PUNJAB TECHNICAL UNIVERSITY, JALANDHAR

M. Pharm. Industrial Pharmacy

Scheme and Syllabus

First Semester — Contact Hours: 28 hrs / Week

Course Code	Course Title	Load Allocation			Marks Distribution			Credits
		L	T	P	Internal	External	Total	
MPIP 511	Advanced Analytical Techniques	3	1	-	20	80	100	5
MPIP 513	Product Development & Formulation	3	1	-	20	80	100	5
MPIP 515	Drug Regulatory Affairs	3	1	-	20	80	100	5
MPIP 517	Industrial Pharmacy Lab. –I	-	-	16	20	80	100	8
Total		09	03	16	80	320	400	23

Second Semester — Contact Hours: 28 hrs / Week

Course Code	Course Title	Load Allocation			Marks Distribution			Credits
		L	T	P	Internal	External	Total	
MPIP 512	Industrial Pharmaceutical Technology	3	1	-	20	80	100	5
MPIP 514	Advanced Product Development & Formulation	3	1	-	20	80	100	5
MPIP 516	Pharmaceutical Packaging Technology	3	1	-	20	80	100	5
MPIP 518	Industrial Pharmacy Lab. –II	-	-	16	20	80	100	8
Total		09	03	16	80	320	400	23

Third and Fourth Semester

Research Work for one year

The thesis shall be presented by the candidate at the end of record academic year. The thesis shall be evaluated as under:

- Evaluation of written thesis: MM 200
- Presentation viva-voce based on seminar of thesis : MM 100

  Total: 300 marks

M. PHARM. SEMESTER-I

Paper	Sub. Code	Subject	Theory per week	Max marks
01	MPIP 511	Advance Analytical Techniques	4	100

1. **UV-Visible Spectroscopy :**
   Introduction, Energy level, choice of solvent and solvent effects and modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (qualitative and quantitative analysis), Woodward – Fieser rule, Fieser Kuhn and Nelson rules, influence of substituent for calculating absorption maximum, Photometric titrations and its applications.

2. **Spectrofluorimetry :**
   Theory, instrumentation, advantages, relationship of chemical structure to fluorescence spectra, solvent effect, effect of acids and bases on fluorescence spectra, concentration effects, factors affecting fluorescence intensity, comparison of fluorescence and UV-Visible absorption methods and applications in Pharmacy.

3. **Infrared Spectroscopy:**
   Introduction, types of vibrations, characteristics regions of the spectrum, influence of substituent, ring size, hydrogen bonding, vibrational coupling, field effects on frequency, methodology, spectral interpretation with examples, Quantitative IR Applications. FTIR theory & applications.

4. **Nuclear Magnetic Resonance Spectroscopy**
   Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, FT-NMR, 2D -NMR, NMDR, DEPT, APT, NOE, NOESY, COSY, INADEQUATE and applications in Pharmacy, interpretation of spectra, ^{13}C NMR-Introduction, Natural abundance, ^{13}C NMR Spectra and its structural applications.

5. **Mass Spectromery**
   Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), GC-MS, LC-MS, interpretation of spectra and applications in Pharmacy.

6. **Thermal Methods Of Analysis**
   Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA)

7. **X-Ray Diffraction Methods**
   Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications

8. **Chromatographic Techniques**

Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange & ion pair chromatography, column chromatography and affinity chromatography, chiral chromatography, size exclusion – techniques and applications.

i. Gas Chromatography: Theory and principle, column operation, instrumentation, derivatisation methods and applications in Pharmacy.
ii. High Performance Liquid Chromatography: Principle, instrumentation, solvents used elution techniques, RP-HPLC, LC-MS and applications in Pharmacy.
iii. HPTLC and Super Critical Fluid Chromatography (SFC): Theory and Principle, instrumentation, elution techniques and pharmaceutical applications.
iv. Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

Reading Material Recommended

1. Spectrometric identification of Organic Compounds, Robert M Silverstein, 6th Edition, Wiley & Sons Publication.
2. Principles of Instrumental Analysis, Donglass A Skoog, Holler, Nieman, 5th edition, Thomson & Brooks Cole Publication.
3. Instrumental Methods of Analysis, Hobert H. Willard, 7th edition, CBS Publication.
4. Analytical Chemistry, Gary D. Christian, 6th edition, Wiley & Sons Publication.
5. Practical Pharmaceutical Chemistry, Volume I & II, A. H. Beckett, J. B. Stenlake, 4th edition, CBS Publications.
6. Fundamentals of Analytical chemistry, Skoog, west, holler and crouch, 8th edition, Thomson & Brooks Cole Publication.
7. Instrumental Methods of Chemical Analysis, B. K. Sharma, 9th edition, Goel Publication.
8. Organic Spectroscopy, William Kemp, 3rd edition, Palgrave Publication.
9. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, P D Sethi, Dilip Charegaonkar, 2nd edition, CBS Publication.

Paper	Sub. Code	Subject	Theory per week	Max marks
02	MPIP 513	Product Development & Formulation	4	100

1. **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.

2. **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.

3. **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.

4. **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.

5. **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.

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

7. **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.

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

Reading Material Recommended

1. Nash R.A. Berry I. R. *Pharmaceutical Process Validation.* Marcel Dekker, Inc.
2. Agalloco J.P., Carleton F.J. *Validation of Pharmaceutical Processes: Sterile Products.* Marcel Dekker, Inc.
3. Sharma D.D. *Total Quality Management-Principles, Implementation and Cases*. Sultan Chand & Sons.
4. Kenneth L. A. *The Managers Guide to ISO 9000*. Free Press.
5. Careleton F.J., Agallow, J.P. *Validation of Aseptic Pharmaceutical Processes*. Marcel Dekker, Inc.
6. Alderban. *Pharmaceutical Powder Compaction Technology.* Marcel Dekker, Inc.
7. Lachman L., Lieberman H.A., Kanig J.L. *The Theory and Practice of Industrial Pharmacy.* Lea & Febiger.
8. Gad S.C. *Pharmaceutical Manufacturing Handbook: Production and Processes*. John Wiley & Sons.
9. Fred M. Nordhauser, Wayne P. Olson. *Sterilization of Drugs and Devices:*
10. *Stability Testing of New Drug Substances and Products*," November 2003.
11. International Organization for Standardization. Quality Management Systems-Requirements, *ISO 9001:2008*.
12. Jacobsen T.M. *Modern Pharmaceutical Industry: A Primer*. Jones & Bartlett Publishers.

Paper	Sub. Code	Subject	Theory per week	Max marks
03	MPIP 515	Drug Regulatory Affairs	4	100

1. Drug Regulatory Affairs :

Harmonization of regulatory requirements including ICH activity. Regulatory requirements of different regions applicable to pharmaceutical developments, manufacturing, quality control on finished products, extended release products, biopharmaceutical and bioequivalence assessment and good clinical practices and Comparison with regulation in India. Filing of INDA, NDA and ANDA for approval and registration.

2. **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.

3. **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.

4. **Intellectual property :**

Concepts and fundamentals of Intellectual property protection (IPP) and Intellectual property Rights (IPR). Economic importance, important mechanism for protection of Intellectual property. Patents, Industrial and layout designs, Copyrights, Trademarks, Trade secrets, factors affecting IP protection, Penalties for violation or infringement. Trade related aspects of IPR. Concepts behind GATT, WTO, TRIPS, TRIMS and GATS. Salient features of Indian Patent act 1970, 1999, 2003, amendments and rules.

5. 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).

6. Pharmaceutical process validation:

Significance of validation and Advantages, Prospective validation, retrospectives validation, concurrent validation, validation phases, installation qualification operational qualification design qualification, process performance qualification, validation report, statistical methods and tools for process validation, validation of tablet and sterile product including sterilization process.

7. Industrial hazards, safety, pollution control and effluent treatmen

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.

Reading Material Recommended

1. Pharmaceutical product development 2006, edited by N.K. Jain, CBS publishers and distributors. New Delhi, and references there in.
2. Good manufacturing practices for pharmaceuticals: A plan for total quality control from manufacturer to customer, 5th edition, revised and expanded by Sidney H. Willig, Marcel and Dekker. USFDA Guidelines.
3. ICH Guidelines.
4. WHO guidelines for Pharmaceutical Products.
5. GMP; by: P P Sharma.
6. Pharmaceutical Validation; By: Signore.
7. ISO 9000 and Total Quality Management by Sadhan K.Ghosh.
8. Indian Laws for protection of IPRs.

Paper	Sub. Code	Subject	Theory per week	Max marks
04	MPIP 517	Industrial Pharmacy Lab.-I	4	100

Practical pertaining to the topics covered under theory subjects.

SEMESTER-II

Paper	Sub. Code	Subject	Theory per week	Max marks
01	MPIP 512	Industrial Pharmaceutical Technology	4	100

1. **Polymers and their Applications in Development of NDDS:**
   Introduction, basic properties of biodegradable and non biodegradable polymers and their uses.

2. **Oral Controlled & Sustained Release Drug Delivery System:**
   a. Principle involved, basic concept, osmotic pressure controlled, membrane permeation controlled, pH independent, ion exchange, controlled gel diffusion, controlled and hydro dynamically balanced systems, evaluation.
   b. Principle involved, advantages and disadvantages, dose considerations, physical–chemical and biological properties of drugs relevant to sustained release formulation, micro encapsulation. evaluation and stability studies of SRDF.

3. **Mucosal Drug Delivery System:**
   Introduction, anatomy and physiology of oral mucosal, mechanism of transmucosal permeation and mucous membrane models, buccal, nasal, pulmonary, rectal, vaginal, drug delivery systems, delivery of peptides based pharmaceuticals.

4. **Transdermal Drug Delivery System:**
   Fundamentals of transdermal permeation and factors affecting it, permeation enhancers, development of transdermal drug delivery systems, evaluation and recent developments.

5. **Targeted Drug Delivery Systems:**
   Principles of targeting, method of targeting preparation and evaluation of vesicular carrier systems such as liposomes, aquasomes, niosomes, pharmacosomes, dendrimers and particulate carrier systems such as nano-particles, micro spheres, modified micro spheres, solid lipid nano particles (SLN), liquid crystals, resealed erythrocytes, monoclonal antibodies, interaction of colloidal delivery systems with biological environment, surface modification of colloidal drug delivery systems.

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

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

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

READING MATERIAL RECOMMENDED

1. Drug Delivery Devices, fundamental and applications; By: P. Tyle;.
2. Controlled release of drugs; By:Morton Rosoff;.
3. Dermatological formulation; By: Barry.
4. Novel Drug Delivery systems; By: Robinson.
5. Controlled and novel drug delivery; By: N.K. Jain.
6. Physiological Pharmaceutics; By: C.G. Wilson & N. Washington.
7. Controlled release delivery systems; By: T.J. Roseman and S.Z.
8. Pharmaceutical Inhalation Aerosol Technology; By: A.J. Hickey.

Paper	Sub. Code	Subject	Theory per week	Max marks
02	MPIP 514	Advanced Product Development & Formulation	4	100

1. **Tablet:**
   Type of tablets, formulation of tablets, granulation techniques, recent advances in granulation technology, equipments and processes involved in granulation, tabletting machinery employed for production of single-layer, multi layer, compression coated, inlay tablets and lozenges and tablet tooling. Physics of tablet making: Strain gauze, measurement of applied and transmitted pressure, distribution of forces during compression, effect of applied pressure on relative volume and forces affecting strength of tablets, Coating of tablet: Coating processes, advances in coating technology and evaluation of coatings Quality control of tablets, In-process quality control of tablets.

2. **Capsules & microencapsulation :**
   Hard gelatin capsules : Development of hard gelatin capsules as a dosage form . Manufacturing process and material used in the shell and the steps used in its manufacturing such as sorting, printing, size and shapes, sealing and self locking closures. Different materials used for automatic filling based on auger, vibratory and piston tamp fill (Dosing Disk and Dosator Machines) principles. General considerations in the design of hard gelatin capsule for formulations ,storage, packaging and stability consideration.
   Soft gelatin capsules: General considerations of the development of soft gelatin capsules as a dosage form composition of shell, formulation strategies and carriers of the drug used and their manufacturing devices.

3. **Micro-encapsulation:** Microencapsules and microspheres as drug delivery systems. Different techniques and methods employed for micro-encapsulation.

4. **Disperse systems:**
   General consideration and recent advances in disperse system technology with main emphasis on pharmaceutical suspensions and emulsions, formulation, stabilization and large scale production of pharmaceutical suspensions and emulsions. Quality control of disperse systems.

5. **Aerosols:**
   General considerations, recent developments, study of various components of aerosol system, formulation, aerosol filling processes and machinery, evaluation of aerosol. Quality control of aerosols.

6. **Semisolid dosage forms:**
   General considerations, recent developments, formulation and large scale production of various types of semi solid dosage forms, factors affecting release of drugs from semisolid dosage forms. Quality control of semisolid dosage forms.

7. **Parenterals:**
   General considerations, recent developments, formulation, stabilization and manufacturing of small and large volume parenterals, production of injectable grac

controls and design consideration for parenterals production facility, freeze drying. Quality control of parenterals. In-house quality control.

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

READING MATERIAL RECOMMENDED

1. Pharmaceutical Dosage Forms: Parenteral Medications Volumes 1, 2 and 3. Kenneth E. Vavis, Loan Lachman and Herbert A.
2. Pharmaceutical Dosage Forms: Dispersed System Vol. 1 & 2; By: Lachman.
3. Pharmaceutical Dosage Forms: Tablets Volumes 1, 2 and 3: By: Lachman.
4. Sterile Dosage Forms; By: Salvatore Turbo and Rebest E. King Lea and Febiger.
5. Pharmaceutics – The Sciences of Dosage Form Design; By: Michael E. Aulton.
6. Dermatological Formulation – Percutaneous Absorption; By: Srian W. Berry.

Paper	Sub. Code	Subject	Theory per week	Max marks
03	MPIP 516	Pharmaceutical Packaging Technology	4	100

1. **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.

2. **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.

3. **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.

4. **PACKAGING**
   a. **Flexible packaging:**
      Types of films, co-extruded films, foils, coating and laminates, shrink and stretch films.
   b. **Product-package compatibility**:
      Stability of product, packaging selection and development criteria.
   c. **Corrugated and solid fiber boards and boxes:** Type of corrugation methods.
   d. **Packaging machinery:**
      Introduction, strip packaging machinery, form, fill and seal machines, liquid and solid filling machines, capping machines, machinery employed for liquid formulation packaging.

5. **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.

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

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

8. **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.

READING MATERIAL RECOMMENDED

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. Hendrickson R. Remington The Science and Practice of Pharmacy, Lippincott Williams & Wilkins, 21st edition.
7. Herrick A.D. Drug Products, Labeling, Packaging, Regulation. General Books, LLC.
8. Yam K.L. The Wiley Encyclopedia of Packaging Technology. John Wiley & Sons.
9. Selke S.E.M. Understanding Plastic Packaging Technology. Karl Hanser Verlag.
10. Hanlon J.F., Kelsey R.J., Forcinio H.E. Handbook of Package Engineering. Technomic Pub. Co.

Paper	Sub. Code	Subject	Theory per week	Max marks
04	MPIP 518	Industrial Pharmacy Lab.-II	4	100

Practical pertaining to the topics covered under theory subjects