

**PROPOSED SYLLABUS FOR
M. Pharm. (Industrial Pharmacy)**

First Semester

Paper No.	Subject	Teaching Hours/Week	Univ. Exam Hrs.	Marks		
				Sessional	Univ. Exam	Total
M.111T	Methods in Pharmaceutical Research, Theory	4	3	25	75	100
M.112P	Methods in Pharmaceutical Research, Practical	6	6	25	75	100
M.IP 113T	Industrial Pharmacy, Theory	4	3	25	75	100
M.IP 114P	Industrial Pharmacy, Practical	6	6	25	75	100
M.IP 115T	Packaging Technology, Theory	4	4	25	75	100
	Professional Practice	12*	-	-	-	-
	Total	36		125	375	500

* These hours will not be counted as workload of teacher.

Second Semester

Paper No.	Subject	Teaching Hours/Week	Univ. Exam Hrs.	Marks		
				Sessional	Univ. Exam	Total
M.121T	Advances in Pharmaceutical Sciences including Biostatistics, Theory	4	3	25	75	100
M.122P	Advances in Pharmaceutical Sciences including Biostatistics, Practical	6	6	25	75	100
M.IP 123T	Advances in Drug Delivery Systems, Theory	4	3	25	75	100
M.IP 124P	Advances in Drug Delivery Systems, Practical	6	6	25	75	100
M.IP 125T	Advanced Industrial Pharmacy, Theory	4	4	25	75	100
	Professional Practice	12*	-	-	-	-
	Total	36		125	375	500

* These hours will not be counted as workload of teacher.

Third semester

Paper No.	Subject	Teaching Hours/Week	Marks		
			Sessional	Univ. Exam	Total
	Dissertation Synopsis	36	To be submitted		
M.IP 211D	Dissertation (Report, Presentation & Viva-voce)		50	150	200

Final semester

Paper No.	Subject	Teaching Hours/Week	Marks		
			Sessional	Univ. Exam	Total
M.IP 221D	Dissertation (Thesis, Presentation & Viva-voce)	36	50	150	200

COURSE CONTENT

First semester

M.IP 113T	Industrial Pharmacy, Theory	60 Hrs.
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Preformulation studies: Introduction, purity, particle size, shape and crystallinity, solubility, pH solubility profile, dissolution & intrinsic dissolution rate, partition coefficient, melting point, polymorphism, hygroscopicity, volatility, flow properties, stability, drug-excipient compatibility, significance of preformulation studies.

Pilot plant scale up techniques: Significance, pilot study of some important dosage forms such as tablets, capsules and liquid orals, discussion on important parameters such as formula, equipments, product uniformity and stability, raw material process and physical layouts, personnel requirements and reporting responsibilities.

Production planning & control and documentation: Production scheduling, forecasting, vendor development, capacity assessment (plant, machines, human resources), production management, production organization, objectives and policies. Productivity, management and cost controls.

Compaction and compression: Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression including- physics of tablet compression; effect of particle size, moisture content, lubrication etc. on strength of tablets.

Sterilization process: Basic concepts, F, D, Z values, sterilization methods and equipments, sterility testing: principle, advantages and disadvantages, general procedure, control tests, sterility testing of ophthalmic preparations, surgical sutures and ligatures, surgical dressings; ampoules, vials, transfusion bottles and other parenterals; vaccine bottles, syringes and needles. Applications of different sterilization methods in pharmaceutical industry, biological indicators.

Stability testing: Introduction, rate equations, physicochemical and biological factors affecting stability of drugs, degradation pathways, objectives and design of stability testing, accelerated stability studies, real-time stability studies, photostability testing, stability testing of dosage forms, prediction of shelf life, overages, ICH guidelines.

Industrial hazards, safety, pollution control and effluent treatment: Introduction, factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, electrical hazards, chemicals hazards and management of over exposure to chemicals, gas hazards and handling of gases, dust explosion and its control, fire prevention and control.

Optimization techniques in pharmaceutical formulation and processing: Concept of optimization, optimization parameters, classical optimization, statistical design, and optimization methods.

Good manufacturing practices: 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).

Pharmaceutical process validation: Prospective validation, retrospective validation, concurrent validation, significance of validation, validation phases, design qualification, operational qualification, installation qualification, process performance qualification, validation report, statistical methods and tools for process validation, validation of tablet manufacturing process and manufacturing process for sterile products.

Intellectual property rights: Definitions, Indian Patent Act & its amendments, patent databases, patent & its procedures for applying. Current scenario of GATT, TRIPS & TRIMS.

Drug regulatory affairs: Brief and comparative introduction to different regulatory agencies: US FDA, MCA, TGA, MHRA, ANVISA etc., new drug application, active ingredient, drug development, investigational new drug, clinical trials, requirements for similar products, guidance documents for NDAs.

M.IP 114P	Industrial Pharmacy, Practical	90 Hrs.
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1. Preformulation studies of few drug(s).
2. Validation of dissolution test apparatus IP/USP.
3. To study effect of humidity and temperature on stability of drug(s).
4. To perform powdered glass test and whole container test as per USP on given glass containers.
5. Preparation and comparative evaluation with marketed products for antacid efficiency of neutralizing property of suspensions.
6. Formulation and evaluation of stability of reconstituted dry syrup of amoxicillin, ampicillin etc.
7. Accelerated stability studies on various formulations, with reference to:
(a) Temperature dependence.
(b) Effect of buffers.
8. Determination of the order of decomposition for drugs like aspirin, benzocaine, valsartan, or any other drugs.
9. Formulation and evaluation of fast dissolving tablets.
10. To perform accelerated stability studies on an emulsion.
11. To study the effect of hardness of the tablets on disintegration time.
12. Studying the stability of suspensions using the data on sedimentation volume and degree of flocculation.
13. Determination of shelf-life of liquid oral dosage form.

Reference Books for M.IP 113T & M.IP 114P
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1. Connors K.A., Amidon G.L, Stella V.J. *Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists*, 2nd edition. John Wiley & Sons.
2. Carstensen J.T., Rhodes C. *Drug Stability: Principles and Practices*. Marcel Dekker, Inc.
3. Mazzo D.J. *International Stability Testing*. Interpharm Press, Inc.
4. Nash R.A., Berry I. R. *Pharmaceutical Process Validation*. Marcel Dekker, Inc.
5. Willing S.H., Stoker J.R. *Good Manufacturing Practices in Pharmaceuticals- A Plan for Total Quality Control*. Marcel Dekker, Inc.

6. Agalloco J.P., Carleton F.J. *Validation of Pharmaceutical Processes: Sterile Products*. Marcel Dekker, Inc.
7. Wilin S.H. Tuckerman M.M., Hitching S. *Good Manufacturing Practices for Pharmaceuticals-A Plan for Total quality Control*. Marcel Dekker, Inc.
8. Sharma P.P. *How to Practice GMPs*. Vandana Publication.
9. Sharma D.D. *Total Quality Management-Principles, Implementation and Cases*. Sultan Chand & Sons.
10. Kenneth L. A. *The Managers Guide to ISO 9000*. Free Press.
11. Pothdar M.A. *Current Good Manufacturing Practices*. BS Publications.
12. Careleton F.J., Agallow, J.P. *Validation of Aseptic Pharmaceutical Processes*. Marcel Dekker, Inc.
13. Alderban. *Pharmaceutical Powder Compaction Technology*. Marcel Dekker, Inc.
14. Yoshoka S., Stella V.J. *Stability of Drugs and Dosage Forms*. Kluwer Academic/Plenum Publishers.
15. Racz Istvan. *Drug Formulation*. Wiley.
16. Woodard F. *Industrial Waste Treatment Handbook*. Butterworth-Heinemann.
17. Levin M. *Pharmaceutical Process Scale Up*. Marcel Dekker Inc.
18. Lachman L., Lieberman H.A., Kanig J.L. *The Theory and Practice of Industrial Pharmacy*. Lea & Febiger.
19. Gad S.C. *Pharmaceutical Manufacturing Handbook: Production and Processes*. John Wiley & Sons.
20. Brewin P.R. Coube O., Doremus P. *Modelling of Powder Die Compact*. Springer.
21. Fred M. Nordhauser, Wayne P. Olson. *Sterilization of Drugs and Devices: Technologies for the 2000s*. Interpharm Press.
22. International Conference on Harmonization (ICH), "Guidance for Industry, Q1A (R2): Stability Testing of New Drug Substances and Products," November 2003.
23. International Organization for Standardization. Quality Management Systems-Requirements, *ISO 9001:2008*.
24. Jacobsen T.M. *Modern Pharmaceutical Industry: A Primer*. Jones & Bartlett Publishers.
25. Swarbrick J., Boylan J.C. *Encyclopedia of Pharmaceutical Technology*. Vol. 1 to 19, Marcel Dekker, Inc.

M.IP 115T	Packaging Technology, Theory	60 Hrs.
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Introduction : Purpose of packaging, prerequisites of an ideal package, various types of inner and outer packages used for different pharmaceutical dosage forms, selection of a suitable package, storage temperature, hazards encountered by the package during storage and distribution.

Glass containers for pharmaceuticals: Glass types, their manufacture, chemical performance, testing and quality control.

Plastics containers for pharmaceuticals: Classification of plastics, plastic polymers and their physico-chemical, mechanical and biological properties; Additives and fabrication processes. Plastic container for parenterals and transfusion sterile drip kits. Quality control testing and biological toxicity.

Paper and paper board: Types of paper, folding cartons, quality control testing of paper and paper board.

Metal containers: Aluminum and tinplate, drums, collapsible tubes and aerosol containers, lacquering, coating and lining.

Caps and closures: Types; caps, closures, liners, child resistant caps. Elastomeric closures for parenterals, classification of elastomers, physical, chemical and biological properties and their quality control.

Flexible packaging: Types of films, co-extruded films, foils, coating and laminates, shrink and stretch films.

Product-package compatibility: Stability of product, packaging selection and development criteria.

Corrugated and solid fiber boards and boxes: Type of corrugation methods.

Packaging machinery: Introduction, strip packaging machinery, form, fill and seal machines, liquid and solid filling machines, capping machines, machinery employed for liquid formulation packaging.

Sterile product packaging: General principles of packaging of sterile products. Various types of containers used for sterile products including small volume and large volume parenterals. Types of closures used for the sterile products. Sterile product filling and sealing machinery i.e. ampoule filling and sealing machine. Limitations and merits of various packages. Evaluation of the sterile product packages.

Advances in packaging technology: Blister packaging, tamper evident packaging systems, child resistant packaging, aerosol packaging, etc.

Environmental considerations: Packaging and recycling of packaging materials along with national and international regulations.

Labels and labeling: Objectives and contents of a pharmaceutical label. Types of label (including bilingual label, bar code label, radiofrequency (RF) label, structured program label, in-mould label and decorative labels), legal requirements of labeling, packaging inserts and outserts. Adhesives and machinery employed for labeling. Concept of paperless labeling and new developments in labeling technologies.

Reference Books for M.IP 115T

1. Dean D.A., Evans E.R. Hall I.H. *Pharmaceutical Packaging Technology*. Taylor & Francis.
2. Jain U.K., Goupale D.C., Nayak S. *Pharmaceutical Packaging Technology*. PharmaMed Press.
3. Kirwan M.J. *Paper and Paper Board Packaging Technology*. Blackwell Publishing Ltd.
4. Walter Soroka. *Fundamentals of Packaging Technology*. Institute of Packaging Professionals.
5. Lockhart H., Paine F.A. *Packaging of Pharmaceuticals and Healthcare Products*. Blackie Academic & Professional.
6. Paine F.A. *Packaging Materials and Containers*. Institute of Packaging.
7. Hendrickson R. *Remington The Science and Practice of Pharmacy*, Lippincott Williams & Wilkins, 21st edition.
8. Ross C.F. *Packaging of Pharmaceuticals*. Newnes-Butterworths.
9. Herrick A.D. *Drug Products, Labeling, Packaging, Regulation*. General Books, LLC.
10. Yam K.L. *The Wiley Encyclopedia of Packaging Technology*. John Wiley & Sons.
11. Selke S.E.M. *Understanding Plastic Packaging Technology*. Karl Hanser Verlag.
12. Hanlon J.F., Kelsey R.J., Forcinio H.E. *Handbook of Package Engineering*. Technomic Pub. Co.
13. Eiri. *Handbook of Packaging Technology*.

M. Pharm. (Industrial Pharmacy)
Second semester

M.IP 123T	Advances in Drug Delivery Systems, Theory	60 Hrs.
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Polymer science: Introduction, synthesis of polymers, polymer classification, biodegradation of polymers, properties of polymers, pharmaceutical application of polymers.

Sustained release formulations: Introduction, concept, advantages and disadvantages. Physicochemical and biological properties of drugs relevant to sustained release formulations, evaluation of SRDFs.

Concept and system design for rate-controlled drug delivery: Classification of controlled drug delivery systems, rate-programmed release, activation modulated and feedback-regulated drug delivery systems, effect of system parameters on controlled release drug delivery.

Controlled release oral drug delivery systems: Dissolution, Diffusion, Combination of dissolution and diffusion controlled systems, osmotic pressure controlled release systems, floating drug delivery systems, pH dependent systems, ion exchange controlled systems.

Mucoadhesive drug delivery systems: Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, mucosal membrane models, mucoadhesive polymers, permeability enhancers, *in vitro* and *in vivo* methods for buccal absorption. Nasal and pulmonary drug delivery systems and its applications.

Ocular drug delivery systems: Drawback of conventional ophthalmic dosage forms, types, formulation and evaluation of ophthalmic inserts, *in situ* ophthalmic gels.

Transdermal drug delivery systems: Anatomy and physiology of skin, permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers, penetration enhancement techniques, iontophoresis, sonophoresis, transferosomes, ethosomes.

Parenteral controlled release drug delivery systems: Approaches for injectable controlled release formulations and development of implantable drug delivery systems.

Intrauterine drug delivery systems: Anatomy & physiology of vagina, development of intra uterine devices (IUDs), copper IUDs, hormone-releasing IUDs, and vaginal rings.

Targeted drug delivery systems: Principles of targeting, classification, advantages and disadvantages, biological processes and event involved in drug targeting, microspheres, magnetic microspheres, nanoparticles, liposomes, niosomes, dendrimers, resealed erythrocytes, and monoclonal antibodies.

Protein and peptide drug delivery: Introduction, classification and structure of protein, drug delivery systems for proteins and peptides, manifestation of protein instability and stability.

Vaccine delivery: Novel vaccination strategies, microparticles as vaccine adjuvants and delivery systems, liposomes and ISCOMs in vaccine delivery, virosomal technology, vaccines for specific targets, nanotechnology for vaccine delivery.

M.IP 124P	Advances in Drug Delivery Systems, Practical	90 Hrs.
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1. Characterization of polymers.
2. Preparation and evaluation of polymeric microspheres.
3. Preparation and evaluation of microcapsules by different microencapsulation techniques.
4. Preparation and evaluation of matrix tablets using various polymers.
5. Formulation and evaluation of floating tablets.
6. Formulation and evaluation of *in situ* ophthalmic gels.
7. Preparation and characterization of ophthalmic inserts.
8. Study on *in vitro* diffusion of drugs through various polymeric membranes.
9. Preparation and evaluation of buccal mucoadhesives systems.
10. Preparation and evaluation of drug-free polymeric films.
11. Preparation and evaluation of transdermal patches.
12. Preparation and evaluation of floating microspheres.
13. Preparation and characterization of liposomes.
14. Preparation and characterization of niosomes.
15. Study of *in vitro* dissolution of various sustained release formulations of marketed products.
16. Demonstration of skin sensitivity testing of TDDS on a suitable animal model.

Reference Books for M.IP 123T & M.IP 124P

1. Fried J.R. *Polymer Science & Technology*, 2nd edition. Prentice-Hall India Pvt. Ltd.
2. Coleman M.M., Painter P.C. *Fundamentals of Polymer Science: An Introductory Text*. CRC Press.
3. Lliun Lisbeth, Davis Stanley S. *Polymers in Controlled Drug Delivery*. Wright Bristol.
4. Robinson J.R., Lee V.H.L. *Controlled Drug Delivery*. Marcel Dekker, Inc.
5. Juliano R.L., *Drug Delivery Systems: Characteristics and Biomedical Applications*. Oxford University Press.
6. Chien Y.W. *Novel Drug Delivery Systems*. Marcel Dekker, Inc.
7. Vyas S.P., Khar R.K. *Controlled Drug Delivery-Concepts and Advances*. Vallabh Prakashan.
8. Mathiowitz E. *Encyclopedia of Controlled Delivery*. John Wiley & Sons, Inc.
9. Jain N.K. *Controlled and Novel Drug Delivery*. CBS Publishers & Distributors.
10. Carstensen J. T. *Drugs and Pharm.Sci. Series*, vol. 43, Marcel Dekker Inc.
11. Johnson P., Lloyd-Jones, J.G. *Drug Delivery Systems: Fundamentals and Techniques*. VCH.
12. Audus K.L., Juliano R.L. *Targeted Drug Delivery*. Springer-Verlag.
13. Lee V.H.L. *Peptide and Protein Drug Delivery*. Marcel Dekker, Inc.
14. Guy R.H., Hadgraft G. *Transdermal Drug Delivery*. Marcel Dekker, Inc.
15. Edith Mathiowitz, Donald E. Chickering, Claus-Michael Lehr. *Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches and Development*. Marcel Dekker, Inc.
16. Kasliwal N. *Liposomes/Niosomes As a Drug Delivery System*. Lambert Academic Publishing.
17. Dietrich G., Goebel W. *Vaccine Delivery Strategies*. Horizon Scientific Press.
18. Kaufmann S.H.E. *Novel Vaccination Strategies*. Wiley-VCH.

M.IP 125T	Advanced Industrial Pharmacy, Theory	60 Hrs.
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Particle size and surface area: Concept and applications: statistical diameters, specific surface area; modern methods of analysis including Coulter Counter, SEM, TEM, methods based on photon correlation spectroscopy and laser diffraction spectroscopy.

Solubilization: Solubility and its phrases, BCS classification, mechanisms for enhancing solubility such as chemical modification, micellar solubilization, co-solvency, complexation, hydrotropy, and dielectric constant modification.

Dissolution and dissolution testing: Introduction, theories of dissolution, dissolution rate testing apparatus, mathematical models, *in vitro-in vivo* correlation.

Bioavailability and bioequivalence: Introduction, methods of assessing bioavailability, bioequivalence studies, assessment of bioequivalence.

Excipients in pharmaceutical formulations: Introduction to excipients and their importance in pharmaceutical industry; requirement of excipients, classification and properties of excipients, specialized type of excipients used in tablets such as directly compressible excipients and super-disintegrants; surfactants and hydrocolloids in disperse systems, taste masking excipients, colors, flavours, sweetening agents, gel and film forming agents, solubilizers etc. and their quality control, pharmaceutical-excipient interaction.

Pelletization technology: Introduction, pelletization process and formulation, equipments for pelletization spheronizers.

Recent advances in dosage form development: Newer concepts and technology in development of solid, liquid, semi-solid and parenteral dosage forms.

Prodrugs: Introduction, classification, application of prodrugs such as to improve solubility and membrane permeability, prolong drug activity, lower solubility, mask drug toxicity, site specific delivery, increase chemical stability etc.

Cosmeticology: Introduction, history of cosmetics, classification of cosmetics, definition, types, preparation and quality control of creams, lotions, shampoos, lipsticks, face powder, hair preparations, sunscreen preparations, men toiletries and baby care products.

Automated process control systems: Process variables; temperature, pressure, flow, level and vacuum and their measurements. Elements of automatic process control, Introduction to computer aided manufacturing (CAM), robotics.

Software systems: ERP, LIMS Software systems for computerizing various important activities including quality control and assurance activities in pharmaceutical industries; software validation

Reference Books for M.IP 125T

1. Loyd V. Allen, Nicholas G. Popovich, Howard C. Ansel. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. Lippincott Williams & Wilkins
2. Shargel L., Wu-Pong S., Yu A.B.C. *Applied Biopharmaceutics & Pharmacokinetics*. McGraw-Hill.

3. Brahmankar D.M., Jaiswal S.B. *Biopharmaceutics and Pharmacokinetics A Treatise*. Vallabh Prakashan.
4. Lachman L., Lieberman H.A., Kanig J.L. *The Theory and Practice of Industrial Pharmacy*. Lea & Febiger.
5. Qiu Y., Chen Y. Zhang G.G.Z., Liu L., Porter W.R. *Developing Solid Oral Dosage Forms*. Academic Press.
6. Snolinske S.C. *Handbook of Food, Drug and Cosmetic Excipients*. CRC Press.
7. Banker G.S., Rhodes C.T. *Modern Pharmaceutics*. Marcel Dekker, Inc.
8. Rawlins E.A. *Bentley's Textbook of Pharmaceutics*. Bailliere Tindall.
9. Poucher W.A. *Poucher's Perfumes, Cosmetics and Soaps*, Vol.3. Chapman and Hall.
10. Sharma P.P. *Cosmetics- Formulation, Manufacturing, Quality Control*. Vandana Publication.
11. Mithal B.M., Saha R.N. *A Handbook of Cosmetics*. Vallabh Prakashan.
12. Lachman, Libermann, and Avis. *Pharmaceutical Dosage Forms: Parenteral. Vol. I & II*
Marcel Dekker, Inc.
13. Sinko P.J. *Martin's Physical Pharmacy and Pharmaceutical Sciences*. Lippincott Williams & Wilkins.
14. Sloan K.B. *Prodrugs: Topical and Ocular Drug Delivery*. Marcel Dekker, Inc.
15. Hendrickson R. *Remington The Science and Practice of Pharmacy*, Lippincott Williams & Wilkins, 21st edition.
16. Milo Gibaldi and Donald Perrier. *Pharmacokinetics. Drugs and Pharm. Sci. Series*, Vol 15, Marcel Dekker Inc.
17. Tanwar Y.S., Sharma A. *Pharmaceutical Dosage Form Design*. Jaypee Medical Publishers.
18. Tanwar Y.S., Tanwar N. *Computer Application in Pharmaceutical Science and Management*. CBS Publishers & Distributors.
19. Dunlop, John T. *Automation and Technological Change: Report of the Twenty-First American Assembly*. Prentice-Hall.
20. Abdou H.M. *Dissolution, Bioavailability and Bioequivalence*. Mack Publishing Co.
21. Bundgaard H. *Design of Prodrugs*. Elsevier Science Ltd.
22. Ray and Weller. *Handbook of Pharmaceutical Excipients*. Pharmaceutical Press.
23. Aulton M.E. *Pharmaceutics-The Science of Dosage Form Design*. Churchill Livingstone.
24. Isaac Ghebre-Sellassie. *Pharmaceutical Pelletization Technology*. Marcel Dekker, Inc.
25. The United States Pharmacopeia and The National Formulary, *USP31, NF 26*, Vol. 1-2. The United State Pharmacopoeial Convention, Rockville.