Maharshi Dayanand University, Rohtak

Department of Pharmaceutical Sciences

M. PHARM. INDUSTRIAL PHARMACY

PROGRAM SPECIFIC OUTCOMES

PSO1 Possess the skills to use modern pharmaceutical tools, software, equipments to analyze & solve problems.

PSO2 Demonstrate an adaptable, flexible and effective approach towards organizational development.

PSO3 Acquire adequate scientific information regarding basic principles of pharmaceutics including cosmetology and specialized drug delivery systems.

PSO4 Trained on the practical aspects of formulation development, analysis and quality assurance of various pharmaceutical dosage forms.

PSO5 Develop the ability to conduct, analyze and interpret data as per the needs of pharmaceutical industries

SCHEME OF EXAMINATION

Table- Scheme for internal assessments and end semester examinations

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER I								
MPA101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3 Hrs	100
MIP101T	Pharmaceutical Formulation Development	10	15	1 Hr	25	75	3 Hrs	100
MIP102T	Customized drug Delivery System	10	15	1 Hr	25	75	3 Hrs	100
MIP103T	Drug Regulations and Intellectual Property Rights	10	15	1 Hr	25	75	3 Hrs	100
MIP104P	Industrial Pharmacy Practical I	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**
SEMESTER II								
MIP201T	Advanced Biopharmaceutics and Pharmacokinetics	10	15	1 Hr	25	75	3 Hrs	100
MIP202T	Scale up and Technology Transfer	10	15	1 Hr	25	75	3 Hrs	100
MIP203T	Pharmaceutical Production Technology	10	15	1 Hr	25	75	3 Hrs	100
MIP204T	Entrepreneurship Management	10	15	1 Hr	25	75	3 Hrs	100
MIP205P	Industrial Pharmacy Practical II	20	30	6 Hrs	50	100	6 Hrs	150
-	Seminar /Assignment	-	-	-	-	-	-	100
							Total	**650**

Table- Schemes for internal assessments and end semester examinations

(Semester III& IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total
		Continuous	Sessional Exams		Total	Marks	Duration	Marks
		Mode	Marks	Duration				
SEMESTER III								
MRM101T	Research Methodology and Biostatistics	10	15	1 Hr	25	75	3 Hrs	100
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	50	-	-	50
-	Research work	-	-	-	-	350	1 Hr	350
							Total	**525**
SEMESTER IV								
-	Journal club	-	-	-	25	-	-	25
-	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Research work and Colloquium	-	-	-	-	400	1 Hr	400
							Total	**500**

SYLLABUS

SEMESTER-1

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA101T)

Course outcomes

After completion of course student is able to know,

CO1 The analysis of various drugs in single and combination dosage forms

CO2 Theoretical and practical skills of the instruments

CO3 Application of the Analytical techniques in the Pharmaceutical industries

THEORY **60 HOURS**

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

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

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.

12 Hrs

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

12 Hrs

3 Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

12 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

a) Paper chromatography b) Thin Layer chromatography c) Ion exchange chromatography d) Column chromatography e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography

12 Hrs

5 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 methods, Bragg‘s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

12 Hrs

REFERENCES

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

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

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

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

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

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

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

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP101T)

Course outcomes

At completion of this course it is expected that students will be able to understand-

CO1 The scheduled activities in a Pharmaceutical firm.

CO2 The pre formulation studies of pilot batches of pharmaceutical industry.

CO3 The significance of dissolution and product stability

THEORY **60Hrs**

12 Hrs

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

12 Hrs

2. 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.

12 Hrs

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

12 Hrs

4. **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.

12 Hrs

5. 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.

REFERENCES:

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

2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 th 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.

CUSTOMIZED DRUG DELIVERY SYSTEMS (MIP102T)

Course outcomes

At completion of this course it is expected that students will be able to understand-

CO1 The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.

CO2 To formulate and evaluate various customized/novel drug delivery systems

CO3 Application of the various drug delivery system.

THEORY **60Hrs**

12 Hrs

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.

12 Hrs

2. Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oral DDS, Mucoadhesive DDS (buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems.

12 Hrs

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

Sub Micron Cosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, oral cavity, eye etc and it's regulatory aspects.

12 Hrs

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.

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 are as recombinant DNA technology, monoclonal antibodies, gene therapy.

12 Hrs

5. 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.

REFERENCES:

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.

DRUG REGULATIONS AND INTELECTUAL PROPERTY RIGHTS (MIP103T)

Course outcomes

At completion of this course it is expected that students will be able to understand-

CO1 Assist in Regulatory Audit process.

CO2 Establish regulatory guidelines for drug and drug products

CO3 The Regulatory requirements for contract research organization

THEORY **60Hrs**

12 Hrs

1. Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

12 Hrs

2. Role of GATT, TRIPS, and WIPO.

12 Hrs

3. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector,

12 Hrs

4. Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

12 Hrs

5. Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition

2. Applied Production and Operation Management By Evans, Anderson and Williams

3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers

4. ISO 9000-Norms and explanations

5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker

INDUSTRIAL PHARMACY PRACTICAL-I (MIP104P)

Course Outcomes

At completion of this course it is expected that students will be able to

CO1 Determine the various aspects of the formulation

CO2 Understand the development and the application of the different drug delivery system.

CO3 Perform the stability studies on the formulations

Practicals

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. Effect of surfactants on the solubility of drugs.

8. Effect of pH on the solubility of drugs.

9. Dissolution methods of transdermal drug delivery systems.

10. Stability testing of solution and solid dosage forms for photo degradation..

11. Stability studies of drugs in dosage forms at 25 ^{o}C, 60% RH and 40^{o}C, 75% RH.

12. Compatibility evaluation of drugs and excipients.

13. Preparation and evaluation of different polymeric membranes.

14. Formulation and evaluation of sustained release oral matrix tablet.

15. Formulation and evaluation of sustained release oral reservoir system.

16. Formulation and evaluation of microspheres / microcapsules.

17. Formulation and evaluation of transdermal films.

18. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.

SEMESTER-II

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP201T)

Course outcomes

At completion of this course it is expected that students will be able to understand–

CO1 The basic concepts in Biopharmaceutics and pharmacokinetics.

CO2 The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.

CO3 To critically evaluate Biopharmaceutics studies involving drug product equivalency.

CO4 To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

THEORY **60Hrs**

12Hrs

1. Drug Absorption From The Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH– partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes– Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form ,Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, 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, Drug Product Considerations.

12Hrs

3. Pharmacokinetics: Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra-vascular; Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation 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.

12Hrs

4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability, , Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process, The Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12Hrs

5. Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Relationship between Pharmacokinetics and Pharmacodynamics: Generation of a pharmacokinetic– pharmacodynamic (PKPD) equation, Pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs: Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy),Gene therapies.

REFERENCES:

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

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

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

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

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

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

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

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

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

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

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

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

13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc,2003.

SCALE UP AND TECHNOLOGY TRANSFER (MIP202T)

Course outcomes

CO1 Manage the scale up process in pharmaceutical industry.

CO2 Assist in technology transfer.

CO3 To establish safety guidelines, which prevent industrial hazards.

THEORY **60Hrs**

12Hrs

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.

12Hrs

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

12Hrs

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.

12Hrs

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

12Hrs

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

REFERENCES:

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.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP203T)

Course outcomes

At completion of this course it is expected that students will be able to understand–

CO1 Handle the scheduled activities in a Pharmaceutical firm.

CO2 Manage the production of large batches of pharmaceutical formulations.

CO3 Needs and the problem of the pharmaceutical industries

THEORY **60Hrs**

12Hrs

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.

12Hrs

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.

12Hrs

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

12Hrs

4. 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.

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

12Hrs

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.

REFERENCES:

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. 156

ENTREPRENEURSHIP MANAGEMENT (MIP204T)

Course outcomes

At completion of this course it is expected that students will be able to understand-

CO1 The Role of enterprise in national and global economy

CO2 Dynamics of motivation and concepts of entrepreneurship

CO3 Demands and challenges of Growth Strategies And Networking

THEORY **60Hrs**

12Hrs

1. 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

12Hrs

2. 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.

12Hrs

3. 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.

12Hrs

4. 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.

12Hrs

5. Preparing Project Proposal To Start On New Enterprise

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

REFERENCES:

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.

INDUSTRIAL PHARMACY PRACTICAL-II (MIP205P)

Course outcomes

At completion of this course it is expected that students will be able to understand

CO1 Designing and development of formulations

CO2 optimization and standardization of the formulations

CO3 Problem encounters in the development, optimization and storage of the formulation.

Number of Practicals based on above mentioned Theory.