 10th Ed. London: Kluwar academic publishers.
3. Sharma, P.P. (2008). Cosmetics - Formulation, Manufacture and quality control. 4th Ed. New Delhi: Vardhan publishing pvt ltd.
4. Barel, A.O., Paye M, Maibach H.I. (2001). Handbook of cosmetic science and Technology.3rd Ed. NewYork: Marcel Decker Inc.
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

MPH 205P Title of the Course: PharmaceuticsLab II

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/ethosomes / nanoparticle
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 WinnolineR 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.

Second Year

MPH 301 Title of the Course: Research Methodology & Biostatistics

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.