Scheme of Instruction and Evaluation for M. Pharmacy (Pharmaceutics)

I – Semester – Revised-2009

Subject Code	Subject / Paper	Theory / Practical	Instruction Hours per week		Evaluation		Duration of External Examination
			Theory	Practical	Internal	External	
M PCT.T. 1.101	Pharmaceutical Analytical Techniques	Theory	4	---	30	70	3
M PCT.T. 1.102	Industrial pharmacy-I (pharmaceutical production technology)	Theory	4	---	30	70	3
M PCT.T.1.103	Pharmaceutical Product Development	Theory	4	---	30	70	3
M PCT.T. 1.104	Quality Assurance	Theory	4	---	30	70	3
M PCT.P. 1.105	Pharmaceutical Analytical Techniques	Practical	-	6	30	70	6
M PCT.P. 1.106	Pharmaceutical Product Development	Practical	--	6	30	70	6
M PCT.T. 1.107	Scientific and Technical Writing (SAIL)	Tutorial	2	-	A/B/C/D	-	-
M PCT .1.108	Seminar	Theory		8	60		
			18	20	240	420	

Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmaceutics)
II– Semester – Revised-2009

Subject Code	Subject / Paper	Theory / Practical	Instruction Hours per week		Evaluation		Duration of External Examination
			Theory	Practical	Internal	External	
M PCT.T. 1.201	IPR & Regulatory Affairs	Theory	4	---	30	70	3
M PCT.T. 1.202	Industrial pharmacy – II (scale up and validation)	Theory	4	---	30	70	3
M PCT.T. 1.203	Biopharmaceutics and Pharmacokinetics	Theory	4	---	30	70	3
M PCT.T. 1.204	Advances in drug delivery system	Theory	4	---	30	70	3
M PCT.P. 1.205	Advances in drug delivery system.	Practical	--	6	30	70	6
M PCT.P. 1.206	Biopharmaceutics and Pharmacokinetics	Practical	--	6	30	70	6
M PCT.T. 1.207	Entrepreneurship Management (SAIL)	Tutorial	2	-	A/B/C/D	-	-
M PC. 1.208	Seminar	Theory		8	50		
			18	20	230	420	

SAIL: Self assess Instrumentation Learning

Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmaceutics)

Semester III and IV

DISSERTATION – Original research work carried out by the candidate under the guidance of regular teaching faculty/visiting faculty of the department should be submitted in a bound form.

Evaluation of the dissertation shall be done by external and internal examiners appointed by the university.

Dissertation viva-voce	Grade A/B/C/D/F
Dissertation report	Grade A/B/C/D/F

A. Excellent B. Very good C. Good D. Fair F. Fail

PHARMACEUTICAL ANALYTICAL TECHNIQUES

M PCT. T.1.101 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

UV-Visible Spectroscopy: Basic principles, interaction of electromagnetic radiation with matter and its effects (electronic transitions). Concept of chromophore and auxochrome, effect of conjugation, solvent and pH. Instrumentation (components and their significance). Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs including multicomponent analysis. Woodward-Fieser rules for caculating absortion maximum for unsaturated hydrocarbons. Difference and derivative spectra.

Infra-Red Spectroscopy: Interaction of infrared radiation with organic molecules and it's effects on bonds. Instrumentation- Dispersive IR spectrophotometers and Fourier transform spectrophotometers. Sample handling for IR spectroscopy. Interpretation of IR spectra. Brief note on ATR. (Attenuated Total Reflectance).

UNIT – II

Nuclear Magnetic Resonance Spectroscopy: Fundamental principles of NMR, instrumentation (components and their significance). Chemical shifts concept, spin- spin coupling, spin-spin decoupling, shielding and deshielding, solvents. signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra.

Brief introduction about Carbon-13 NMR and 2D NMR Spectroscopy.

UNIT – III

Mass Spectrometry: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT – IV

Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation and their basic principles. **Gas chromatography**: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis. **Liquid chromatography**: Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

UNIT – V

Electrophoresis: Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.

Radio immunoassay and ELISA: Principle, instrumentation, applications and limitations.

Recommended books:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of instrumental analysis. 6th ed., Baba Barkha Nath printers, Haryana, 2007.
2. Silverstein, RM, Webstar, FX. Spectrometric identification of organic compounds. 6th ed., John Wiley & Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic spectroscopy, 3rd ed., Palgrave, New York, 2006.
4. Jag Mohan, Organic spectroscopy: Principles and Applications, 2nd ed., Narosa publishing house Pvt Ltd., New Delhi, 2005.
5. Conners KA. A Text book of pharmaceutical analysis, 3rd ed., John Wiley & Sons, Singapore, 2004.
6. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental methods of analysis, 7th ed., CBS Publishers & Distributors, New Delhi, 1986.
7. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to spectroscopy. 4th ed., Brookescole publishers, California, 2008.
8. Sharma BK. Instrumental methods of chemical analysis, 25th Ed., Goel Publishing house, Meerut, 2006.
9. Beckett, AH, Stenlake, JB. Practical pharmaceutical chemistry, Part I & II, 4th ed., CBS Publishers & distributors, New Delhi, 2004.
10. Ewing, GW. Instrumental methods of chemical analysis, 5th ed., McGraw Hill Book Company, New York, 1985.
11. Schirmer, RE. Modem methods of pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.

INDUSTRIAL PHARMACY-I
(PHARMACEUTICAL PRODUCTION TECHNOLOGY)

M PCT.T.1.102 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT -1

Improved Tablet Production: Tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, speronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating Technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

UNIT – 2

Parenteral Production: Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Lyophilization Technology: Principles, process, freeze-drying equipments.

UNIT -3

Capsule Production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Disperse Systems Production: Production processes, applications of mixers, mills, disperse equipments including fine solids dispersion, problems encountered.

UNIT -4

Packaging Technology: Types of packaging materials, machinery, labeling, package printing for different dosage forms.

UNIT -5

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems, dust collectors.

Water Treatment Process: Techniques and maintenance – RO, DM, ultra – filtration, WFI.

Recommended books:

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.

5. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Product design and testing of polymeric materials by N.P. Chezerisionoff.
8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker, NY.
9. Packaging Pharmaceutical and Health Care, H.Lockhard.
10. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
12. Tablet Machine instrumentation in pharmaceuticals, PR Watt, Ellis Horwoods, UK.

PHARMACEUTICAL PRODUCT DEVELOPMENT

M PCT.T.1.103 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – I

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

UNIT – II

Formulation Additives: Study of different formulation additivies, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science, determination methods, drug excipient interactions. Design of experiments – factorial design for product and process development.

UNIT – III

Solubility: Importance, experimental determination, phase-solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotropy.

UNIT – IV

Dissolution: Theories, mechanisms of dissolution, *in-vitro* dissolution testing models – sink and non-sink. Factors influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevent media, *in-vitro* and *in-vivo* correlations, levels of correlations.

UNIT – V

Product Stability: Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

Recommended books:

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.

4. Conners KA. A Text book of pharmaceutical analysi Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981.
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005..
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention, Inc, USA, 2003.

QUALITY ASSURANCE

M PCT.T.1.104 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – 1

Quality Assurance Systems: Basic concept of quality control & quality assurance, functions, sources of variation, quality assurance for raw materials, APIs, packing materials & finished products (specifications, receipt, testing, sampling and certificate of analysis), production (change control, aseptic process control, temperature, pressure & humidity control tests, tests for air flow pattern, microbiological monitoring) buildings & facilities (design and construction features, construction materials, lighting, air handling systems, sanitation & maintenance) equipments (construction, cleaning and maintenance, calibration & handling).

UNIT - 2

In-process quality control: Importance, inspection, IPQC tests for tablets (weight variation, hardness, thickness, friability, disintegration tests and content uniformity), suspensions and emulsions (appearance and feel, volume check, viscosity, particle size distribution, electrical conductivity and content uniformity) and parenterals (pH, volume check, clarity, content uniformity, integrity of seals and particulate matter). Problems encountered and trouble shooting.

UNIT - 3

Thermal Methods of Analysis: Principles, instrumentation and applications of thermogravimetric analysis (TGA), differential thermal analysis (DTA), differential scanning calorimetry (DSC), and thermo mechanical analysis (TMA).

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

UNIT – 4

Good Laboratory Practices: Scope, organization, personnel – desirable qualities of analyst, responsibilities of key personnel in the QC lab. Validation of analysis methods. Facilities, equipments, testing facilities operation – systems and procedures in QC lab, analytical worksheet, test methods, evaluation of test results. Test and control articles – incoming samples, retention samples, reference materials, reagents, specification reportory. Safety guidelines in QC lab.

UNIT – 5

Statistical Quality Control: Scope, sampling – importance, sampling plans, sample size, statistical consideration - probability, frequency distribution. Sampling procedures, handling, labeling & preservation. Analysis of data, Control charts – X charts, R charts, applications.

Recommended books:

1. Quality assurance of Drugs in Pharmaceuticals, P.D.Sethi, Vandana Publ, New Delhi.
2. Pharmaceutical statistics, S.B. Bolton, Vol 80, Marcel Dekker, NY.
3. Good Manufacturing Practices for Pharmaceuticals, SH Wllig, Vol 78, Marcel Dekker, NY.
4. Statistical design and analysis in pharmaceutical sciences, Marcel Dekker, NY.
5. Statistical Methodology in Pharmaceutical Science, D.A. Berry, Marcel Dekker, NY.
6. Latest edition of IP, BP, USP.
7. Medical Statistics at a Glance, A. Petric, Blackwell Sc, UK.
8. Good Laboratory Practice Regulations, S.Weinberg, Vol 69, Marcel Dekker, NY.
9. How to Practice GLP, P.D. Sethi, Vandana Publ, New Delhi.

PHARMACEUTICAL ANALYTICAL TECHNIQUES (PRACTICAL)

M PCT. P.1.105 **Period / Week: 6**
Sessional: 30 **Duration of Exam: 6hrs**
Examination: 70 **Nature of Exam: Practical**

List of Experiments

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments) .
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
8. Separation of protein drug substances by electrophoresis.
9. Any other relevant experiments based on theory.

PHARMACEUTICAL PRODUCT DEVELOPMENT (PRACTICAL)

M PCT. P.1.106	**Period/week: 6**
Sessional: 30	**Duration of Exam: 6 hrs**
Examination: 70	**Nature of Exam: Practical**

1. Effect of surfactants on the solubility of drugs.
2. Effect of pH on the solubility of drugs.
3. Dissolution methods of transdermal drug delivery systems.
4. Dissolution studies of drug in three different biorelevant dissolution media (2 experiments).
5. Effect of solid dispersion and hydrotropy on the dissolution.
6. Test for degradation of compounds using TLC for any two drugs.
7. Stability testing of solution and solid dosage forms for photo degradation.(2 experiments).
8. Effect of hydrogen peroxide, hydrochloric acid and sodium hydroxide solutions on the stability of drugs in solution at elevated temperatures and room temperature. (2 experiments).
9. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40 ^{o}C, 75% RH.
10. Compatibility evaluation of drugs and excipients.
11. Product development and protocol preparation using preformulation data for tablets and capsules.
12. Dissolution of drugs in different pH media for comparison of performance with innovator.

ENTREPRENEURSHIP MANAGEMENT

Subject Code : M PCT .T 1.107	Grade : A/B/C/D.
Periods/week : 2	Examination : --
Nature of Exam: Tutorials	Exam Duration: --

Course Objectives:

- To provide conceptual inputs regarding entrepreneurship management.
- To sensitise and motivate the students towards entrepreneurship management.
- To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.
- To develop management skills for entrepreneurship management.

UNIT – I: CONCEPTUAL FRAME WORK

- Concept need and process in entrepreneurship development.
- Role of enterprise in national and global economy
- Types of enterprise – Merits and Demerits
- Government policies and schemes for enterprise development
- Institutional support in enterprise development and management

UNIT – II: THE ENTREPRENEUR

- Entrepreneurial motivation – dynamics of motivation.
- Entrepreneurial competency – Concepts.
- Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur'' role.

UNIT – III: LAUNCHING AND ORGANISING AN ENTERPRISE

- Environment scanning – Information, sources, schemes of assistance, problems.
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis.
- Resource mobilisation - finance, technology, raw material, site and manpower.
- Costing and marketing management and quality control.
- Feedback, monitoring and evaluation.

UNIT – IV: GROWTH STRATEGIES AND NETWORKING

- Performance appraisal and assessment
- Profitability and control measures, demands and challenges
- Need for diversification
- Future Growth – Techniques of expansion and diversification, vision strategies
- Concept and dynamics
- Methods, Joint venture, co-ordination and feasibility study

UNIT – V: PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE

- Project work – Feasibility report; Planning, resource mobilisation and implementation.

Reference

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.

2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

IPR & REGULATORY AFFAIRS

M PCT.T.1.201 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – 1

Patents and Intellectual Property Rights (IPR): Definition, scope, objectives, sources of patent information, patent processing & application, Patents, copyrights, trademarks, salient features, trade related aspects (TRIPS), international & regional agreements.

UNIT – 2

GATT and WTO: GATT – Historical perspective, objectives, fundamental principles, impact on developing countries. WTO – objectives, scope, functions, structure, status, membership & withdrawal, dispute settlement, impact on globalization, India – tasks & challenges.

UNIT – 3

Regulatory Affairs: Indian context – Requirements and guidelines of GMP, understanding of Drugs and Cosmetic Act 1940 and Rules 1945, with reference to Schedule M, U and Y.

UNIT – 4

Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.

UNIT – 5

Documentation: Types related to pharmaceutical industry, protocols, ammonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended books:

1. Good Manufacturing Practices for Pharmaceuticals, S.H.Willig, Vol 78, Marcel Dekker, NY.
2. Protection of Industrial Property Rights, P. Das and Gokul Das.
3. Law and Drugs, law publ. SN Katju.
4. Original laws published by Govt. of India.
5. Laws of drugs in India, Hussain.
6. New Drug Approval Process, R.A. Guarino, Vol 100, Marcel Dekker, NY.
7. Fda.org, wipo.int, patentlawlinks.com, hc-sc.gc.ca, ich.org, cder.org.

INDUSTRIAL PHARMACY – II
(SCALE UP AND VALIDATION)

M PCT.T.1.202 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT – 1

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentrals and semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquid orals, semisolids, parentrals, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physical layout, input, in-process and finished product specifications, problems encountered during transfer of technology.

UNIT - 2

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification.

UNIT - 3

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membrane filter, rapid mixer granulator, cone blender, FBD, tablet compression machine, liquid filling and sealing machine.

UNIT - 4

Process validation: importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control.

UNIT - 5

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical, Monitoring & prevention systems, industrial effluent testing & treatment. Control of environmental pollution.

Recommended books:

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY.
2. Pharmaceutical Production facilities, design and applications, by GC Cole, Taylor and Francis.
3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker, NY.
4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman, Varghese Publ. Bombay.
5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.

6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
9. Subrahmanyam, CVS, Pharmaceutical production and Management,2007,Vallabh Prakashan,Dehli.

BIOPHARMACEUTICS AND PHARMACOKINETICS

M PCT.T.1.203 **Period / Week: 4**
Sessional: 30 **Duration of Exam: 3 hrs**
Examinations: 70 **Nature of Exam: Theory**

UNIT -1

Bioavailability and Bioquiovalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.

UNIT -2

Drug Absorption: General consideration, absorption / drug transport mechanisms, role factors affecting absorption, absorption of drug non-peroral routes, methods of determining absorption-*in-vitro, in-situ,* and *in-vivo* methods.

Drug Distribution: Factors affecting, protein & tissue binding, kinetics, determination of rate constants & different plots (direct, Scatchard, & reciprocal).

UNIT -3

Pharmacokinetcs: Parameters & determination, pharmacokinetic models – one compartment, multi compartment in IV bolus, IV infusion & extra vascular, drug & metabolites levels in blood, urine and other
biological fluids. Integration of kinetics.
Application of pharmacokinetics in new drug development, design of dosage forms and novel drug delivery systems.

UNIT - 4

Drug Disposition and Excretion: Biotransformation, factors affecting biotrasformation, Phase I & Phase-II reactions.

Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

UNIT – 5

Pharmacokinetics of Multiple Dosing: Various terminology, determination, adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.

Non-linear kinetics: Cause of non-linearity, estimation of various parameters, bioavailability of drugs that follow non-linear kinetics. Chronopharmacokinetics & pharmacokinetics of elderly and infants.

Recommended books:

1. Biopharmaceutics and Clinical Pharmacokinetics, Mile Gibaldi, Lea and Febriger, Philadelphia.
2. Current concepts in Pharmaceutical Sciences, Swarbrick, Lea and Febriger, Philadelphia.
3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
4. Clinical Pharmacokinetics, Rowland and Tozer, Lea and Febriger, Philadelphia.
5. Biopharmaceutics and Clinical Pharmacokinetics, Niazi, Prentice Hall, London.
6. Remingtons Pharmaceutical Sciences, Mack & Co.
7. Biopharmaceutics & Clinical Pharmacokinetics, DM Brahmankar, Vallabh, Delhi.
8. C.V.S.Subrahmanyam, Textbook of Biopharmaceutics and Pharmacokinetics, 2009, Vallabh Prakashan, Delhi.

ADVANCES IN DRUG DELIVERY SYSTEMS

M PCT.T.1.204 | **Period / Week: 4**
Sessional: 30 | **Duration of Exam: 3 hrs**
Examinations: 70 | **Nature of Exam: Theory**

UNIT – 1

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymers-introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

UNIT -2

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary).

UNIT -3

Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

Advances in Drug Delivery: Pulsatile, colon specific, liquid sustained release systems.

UNIT – 4

Targeted Drug Delivery Systems: Importance, concept, biological process and events involved in drug targeting, design, formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealed erythorocytes, microspheres, magnetic microspheres. Specialized pharmaceutical emulsions – multiple emulsions, micro-emulsions.

UNIT - 5

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stability and destabilization.

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

Recommended books:

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.
5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.

6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.
9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker, NY.
10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

ADVANCES IN DRUG DELIVERY SYSTEMS

M PCT.P.1.205 | **Period / Week: 6**
Sessional: 30 | **Duration of Exam: 6 hrs**
Examinations: 70 | **Nature of Exam: Practicals**

Suggested experiments

1. Preparation and evaluation of different polymeric membranes.
2. Formulation and evaluation of sustained release oral matrix tablet.
3. Formulation and evaluation of sustained release oral reservoir system.
4. Formulation and evaluation of microspheres / microcapsules.
5. Study of in-vitro dissolution of various SR products in market.
6. Formulation and evaluation of transdermal films.
7. Formulation and evaluation of mucoadhesive system.

BIOPHARMACEUTICS AND PHARMACOKINETICS

M PCT.P.1.206 **Period / Week: 6**
Sessional: 30 **Duration of Exam: 6 hrs**
Examinations: 70 **Nature of Exam: Practicals**

Suggested experiments

1. Comparative dissolution studies on different dosage forms for drugs.
2. Effect of pH / particle size on dissolution studies.
3. Plasma protein binding studies on different drugs.
4. Estimation of pharmacokinetic parameters in urine / serum samples.
5. Estimation of creatinine clearance.
6. Estimation of pharmacokinetic parameters for the given urinary excretion data.
7. Estimation of pharmacokinetic parameters for the given oral absorption data.

SCIENTIFIC AND TECHNICAL WRITING

Subject Code : M PCT. T 1.207	Grade: A/B/C/D.
Periods/week : 2	Examination : --
Nature of Exam : Tutorials	Exam Duration: --

Course Objectives: To be able to appreciate and understand importance of writing scientifically.

- To Develop competence in writing and abstracting skills.
- To write either a draft research proposal or a chapter of dissertation.

UNIT – I: COLLECTION AND EVALUATION OF INFORMATION

Identification, sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

UNIT – II: WRITING AS A MEANS OF COMMUNICATION

- Different forms of scientific and technical writing.
- Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.

How to formulate outlines: The reasons for preparing outlines

- as a guide for plan of writing
- as skeleton for the manuscript

Kinds of outline: topic outlines, conceptual outline, sentence outlines and combination of topic and sentence outlines

UNIT – III: DRAFTING TITLES, SUB TITLES, TABLES, ILLUSTRATIONS

- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
- Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
- Appendices: use and guidelines

The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading

Checking: Organization, Headings, Content, Clarity and Grammar

Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

UNIT - IV: PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE

Introduction, Review of Literature, Methodology, Results and Discussion

Ask questions related to: content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

UNIT – V: WRITING FOR GRANTS

- Clearly state the question to be addressed
- Rationale and importance of the question being address
- Emperial and theoretical conceptualization
- Presenting pilot study/data
- Research proposal of method
- Clarity, specificity of method.
- Clear organization
- Outcome of study and its implications
- Budgeting
- Available infra-structure and recourses
- Executive summary

References

1. APA (1984): Publication Manual of Americal Psychological Association (3rd Edition), Washington: APA.
2. Cooper, H.M. (1990): Integrating Research: A Guide for Literature Reviews (2nd Edition). California: Sage.
3. Dunn, F.V & Others.(Ed.) (1984): Disserninating Research: Changing Practice. NY:Sage.