Singhania University

Syllabus For M. Pharm
in
Pharmaceutics
Effective from Session

2008-2009

SEMESTER-I

Consist of four papers (Paper-I, II, III & IV)

Paper - I	**Duration of Exam - 3 Hrs**
Teaching Hours - 4 Hrs/week	Maximum Marks - 100
Paper - II	**Duration of Exam - 3 Hrs**
Teaching Hours - 3 Hrs/week	Maximum Marks - 100
Paper - III	**Duration of Exam - 3 Hrs**
Teaching Hours - 3 Hrs/week	Maximum Marks - 100
Paper – IV (Practical)	**Duration of Exam - 3 Hrs**
Teaching Hours - 6 Hrs/week	Maximum Marks - 100

Paper - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (THEORY & RACTICAL)

1. Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

2. Infrared spectroscopy

Introduction: The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

3. **Ultraviolet spectroscopy** :

Introduction: The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophore $\sigma \rightarrow \sigma^*$, $\eta \rightarrow \sigma^*$, $\pi \rightarrow \pi^*$, $\eta \rightarrow \pi^*$, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

4. **Nuclear Magnetic Resonance spectroscopy** :

A. ^{1}H NMR Spectroscopy: Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

B. ^{13}C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

5. **Mass Spectrometry**:

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

6. Thermal analysis:

Introduction to various thermal methods of analysis, basic principle and theory; differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

7. Pharmacological evaluation of drugs in biological fluids: Bioassay.

8. **Microbiological assays.**

9. **Radioimmunoassays.**

10. Quantitative microscopy of herbal drugs. Lycopodium spore method, stomatal number, stomatal index, palisade ratio, vein-islet number, and vein-termination number.

II. BIOSTATISTICS AND COMPUTER APPLICATION

1. Methods of collection of data, classification of data, graphical representation of data, frequency, polygon, histogram, measure of central tendency, mean mode and median dispersion and standard deviation.

2. Confidence level, Null hypothesis, calculation of statistical significance between two means, analysis of variance.

3. Association of attributes centigency, classification of attributes, coefficient of association, chi square test.

4. Theory of probability, simple probability, law of probability, Permutation and combinations, ratios percentages and proportions and statistical difference between proportions. Analysis of variance two way ANOVA and multiple comparison procedures.

5. Correlation and regression, least square method and its application, significance of coefficient of correlation, non linear regression.

6. Calculation of ED_{50}, LD_{50}, probit analysis.

II COMPUTER APPLICATIONS

BOOK RECOMMENDED

1. R.M.Silverstein, F.X.Webster, Spectrometric Identification of organic compounds, 6th ed. John Wiley & sons, New-York, 1998.

2. Remington, The science and practice of pharmacy, Mack publishing company. Easton Pennsylvania.

3. Organic spectroscopy by Willam Kemp

4. E. Heftmann, A laboratory handbook of chromatography, New - York.

5. H.H.Willard, L.L.Merritt and J.A.Dean, Instrumental methods of analysis, Van Nostrend Reinhold, New York.

6. WWM. Wenland, Thermal analysis, John Willy and sons, New-York.

7. Principle of instrumental analysis,V ed. By Skoog, Holler-Niemen.

8. Modern analytical chemistry by David Harvey. (MC Graw-Hill international edition).

Paper - II

PHARMACEUTICS I PRODUCT DEVELOPMENT

1. Preformulation Studies :

Timings and goals of Preformulation, Pre-formulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, compatibility tests, dissolution of drug substances and dosage.

2. Kinetic principles and stability testing :

Order of reaction, influence of pH, temperature, Acid - base catalysis. Effect of Ionic strength on degradation, Complex reactions, amide hydrolysis, Ring alteration, Oxidation - reduction, Chemical &Physical stability of dosage forms, Influence of packaging components on dosage form stability.

3 . Optimization Techniques in Pharmaceutics, Formulation and Processing

Optimization parameters, statistical design, and other application.

BOOKS RECOMMENDED :

1. Lachman, Leon and H. A. Lieberman, The theory and Practice of Industrial pharmacy, 3rd edition, Varghese Publishing Co.

2. Gilbert S. Banker and C.T Rhodes, Modern Pharmaceutics, Marcel Decker.

3. Bernard T. L. and Robert A. Narth, Pharmaceutical process validation, volumes 23, Marcel Decker.

4. Norman A., Hodges and Stephen P. Denyer, haul book of Microbiological Quality control, Tayler and Francis, London.

5. Horth Tonneson, Photostability of Drugs and Drug Formulations, Taylor and Francis, London.

Paper – III

QUALITY ASSURANCE

1. Documentation

Relevance and importance of documentation, statuary requirements and procedure for documentation, critical examination of documents.

2. Pharmaceutical Process Validation :

Regulatory basis, Validation of sterile products, Solid dosage forms, Process Validation and non-sterile Analytical method Validation.

3. Quality Control : Process of dosage forms :

Process control ; Control of quality Validation, Control of manufacturing Process, Statistical quality control, control charts, sampling plans, Automated & process control, Dosage form control, Testing programme & method, Product identification systems, Adulteration, Misbranding, maintenance of records, Bioavailability, Bioequivalence, manufacturer's reliability, Manufacturer/drug information profile.

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4. Norman A., Hodges and Stephen P. Denyer, haul book of Microbiological Quality control, Tayler and Francis, London.

5. Horth Tonneson, Photostability of Drugs and Drug Formulations, Taylor and Francis, London.

Paper – IV

Pharmaceutics I Practicals

- To illustrate the topics included under theory.
- Practicals based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.

SEMESTER-II

Consist of two papers (Paper-I, II, III &IV)

Paper - I **Duration of Exam - 3 Hrs**

Teaching Hours - 3 Hrs/week Maximum Marks - 100

Paper - II **Duration of Exam - 3 Hrs**

Teaching Hours - 3 Hrs/week Maximum Marks - 100

Paper - III **Duration of Exam - 3 Hrs**

Teaching Hours - 4 Hrs/week Maximum Marks - 100

Paper – IV (Practical) **Duration of Exam - 3 Hrs**

Teaching Hours - 6 Hrs/week Maximum Marks - 100

Paper - I

Pharmaceutics II - Industrial Pharmacy and Packaging Technology

1. General Consideration, Preparation of Master Manufacturing Procedure

Material Handling, Blending, Granulation, Drying, Slugging Compression, Coating liquid Dosage Forms Contract Manufacturing

2 . Production and Planning Management

Space Allocation, environmental factors, Manufacturing, Materials

Management, Sales forecasting, Cost Control.

3. Drug Regulatory Methods

Definitions ; Federal food, Drug and Cosmetic Act ; Kafaurver Harre's Amendments, New Drug Application, Drug efficacy study, Implementation Review, OTC Drug review, Drug Listing. Drug amendments, Patents, Copy right, Trade Marks, Drug recalls,

product liability, Clinical Trials.

BOOKS RECOMMENDED :

1. Lachman Leon & H. A. Liberman, The theory and practice of Industrial Pharmacy, Varghese Publishing Co.

2. Gilber S. Banker and C. T. Rhodes, Modern Pharmaceutics Marcel Dekker Inc.

3. Kenneth Harburn, Quality Control of Packaging materials in the pharmaceutical Industry.

4. Sidney H. Willing, Good Manufacturing Practice for pharmaceuticals, Mercel Decker Inc.

5. Kinam Park, Shalaby. S. W, and Haesun park, Biodegradable Hydrogel for Drug Delivery, Technomic Basel.

6. Armstrong, N. A. and James K. C. , Pharmaceutical Experimental Design and Interpretation, Taylor and Francis, London.

7. Brody, A. L. and Marsh , K.S. , Encyclopedia of Packaging Technology, John wiley and sons, New York.

Paper - II

1 . Good Manufacturing Practices

GMP in manufacturing, Processing, Packaging and holding of Drugs ; Control of Components, Containers and closures, Production and process controls : Packaging & labeling controls ; Inspection for compliance with GMP Potable water standards ; Premises : Design, Construction, maintenance, equipment ; maintenance, warehousing, . ISO 9000 certification.

2 . Polymers and their application

Nomenclature, Polymer classification, Physicochemical properties, Chemistry, blends of polymer and properties of blends, Evaluation of polymers, Medical and surgical applications of polymers, polymerization mechanisms, Polymerization methods, Properties of Polymers & their characterization, Mechanism of Drug release from polymers, Applications of Polymers in controlled release of active agents and in other formulations.

3 . Packaging materials science

Packaging design and specifications, packaging validation trials, material of construction, component product validation, Regulatory requirements, Quality control Testing and Standards, GMP requirements & its deficiencies ; In process control during component manufacture Documentation ; Sterilization of packaging components ; Packaging and filling equipment ; Pharmaceutical Packaging including sterile filling area ; customer complaints.

BOOKS RECOMMENDED :

1. Lachman Leon & H. A. Liberman, The theory and practice of Industrial Pharmacy, Varghese Publishing Co.

2. Gilber S. Banker and C. T. Rhodes, Modern Pharmaceutics Marcel Dekker Inc.

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7. Brody, A. L. and Marsh , K.S. , Encyclopedia of Packaging Technology, John wiley and sons, New York.

Paper – III

Pharmaceutics III - Advances in Drug Delivery Systems :

1. Fundamentals of Controlled release drug delivery systems :

Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

2 . Design & Fabrication of Controlled Drug Delivery Systems :

Novel chemical approaches for sustained drug delivery, Design & fabrication of oral controlled release drug delivery systems. Parenteral products, Implantable systems. Transdermal systems, ocular , Intra - Vaginal, intra - uterine systems.

3 . Biochemical and Molecular Biology approaches Controlled Drug Delivery :

Microparticulate drug Carriers ; Liposomes, Microspheres and cells, selective endocytosis of macromolecular drug carriers, Antibodies for drug delivery, Resealed erythrocytes, Niosomes.

4 . Advances in the monitoring of pharmacotherapeutics and in drug delivery system design.

BOOKS RECOMMENDED :

1. Robinson & Lee, Controlled Drug Delivery Fundamentals & Applications, Volume 29, 2nd edition, Marcel Dekker Inc.

2. James Swarbrick, Novel Drug Delivery Systems.

3. Gilbert S. Banker and C. T. Rhodes, Modern Pharmaceutics 2nd Edition.

4. Robinson J. R. and Vincet H. L Lee, Controlled Drug Delivery, Fundamentals And Applications, Volume 29, 2nd edition, Mercel Dekker Inc.

5. Avis, K. E, Leon Lachman, And H. Lieberman, Pharmaceutical Dosage Forms : Parenteral Medications Volume - 2.

6. Lierberman H. A. and Leon Lachman , Pharmaceutical Dosage Forms : tablets Volume 3, Marcel Dekker.

7. Scher, H. B., Controlled release Delivery Systems of Pesticides, Marcel Dekker.

8. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.

Paper – IV

Pharmaceutics I Practicals

- To illustrate the topics included under theory.
- Practicals based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.

SEMESTER-III

- Pharmaceutics Practical-II Marks : 100
- Synopsis of Research Project
- Seminar & Viva Voce on Research methodology & Research project

SEMESTER-IV

Thesis	-	300 Marks
Viva Voce	-	200 Marks