SYLLABUS FOR M.PHARMACY

Branch: INDUSTRIAL PHARMACY
INDUSTRIAL PHARMACY

I SEMESTER

Paper IP 101 - ADVANCED INSTRUMENTAL METHODS OF ANALYSIS
Paper IP 102 - ADVANCED PHARMACEUTICAL TECHNOLOGY
Paper IP 103 - DRUG REGULATORY AFFAIRS
Paper IP 104 - ADVANCED INSTRUMENTAL METHODS OF ANALYSIS (Laboratory)
   PRACTICAL EXPERIMENTS BASED ON THEORY.
Paper IP 105 - ADVANCED PHARMACEUTICAL TECHNOLOGY (Laboratory)
   PRACTICALS BASED UPON THEORY.
Paper IP 106 - SEMINAR
Paper IP 107 - ASSIGNMENTS

II SEMESTER

Paper IP 201 - ADVANCES IN DRUG DELIVERY SYSTEMS
Paper IP 202 - PHARMACEUTICAL BIOTECHNOLOGY
Paper IP 203 - ADVANCED INDUSTRIAL PHARMACY
Paper IP 204 - ADVANCES IN DRUG DELIVERY SYSTEMS (Laboratory)
   PRACTICALS EXPERIMENTS BASED ON THEORY
Paper IP 205 - PHARMACEUTICAL BIOTECHNOLOGY (Laboratory)
   PRACTICALS EXPERIMENTS BASED UPON THEORY
Paper IP 206 - SEMINAR
Paper IP 207 - ASSIGNMENTS

III SEMESTER & IV SEMESTER

Paper IP 301 - Seminar-I (On the proposed project work with aims and objectives)
Paper IP 401 - Seminar-II (On the experimentation and results obtained in the project work)
Paper IP 402 - Thesis evaluation
M.PHARM SYLLABUS FOR INDUSTRIAL PHARMACY
I SEMESTER

Paper IP 101 : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS (THEORY)

1. UV-VISUAL SPECTROSCOPY: Brief review of electromagnetic spectrum, UV-Visual range, energy-wavelength-color relationship. Interaction of electromagnetic radiation (UV-Vis) and matter and its effects. Chromophores and their interaction with Electromagnetic Radiation. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative analysis of drugs. Shifts and their Interpretation (including solvent effects).


3. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY:
   Fundamental principles of NMR (Magnetic Properties of nuclei, applied field and precession; absorption and transition frequency). Chemical shifts concept; Isotopic nuclei, Reference standards; Proton Magnetic spectra, their characteristics, presentational terms used in describing spectra and their interpretation (Signal no. Position, intensity). Brief outline of instrumental arrangements and some practical details. Signal multiplicity phenomena in high resolution PMR Spin spin coupling. Application of Signal SPrin and coupling constant data to interpretation of spectra.

Brief outline of principles of FT-NMR with reference to 13 CNMR;
Spin-spin and spin-lattice relaxation phenomena. Free induction decay (FID) proton noise decoupling signal averaging time domain and frequency domain signals nuclear overhauser enhancement; CNMR spectra, their presentation, characteristics, interpretation examples and application in drug analysis.

4. MASS SPECTROMETRY:
   Basic principles and brief outline of instrumentation. Ion formation and types, molecular ion, meta stable ions, fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristics peaks. Mass spectrum, its characteristics, presentation and interpretation. Chemical ionization mass spectrometry, GC-MS.
   Other recent advances in MS, FAST ATOM BOMBARDMENT MASS spectroscopy. Application of mass spectrometry in the analysis of drug.

5. GAS CHROMATOGRAPHY:
   Instrumentation packed and open tubular column, column efficiency parameters, the Van Deemeter equation, Resolution, liquid stationary phases, Derivatisation methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors; FID, ECD, TCD, NPD. A critical comparison of sensitivity, selectivity and field of application of these detectors. Examples of GC applications in Pharmaceutical Analysis.

6. LIQUID CHROMATOGRAPHY:
   Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and micropore columns, normal and reversed-phase packing materials, Reversephases HPLC, column selection, mobile phase selection, efficiency parameters, resolution, detectors in HPLC; refractive index, Photometric and electrochemical. Comparison of sensitivity, selectivity and field of applications of these detectors. HPTLC-instrumentation and applications.

7. X-RAY DIFFRACTION AND DSC, DTA METHODS:

8. RADIO IMMUNO ASSAY METHODS:
Recommended Books:
1. Instrumental Methods of Analysis - Willard, Merrit, Dean et. Al
2. A Text Book of Pharmaceutical Analysis (Vol. 1 & 2) - Roger E. Schirmer
3. Methods of Drug Analysis - Gaerian & Grabowski
5. Practical Pharmaceutical Chemistry (Vol. 1 & 2) - Beckette & Stenlake
6. Pharmaceutical Analysis - P. Parimoo
7. Spectroscopy - Silverstein
8. Organic Spectroscopy - William Kemp

Paper IP 102: ADVANCED PHARMACEUTICAL TECHNOLOGY (THEORY)

1. Preformulation Studies :
   A) Goals of preformulation, Preformulation parameters, Methodology; Solid state properties, Solubility and Partition coefficient, Solubility, Modern concepts in rheology, Drug excipient compatibility.
   B) Dissolution : Theory, Mathematical models, types of dissolution equipments, sink condition and its importance. Automation in dissolution. “In-vitro / In-vivo” correlations, Recent advances in dissolution testing.

2. Excipients used in Pharmaceutical Dosage forms :
   A) Polymers
   B) Properties and selection criteria for various excipients like surfactant, viscosity promoters, diluents, coating materials, plasticizers, preservatives, flavors and colours.

3. Formulation Development :
   A) Solid dosage forms :
      Improved Production techniques for tablets : New materials, process, equipments improvements, high shear mixers, compression machines, coating machines, Coating techniques in tablet technology for product development, Physics of tablet compression computerization for in process quality control of tablets, types of tablets and their manufacture formulations production and evaluation of hard and soft gelatin capsules.
      Powder Dosage Forms :
      Formulation development and manufacture of power dosage form for internal and external use including inhalations dosage forms.
      B) Compaction and compression :
      Compaction of powders with special reference to distribution and measurement of forces in the powder mass undergoing compression. Effect of particle size, moisture content and lubrication on the strength of tablets.
      C) Liquid and Semi-solid dosage forms :
      Recent advances in formulation aspects and manufacturing of monophasic dosage forms, Recent advances in formulation aspects and manufacturing of suspensions, dry syrup and semi-solid dosage forms.
      D) Parenteral dosage forms :
      Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.
      Aseptic processing operation :
Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

5. Pilot plant and scale-up techniques for the production of different pharmaceutical dosage forms.


Recommended Books:
11. GMP by Sidney H, Willing.
15. P.P.Sharma, How to practice GMP’s Vandhana Publications, Agra.
Paper IP 103 : DRUG REGULATORY AFFAIRS (THEORY)

1. **Formulation Development**: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United states and Indian regulatory authorities.

2. **Manufacturing**: Regulatory requirements as per European community, united states and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories, Regulatory, guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastomer test, microbiological test and evaluation of closures.

3. **Stability Testing**: Scientific and technical background to the design of stability testing regulatory requirements as per European community, united states and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of self-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines Analytical method validation, pharmacokinetic and toxicokinetic validation.

4. **Biopharmaceutics**: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

5. **Preclinical Aspects of Biopharmaceutics**: Current guidelines and developments as per regulatory requirements of European community, united states and Indian regulatory authorities in respect of clinical bioavailability, study, design, presentation, documentation and statistical analysis.

6. **Clinical Pharmacology and Pharmacodynamics**: Regulatory guidelines as per European community, united states and Indian regulatory authorities on Clinical study design, documentation, presentation and interpretation.

   **Clinical Trials**: Definition, Phase-I, Phase-II, Phase-III and Phase-IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

7. **Intellectual Property Rights**: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United states and Indian regulatory authorities, documentation, presentation and application.

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**Paper IP 104 : ADVANCED INSTRUMENTAL METHODS OF ANALYSIS-(PRACTICALS)**

Practicals based on Theory will be conducted.

**Paper IP 105 : ADVANCED PHARMACEUTICAL TECHNOLOGY-(PRACTICALS)**

Practicals based on Theory will be conducted.

**Paper IP 106 : SEMINAR**

**Paper IP 107 : ASSIGNMENTS**
II SEMESTER

Paper IP 201: ADVANCES IN DRUG DELIVERY SYSTEMS

I. Fundamentals of controlled drug delivery system, Theory of mass transfer, use of polymers in controlled drug delivery, pharmacokinetic and Pharmacodynamic basis of controlled drug delivery, Design, fabrication, evaluation and applications of the following controlled release systems.
1. Controlled release oral drug delivery systems.
2. Parenteral controlled release drug delivery systems
3. Implantable therapeutic systems.
4. Transdermal therapeutic systems and iontophoresis.
5. Ocular and intrauterine delivery systems.
7. Proteins and peptide drug delivery.

II. Biochemical and molecular biology approaches to controlled drug delivery

III. Drug targeting to particular organs:
1. Drug delivery to respiratory system.
2. Problems of drugs delivery to the brain and targeting to brain.
3. Drug delivery to eye.
4. Drug targeting in neoplastic diseases.

IV. Drug carrier systems targeted to widely dispersed cells.
1. Delivery to Macrophages.
2. Delivery to lymphoid cells of Immune network.
3. Delivery to lysosomal storage diseases.

TEXT BOOKS:

REFERENCE BOOKS & JOURNALS:

JOURNALS:
1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) {desirable}
4. Drug Development and Industrial Pharmacy (Marcel & Decker) {desirable}
Paper IP 202: PHARMACEUTICAL BIOTECHNOLOGY

1. Enzyme Technology: Sources of enzymes; production; isolation and purification of enzymes, applications of enzymes in pharmaceutical industry, in therapeutics and in clinical analysis. Production of amylglucosidase, glucose isomerase, amylase, cellulase, takadiastase, trypsin, streptokinase and urokinase.

2. Immobilized enzyme engineering: Different techniques of immobilization of enzymes, kinetics of immobilized enzyme, design and operation of immobilized enzyme reactors, multi step immobilized enzyme systems, applications and future of enzyme engineering.


4. Biosynthesis of microbial metabolites: General consideration of metabolic pathways, biosynthesis of alcohol, citric acid, antibiotics (Penicillin, Streptomycin, Tetracycline & Erythromycin), ergot alkaloids, riboflavin, vitamin B12 and Glutamic acid.


8. Bio-Informatics: Information theory and biology, redundancy networking, network access, Internet & E-mail services, use of data base in biology, sequence data base for comparisons.

9. Immunobiotechnolology: Hybridoma, techniques, fusion method for myeloma cells and by-lymphocytes, selection and screening techniques, production and purification of monoclonal antibodies and their application in clinical diagnosis, immunotherapy, recombinant and submit vaccines.

TEXT BOOKS:
01. Selected topics in enzyme Engineering by Wingard Jr., L.B.edited for items 1 and 2.
02. Immobilized enzymes by Messing for item 2
03. Chapter 1, 2, 7 in Advances in Applied Microbiology Vol. 15, 1972 on enzymes. Immobilized enzymes and Animal and plant cell culture.
05. Molecular Biotechnology by Glick
06. Therapeutic Peptides and Proteins; Formulation, processing and delivery systems; Ajay K Banga
07. Industrial Biotechnology: vedpal S Malik and Padma Sridhar
Paper IP 203: ADVANCED INDUSTRIAL PHARMACY (THEORY)

01. 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.

02. Production, Planning, Control and Documentation: Production scheduling, forecasting, vendor development capacity assessment (Plant, machines, human resources), production management, production organisation, objectives and policies. Productivity, good manufacturing practices, guide to pharmaceutical manufacturing practices, guide to pharmaceutical manufacturing facilities, tablets and liquid orals, materials management and cost controls.

03. Inventory management, Material Management and Maintenance Management: Cost in inventory, inventory categories special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock-stock out, lead time-reorder time methods, modern inventory management systems, inventory evaluation. Materials-quality and quantity, value analysis, purchasing-centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management, salvaging and disposal of scrap and surplus. Selection of material handling systems, maintenance of material handling equipment, unitload, palletization and containerization, types of material handling systems. Classification of maintenance, corrective (breakdown) maintenance, scheduled maintenance, preventive maintenance, predictive maintenance.

04. Human Resource Development: Personal training, job specification, job enlargement and enrichment, blue and white-collar jobs. Labor welfare

Industrial hazards, pollution and effluent treatment: Introduction, Factory act and rules, fundamentals of accident prevention, organizing for safety, electrical hazards, industrial chemicals and their health hazards, material handling, Fire prevention and control, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants. Effluent treatment procedure, treatment of some characteristic effluent.

06. ISO 9000 and 1400 Validation: Sraitent features, total quality management and productivity, process products and equipment and instrument validation.


08. Optimisation techniques in Pharmaceutical and Processing:
Optimization parameters, statistical design and other applications, design development and optimization of in-vitro test systems to evaluate and monitor the performance of different types of dosage forms, the relevance and importance of in-vitro/in-vivo associations at every stage of product development and manufacture, the regulatory evaluation and current thinking on this aspect, application of statistical techniques in product development and evaluation including quality control.

09. Industrial Safety: Industry hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals, Monitoring and prevention systems. Industrial efficiency testing.

10. Unit Operations: An advanced study of the following unit operations with special reference to formulation and production of pharmaceuticals milling, mixing, tablet compression, tablet coating, filtration, drying and sterilization.

REFERENCE BOOKS:
01. Evans, Anderson, Sweeney and Williams Applied production and operations management 3rd edition, West publishing company Ltd., St., Paul.
02. Peter F.Drucker, Management (tast, responsibility and practices) Allied publication, Bangalore.
03. H W Tomski A Text of Pharmacy management Kogan Page Ltd. London.
07. ISO 9000 and 14000 Series.

**Paper IP 204: ADVANCES IN DRUG DELIVERY SYSTEMS PRACTICALS**
Practicals based on Theory will be conducted

**Paper IP 205: PHARMACEUTICAL BIOTECHNOLOGY PRACTICALS**
Practicals based on Theory will be conducted.

**Paper IP 206: SEMINAR**

**Paper IP 207: ASSIGNMENTS**