# SOLAPUR UNIVERSITY, SOLAPUR

## FACULTY OF ENGINEERING & TECHNOLOGY

## Master of Pharmacy

## First Year M. Pharmacy 2015-16

**CBCS Syllabus**

Faculty of Engineering & Technology

**Master of Pharmacy (Pharmaceutics)**

Choice Based Credit System Structure of Teaching & Examination w.e.f. 2015-16

**First Year M. Pharmacy (Semester-I)**

| Code | Course | Hrs./Week | | | Credits | Examination Scheme | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | L | T | P | | ISE | ESE | ICA | Total |
| 1.1.1 | Advanced Pharmaceutical Analysis | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.2 | Advanced Pharmaceutics - I | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.3 | Elective - I | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.4 | Seminar - I | - | 3 | - | 2 | 100 | - | - | 100 |
| | **Total** | **12** | **3** | **-** | **14** | **190** | **210** | **-** | **400** |
| **Practical** | | | | | | | | | |
| 1.1.5 | Advanced Pharmaceutical Analysis | - | - | 6 | 3 | - | 70 | 30 | 100 |
| 1.1.6 | Advance Pharmaceutics - I | - | - | 6 | 3 | - | 70 | 30 | 100 |
| | **Total** | **-** | **-** | **12** | **6** | **-** | **140** | **60** | **200** |
| | **Grand Total** | **12** | **3** | **12** | **20** | **190** | **350** | **60** | **600** |

**First Year M. Pharmacy (Semester-II)**

| Code | Course | Hrs./Week | | | Credits | Examination Scheme | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | L | T | P | | ISE | ESE | ICA | Total |
| 1.2.1 | Advanced Pharmaceutics - II | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.2 | Advanced Pharmaceutics - III | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.3 | Elective - II | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.4 | Seminar - II | - | 3 | - | 2 | 100 | - | - | 100 |
| | **Total** | **12** | **3** | **-** | **14** | **190** | **210** | **-** | **400** |
| **Practical** | | | | | | | | | |
| 1.2.5 | Advanced Pharmaceutics - II | - | - | 6 | 3 | - | 70 | 30 | 100 |
| | **Total** | **-** | **-** | **6** | **3** | **-** | **70** | **30** | **100** |
| | **Grand Total** | **12** | **3** | **6** | **17** | **190** | **280** | **30** | **500** |

**Abbreviations: L**- Lectures, **T**- Tutorials, **P**-Practicals,

**ISE** - In Semester Exam.**, ESE** - End Semester exam, **ICA**- Internal Continuous Assessment

**Note : ISE** -Three Tests/Seminar , **ESE** - University Theory paper shall be of 70 marks of 3 hrs. duration

**Master of Pharmacy (Quality Assurance)**

Choice Based Credit System Structure of Teaching & Examination w.e.f. 2015-16.

**First Year M. Pharmacy (Semester-I)**

| Code | Course | Hrs./Week | | | Credits | Examination Scheme | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | L | T | P | | ISE | ESE | ICA | Total |
| 1.1.1 | Advanced Pharmaceutical Analysis | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.2 | Quality Assurance Techniques - I | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.3 | Elective - I | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.4 | Seminar - I | - | 3 | - | 2 | 100 | - | - | 100 |
| | **Total** | **12** | **3** | **-** | **14** | **190** | **210** | **-** | **400** |
| **Practical** | | | | | | | | | |
| 1.1.5 | Advanced Pharmaceutical Analysis | - | - | 6 | 3 | - | 70 | 30 | 100 |
| 1.1.6 | Quality Assurance Techniques - I | - | - | 6 | 3 | - | 70 | 30 | 100 |
| | **Total** | - | - | 12 | 6 | - | **140** | **60** | **200** |
| | **Grand Total** | **12** | **3** | **12** | **20** | **190** | **350** | **60** | **600** |

**First Year M. Pharmacy (Semester-II)**

| Code | Course | Hrs./Week | | | Credits | Examination Scheme | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | L | T | P | | ISE | ESE | ICA | Total |
| 1.2.1 | Quality Assurance Techniques - II | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.2 | Quality Assurance Techniques - III | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.3 | Elective - II | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.4 | Seminar - II | - | 3 | - | 2 | 100 | - | - | 100 |
| | **Total** | **12** | **3** | **-** | **14** | **190** | **210** | **-** | **400** |
| **Practical** | | | | | | | | | |
| 1.2.5 | Quality Assurance Techniques - II | - | - | 6 | 3 | - | 70 | 30 | 100 |
| | **Total** | **-** | **-** | **6** | **3** | **-** | **70** | **30** | **100** |
| | **Grand Total** | **12** | **3** | **6** | **17** | **190** | **280** | **30** | **500** |

**Abbreviations:** **L**- Lectures, **T**- Tutorials, **P**-Practicals,

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**Note : ISE** -Three Tests/Seminar , **ESE** - University Theory paper shall be of 70 marks of 3 hrs. duration

Faculty of Engineering & Technology

**Master of Pharmacy (Pharmaceutical Chemistry)**

Choice Based Credit System Structure of Teaching & Examination w.e.f. 2015-16.

**First Year M. Pharmacy (Semester-I)**

| Code | Course | Hrs./Week | | | Credits | Examination Scheme | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | L | T | P | | ISE | ESE | ICA | Total |
| 1.1.1 | Advanced Pharmaceutical Analysis | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.2 | Advanced Pharmaceutical Chemistry - I | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.3 | Elective - I | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.1.4 | Seminar - I | - | 3 | - | 2 | 100 | - | - | 100 |
| | **Total** | **12** | **3** | **-** | **14** | **190** | **210** | **-** | **400** |
| **Practical** | | | | | | | | | |
| 1.1.5 | Advanced Pharmaceutical Analysis | - | - | 6 | 3 | - | 70 | 30 | 100 |
| 1.1.6 | Advanced Pharmaceutical Chemistry - I | - | - | 6 | 3 | - | 70 | 30 | 100 |
| | **Total** | **-** | **-** | **12** | **6** | - | **140** | **60** | **200** |
| | **Grand Total** | **12** | **3** | **12** | **20** | **190** | **350** | **60** | **600** |

**First Year M. Pharmacy (Semester-II)**

| Code | Course | Hrs./Week | | | Credits | Examination Scheme | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | L | T | P | | ISE | ESE | ICA | Total |
| 1.2.1 | Advanced Pharmaceutical Chemistry - II | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.2 | Advanced Pharmaceutical Chemistry - III | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.3 | Elective - II | 4 | - | - | 4 | 30 | 70 | - | 100 |
| 1.2.4 | Seminar - II | - | 3 | - | 2 | 100 | - | - | 100 |
| | **Total** | **12** | **3** | **-** | **14** | **190** | **210** | **-** | **400** |
| **Practical** | | | | | | | | | |
| 1.2.5 | Advanced Pharmaceutical Chemistry - II | - | - | 6 | 3 | - | 70 | 30 | 100 |
| | **Total** | **-** | **-** | **6** | **3** | - | **70** | **30** | **100** |
| | **Grand Total** | **12** | **3** | **6** | **17** | **190** | **280** | **30** | **500** |

**Abbreviations: L**- Lectures, **T**- Tutorials, **P**-Practicals,
**ISE** - In Semester Exam.**, ESE** - End Semester exam, **ICA**- Internal Continuous Assessment
**Note : ISE** -Three Tests/Seminar , **ESE** - University Theory paper shall be of 70 marks of 3 hrs. duration

## *M. PHARM (PHARMACEUTICS)*

**1.1.1 ADVANCED PHARMACEUTICAL ANALYSIS** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Spectroscopic Methods:** Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples.<br><br>**Electron Spin Resonance (ESR) Spectroscopy:** Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems. | 10 | 20-25 |
| 2. **Separation Techniques:** Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, lon Pair Chromatography, Affinity chromatography ,Electro kinetic chromatography & Capillary Electrophoresis. | 10 | 20-25 |
| 3. **Thermal Analysis:** Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter. | 04 | 10-15 |
| 4. **Immunochemical Techniques:** lmmunoelectrophoresis, Immuno- precipitation, ELISA, Radioimmuno assays. | 05 | 10-15 |
| 5. **X-Ray diffraction**: Introduction, Principle, instrumentation and pharmaceutical applications. | 05 | 10-15 |
| 6. Basic principles, classification of laser. | 03 | 10-15 |
| 7. **Referenced standards:** Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol. | 05 | 10-15 |
| 8. **Introduction to Quality Assurance Techniques:** Validation of equipments, processes, products, etc. | 03 | 10-15 |

**1.1.5 ADVANCED PHARMACEUTICAL ANALYSIS** **Practical (6 hrs/wk. )**

1. Experiments based on UV-Vis, FT-IR, HPLC, & GC.
2. Interpretation of UV & IR Spectra of some Chemicals & drugs.
3. ELISA Test / LAL Test.
4. Estimation of drugs in biological fluids.
5. Validation of analytical methods.
6. Analysis of OTC Analgesics by High Performance Chromatographic methods.
7. Demonstration of Reverse Phase HPLC by Internal standard method.

**Reference Books:**

1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)
7. Higuchi : Instrumental Methods of Analysis (CBS Publishers)
8. Analytical Chemistry by open learning series
9. Wim Kok : Capillary Electrophoresis : Instrumentation and Operation
10. R. J. Hamilton - Introduction to High Performance Liquid chromatography, (Chapman and Hall, London)
11. Ewing - Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

**1.1.2 ADVANCED PHARMACEUTICS – I** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| **Physical pharmaceutics covering the following aspects** | | |
| **1. Solids :** | 07 | 17 – 24 |
| Particle characterization by size, shape and surface of individual particle and for contacted particle. Handling of solids, pharmaceutical granulation, compression and compaction properties of binary mixtures, lubricant sensitivity, characterization of granules and compacts. | | |
| **2. Dissolution :** | 08 | 20 – 28 |
| Theory of dissolution, concept of drug release. Dissolution test apparatus: different designs, factors affecting dissolution rate. Dissolution of different dosage forms: solids, suspensions, topicals, suppositories and controlled release systems. Enhancement of dissolution rate. | | |
| **3. Surfactant System :** | 10 | 23 – 30 |
| Phase behavior of surfactant in binary and ternary systems. Factors affecting phase behavior; Micellization; micelle structure, shape, size factors affecting CMC and micelle size, thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of Solubilization, Solubilization in non-aqueous system, interactions with polymers and oppositely charged species. Hydrotrophy in pharmaceuticals, surfactants in emulsions and suspensions. Biological implications of surfactants; Effect on: dissolution of drugs, permeability of membranes, drug absorption, antibacterial activity. Cyclodextrin inclusion complexes and co-solvents. | | |
| **4. Polymer science :** | 06 | 10 – 16 |
| Types and applications of polymers, polymerization reactions, methods of polymerization and characterization of polymers, thermodynamics of polymer solutions. | | |

**5. Solid dispersions :** 06 10 – 16

Types, methods of preparation, selection of carrier, characterization and applications.

**6. Stability studies :** 08 20 – 26

Kinetics activation energy calculations, accelerated stability studies, factors responsible for destabilization of pharmaceutical products and techniques to improve, shelf life calculations. Physical testing of solution, suspension, emulsion, aerosol, powder, tablet and sustained release products.

**Reference Books:**


1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
12. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

**1.1.6 ADVANCED PHARMACEUTICS – I** **Practical (6 hrs/wk. )**

1. **Experiments based on following concepts.**
2. **Powder characterization:**
   - Microscopy – Particle size analysis, calculation of shape factors.
   - Compression and compaction – Huckel plot studies, tensile strength.
3. **Solubilization :**
   - Effect of dielectric constant on solubility
   - Complexation
   - Ternary phase diagram.
   - Solid dispersion
4. **Stability of multiple emulsions**
5. **Polymer science :**
   - Rheological and thermal characterization of polymers.
6. **Stability studies :**
   - Degradation kinetic study of a drug in a solution.
   - Accelerated stability studies of a formulation.
7. **Dissolution studies of various dosage forms.**

**Recommended books**


1. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
2. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
3. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
4. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
5. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
6. J. T. Cartensen; Drug Stability; Marcel Dekker.
7. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
8. Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
12. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
13. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.

**1.2.1 ADVANCED PHARMACEUTICS – II** **Theory (3 hrs/wk.)**

| | | Hrs | Marks |
|---|---|---|---|
| 1. | Fundamental concepts of controlled release including Biopharmaceutical consideration of controlled release dosage forms. | 03 | 05 – 10 |
| **2.** | **Modified release oral drug delivery systems:** | 06 | 20 – 26 |
| | Principle, formulation, in-vivo evaluation of drug delivery systems, osmotic pumps, membrane permeation, pH controlled, ion exchange controlled, gel diffusion controlled, hydrodynamically balanced system, modulation of gastrointestinal transit time. | | |
| **3.** | **Mucosal Drug delivery:** | 05 | 10 – 14 |
| | Mechanism of mucoadhesion, bioadhesive polymers, penetration enhancers. Development of buccal, nasal, pulmonary, rectal and vaginal drug delivery system. In vitro, ex-vivo and in-vivo evaluation techniques. | | |
| **4.** | **Ocular drug delivery:** | 05 | 10 – 14 |
| | Ocular delivery mechanism, factors affecting ocular drug absorption and development of ocular drug delivery systems, mucoadhesive polymers, ocular inserts, iontophoresis, delivery of peptides and proteins. | | |
| **5.** | **Transdermal drug delivery:** | 05 | 10 – 14 |
| | Permeation through skin, physicochemical factors in drug permeation, permeation enhancers, iontophoresis drug delivery, approaches and technologies for developing Transdermal drug delivery systems and their evaluation. | | |
| **6.** | **Parenteral drug delivery :** | 06 | 15 – 20 |
| | • Implants and implantable devices: Types, release mechanism, fabrication, biocompatibility and performance evaluation.<br>• Liposomes and niosomes: Methods of preparation, characterization, stability, applications and evaluation techniques.<br>• Loaded erythrocytes: methods of drug entrapment, characterization of loaded erythrocytes, stability, storage and release from the system. | | |

Applications and immunological consideration.

- Microspheres: Biodegradable polymers, drug entrapment technique and targeting. Evaluation of the formulation.

**7. Colon specific drug delivery:** 05 10 – 14

Advantages of colon specific drug delivery, diseases of colon and drug absorption through colon. Factors affecting colonic absorption. absorption enhancers, Approaches to colon specific drug delivery, Coating with pH dependent polymers ,Time release dosage forms, Delivery systems based on the metabolic activity of colonic bacteria, in vitro, ex vivo and in vivo evaluation of colon specific drug delivery devices.

**8. Pulsatile Drug Delivery:** 05 10 – 14

Chronobiology, chronopharmacology and chronotherapeutics, Built in rhythms of human body, Disorders showing chronological variations, Pulsatile delivery using Multiple unit particulate system (MUPS), Port system, Capsular system, Programmed Polymeric devices, TDDS , Floating pulsatile drug delivery system(DDS), Chronotherapy in cancer treatment.

**9. Protein and peptide drug delivery:** 05 10 – 14

Structural complexity of protein and peptide drugs. Routes for peptide delivery, Physiological barriers in bioavailability of such molecules, Formulation considerations, immunogenicity, stability in delivery of insulin, regulatory perspectives for such drugs.

**Reference Books:**

1. A. F. Kydonieus; Controlled Release Technologies, methods, theory and applications, Vol. I and II, CRC Press Inc.
2. A. J. Hickey; Pharmaceutical Inhalation Aerosol Technology, Marcel Dekker.
3. Barry; Dermatological Formulation, Marcel Dekker.
4. C. G. Wilson and N. Washington; Physiological Pharmaceutics, Ellis Horwood Limited.
5. D. W. Osborne, A. H. Amann; Topical drug delivery formulations, Marcel Dekker.

6. H. S. Bean, A. H. Becket and J. E. Carless; Advances in Pharmaceutical Sciences, Vol. 5, Academic Press.

7. J. Kreuter; Controlled Drug Delivery Systems, Marcel Dekker.

8. K. S. E. Su and S. F. Chang; Nasal Systemic Drug Delivery, Marcel Dekker.

9. Morton Rosoff; Controlled release of drugs, VCH Publishers.

10. N. K. Jain; Novel and Drug Delivery systems, CBS Publishers, New Delhi.

11. N. K. Jain. Progress in controlled and novel drug delivery systems, CBS publishers.

12. P. B. Deasy; Micro encapsulation and release drug processes, Marcel Dekker.

13. P. Johnson and J. G. lioyd- Jones; Drug Delivery Systems, VCH Publishers.

14. P. Tyle and B. P. Ram; Targetted Therapeutic systems, Marcel Dekker.

15. P. Tyle; Drug Delivery Devices, fundamental applications, Marcel Dekker.

16. R. O. Potts and R. H. Guy; Mechanism of Transdermal Drug Delivery, Marcel Dekker.

17. Robinson; Novel Drug Delivery systems. Marcel Dekker.

18. T. J. Roseman and S. Z. Mansdorf; Controlled release delivery Systems, Marcel Dekker.

19. Wise Donald L. , Handbook of pharmaceutical controlled release technology, Marcel Dekker Inc.

20. Y. W. Chein; Transdermal Controlled Systemic Medication, Marcel Dekker.

**1.2.5 ADVANCED PHARMACEUTICS – II** **Practical (6 hrs/wk. )**

**Experiments based on following concepts**

1. Formulation of sustained release tablet formulation.
2. Preparation and characterization of Microcapsules/Microspheres.
3. Preparation and evaluation of Transdermal films.
4. In-vitro permeation studies across skin and nasal mucosa.
5. Bioavailability study of nasal mucosa.
6. Formulation design and evaluation of
    - Liposomes
    - Multiple emulsions.

**Reference Books:**

1. A. F. Kydonieus; Controlled Release Technologies, methods, theory and applications, Vol. I and II, CRC Press Inc.
2. A. J. Hickey; Pharmaceutical Inhalation Aerosol Technology, Marcel Dekker.
3. Barry; Dermatological Formulation, Marcel Dekker.
4. C. G. Wilson and N. Washington; Physiological Pharmaceutics, Ellis Horwood Limited.
5. D. W. Osborne, A. H. Amann; Topical drug delivery formulations, Marcel Dekker.
6. H. S. Bean, A. H. Becket and J. E. Carless; Advances in Pharmaceutical Sciences, Vol. 5, Academic Press.
7. J. Kreuter; Controlled Drug Delivery Systems, Marcel Dekker.
8. K. S. E. Su and S. F. Chang; Nasal Systemic Drug Delivery, Marcel Dekker.

9. Morton Rosoff; Controlled release of drugs, VCH Publishers.

10. N. K. Jain; Novel and Drug Delivery systems, CBS Publishers, New Delhi.

11. P. B. Deasy; Micro encapsulation and release drug processes, Marcel Dekker.

12. P. Johnson and J. G. lioyd- Jones; Drug Delivery Systems, VCH Publishers.

13. P. Tyle and B. P. Ram; Targetted Therapeutic systems, Marcel Dekker.

14. P. Tyle; Drug Delivery Devices, fundamental applications, Marcel Dekker.

15. R. O. Potts and R. H. Guy; Mechanism of Transdermal Drug Delivery, Marcel Dekker.

16. Robinson; Novel Drug Delivery systems. Marcel Dekker.

17. T. J. Roseman and S. Z. Mansdorf; Controlled release delivery Systems, Marcel Dekker.

18. Y. W. Chein; Transdermal Controlled Systemic Medication, Marcel Dekker.

**1.2.2 ADVANCED PHARMACEUTICS – III** **Theory (3 hrs/wk. )**

| | | Hrs | Marks |
|---|---|---|---|
| **1.** | **Absorption:** | 08 | 20 – 26 |
| | Cell membrane, absorption mechanism, oral drug absorption, pHpartition hypothesis. Factors affecting: physicochemical, dosage form related, patient related. Drug absorption through other routes: Transdermal, nasal, buccal, ocular and sublingual. In-vitro, In-situ and In-vivo models for drug absorption studies. | | |
| **2.** | **Distribution:** | 06 | 15 – 20 |
| | Tissue permeability of drugs, barrier to distribution of drugs. Factors affecting drug distribution, Physico-chemical properties of drugs, volume of distribution, drug-protein binding, factors affecting drug-protein binding, significance of drug protein binding. | | |
| **3.** | **Metabolism:** | 08 | 20 – 26 |
| | Drug metabolism, organs and enzymes, chemical pathways, Phase I and Phase II reactions. First pass effect, factors affecting. | | |
| **4.** | **Excretion:** | 05 | 10 – 14 |
| | Renal and nonrenal routes of drug excretion. | | |
| **5.** | **Integration of kinetics:** | 03 | 05 – 10 |
| | Interrelationships between pharmacokinetic parameters and physiological variables. | | |
| **6.** | **Pharmacokinetics:** | 06 | 15 – 20 |
| | Pharmacokinetics in drug discovery and development, pharmacokinetic models, Laplace transformations and concept of compartment modeling.<br>• One compartment model: Intravenous injection, intravenous infusion, first order absorption (urinary and plasma data)<br>• Multicompartment models: Intravenous injection, intravenous infusion, first order absorption, multidose data.<br>• Non-linear pharmacokinetics, Michaelis- Menten kinetics, estimation of Km and Vm, AUC, enzyme induction.<br>• Non compartmental analysis- statistical moment theory. | | |
| **7.** | **Applications of pharmacokinetics:** | 04 | 05 – 10 |
| | Multiple dosing controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronopharmacokinetics. | | |

**8. Bio-availabilty and bioequavalence:** 05 10 – 14

Study design protocols, regulatory requirements and statistical consideration in data analysis.

**Reference Books:**


1. B. Testa; Advances in drug research; Vol. 19; Academic Press.
2. D. M. Bramhankar and S. B. Jaiswal; Biopharmaceutics and Pharmacokinetics A Treatise; Vallabh Prakashan.
3. J. B. Blanchard, R. J. Sawchul and B. B. Brodie; Principle and perspectives in drug bioavailabilty; K. Karger Publication.
4. Jean- Pierre Labaune; Handbook of Pharmacokinetics; John Wiley Sons.
5. M. Gibaldi and Perrier; Pharmacokinetics; Marcel Dekker.
6. M. Rawland and T. N. Tozer; Clinical Pharmacokinetics; Waverly Publications.
7. P. G. Welling and F. L. S. Tse; Pharmacokinetics, Regulatory- Industrial - Academic perspectives; Marcel Dekker.
8. P. Jenner and B. Testa; Concept in drug metabolism; Marcel Dekker.

## *SYLLABUS FOR M. PHARM (QUALITY ASSURANCE)*

**1.1.1 ADVANCED PHARMACEUTICAL ANALYSIS** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Spectroscopic Methods:** Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples.<br><br>**Electron Spin Resonance (ESR) Spectroscopy:** Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems. | 10 | 20-25 |
| 2. **Separation Techniques:** Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, lon Pair Chromatography, Affinity chromatography ,Electro kinetic chromatography & Capillary Electrophoresis. | 10 | 20-25 |
| 3. **Thermal Analysis:** Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter. | 04 | 10-15 |
| 4. **Immunochemical Techniques:** lmmunoelectrophoresis, Immuno- precipitation, ELISA, Radioimmuno assays. | 05 | 10-15 |
| 5. **X-Ray diffraction**: Introduction, Principle, instrumentation and pharmaceutical applications. | 05 | 10-15 |
| 6. Basic principles, classification of laser. | 03 | 10-15 |
| 7. **Referance standards:** Source, preparation, characterization,usage,storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol. | 05 | 10-15 |
| 8. **Introduction to Quality Assurance Techniques:** Validation of equipments, processes, products, etc. | 03 | 10-15 |

**1.1.5 ADVANCED PHARMACEUTICAL ANALYSIS** **Practical (6 hrs/wk. )**

1. Experiments based on UV-Vis, FT-IR, HPLC, & GC.
2. Interpretation of UV & IR Spectra of some Chemicals & drugs.
3. ELISA Test / LAL Test.
4. Estimation of drugs in biological fluids.
5. Validation of analytical methods.
6. Analysis of OTC Analgesics by High Performance Chromatographic methods.
7. Demonstration of Reverse Phase HPLC by Internal standard method.

**Reference Books:**


1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)
7. Higuchi : Instrumental Methods of Analysis (CBS Publishers)
8. Analytical Chemistry by open learning series
9. Wim Kok : Capillary Electrophoresis : Instrumentation and Operation
10. R. J. Hamilton - Introduction to High Performance Liquid chromatography, (Chapman and Hall, London)
11. Ewing - Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

**1.1.2 QUALITY ASSURANCE TECHNIQUES – I** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Introduction:** An understanding of the concepts of Quality Assurance, Good Manufacturing Practice and Quality Control as applied to the pharmaceutical Industry. | 08 | 15 – 25 |
| 2. **Documentation related to Pharmaceutical Industry :** • New application : NDA and ANDA requirements, Data presentation , verification and grant by FDA • Manufacturing documents: BMR, routine records, downtime records, calibration and validation records. • Quality Assurance documents: validation and types of validation, protocols methodology and related GMP /ICH guidelines. • Quality Assurance documents: Internal audits SOP documents security and storage related issue. • Store management documents: Stock reconciliation records for raw material, finished products and packaging materials. • Maintenance and Environment control related documents. • Consumer related documents: Product recall, complaint traceability printed packing, preventive maintenance records. | 20 | 45 – 65 |
| 3. **Good laboratory Practices (GLP)** Regulations , biological evaluation microbiological limit tests, sterility tests for effectiveness of antimicrobial preservative , LD 50 ED 50 teratogenicity , mutagenecity , clinical trials , Bioassays, pyrogens and pyrogen testing safely testing presentation of related data and supporting raw data. | 10 | 25 – 30 |
| 4. **Related quality systems :** ISO, WHO etc, and their applications in pharmaceutical industry. | 07 | 15 – 20 |

**RECOMMENDED BOOKS**

1. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.

2. J. Swarbrick Boylan, Encyclopedia of pharmaceutical technology, Marcel and Dekker.

3. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.

4. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.

5. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.

6. B. Othery. ISO 14000 and ISO 9000 Gower.

7. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.

**1.1.6 QUALITY ASSURANCE TECHNIQUES – I** **Practical (6 hrs/wk.)**

**EXPERIMENTS BASED ON FOLLOWING**

1. Sterility testing of medical devices. LVP antibiotics, ophthalmic preparation.
2. Pyrogen testing.
3. Microbiological limit test of starch, acacia and antacid preparation.
4. Physical and Chemical Examination of plastic containers.
5. Examination of labels, cartons and other printed materials.
6. Designing of following key documents
    a. SOP on SOP
    b. IPQC document
    c. Material receipt, sampling, dispensing & storage document
7. Experiment & documentation of dissolution test
8. IPQC tests for Tablets / Capsules / Injections / Liquid / Ointment

**RECOMMENDED BOOKS**

1. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
2. J. Swarbrick Boylan, Encyclopedia of Pharmaceutical Technology, Marcel and Dekker.
3. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
4. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
5. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
6. B. Othery. ISO 14000 and ISO 9000 Gower.
7. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.

**1.2.1 QUALITY ASSURANCE TECHNIQUES – II** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Rules and Regulations :** | 07 | 15 – 22 |
| Rules governing manufacturing of drugs in India. Drug and Cosmetic Act and rules. Narcotic drugs and Psychotropic substances Act and Rules. Magic Remedies and Objectionable Advertisement Act, Consumer protection Act, Factory Act and intellectual Property Right. | | |
| 2. **Process validation :** | 07 | 18 – 25 |
| Differences and similarities between process qualification and process validation, protocols, methodology and interpretation of data. Validation of process like mixing, granulation, drying, compression filling and water process system. | | |
| 3. **Equipment Validation :** | 07 | 18 – 25 |
| Installation qualification and operational qualification for sterilization equipments like autoclave, oven and membrane filter. | | |
| 4. **Cleaning methods:** | 06 | 12 – 17 |
| Analytical method validation requirements and validation of effective cleaning. | | |
| 5. **Vendor validation :** | 06 | 12 – 17 |
| Vendor audit, sample testing and trend analysis. | | |
| 6. **Validation of service :** | 06 | 12 – 17 |
| Training, maintenance and packing. | | |
| 7. **Validation of electronic data processing :** | 06 | 12 – 17 |
| Software validation methodology. | | |

**RECOMMENDED BOOKS**

1. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.

2. J. Swarbrick Boylan, Encyclopedia of Pharmaceutical Technology, Marcel and Dekker.

3. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.

4. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.

5. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.

6. B. Othery. ISO 14000 and ISO 9000 Gower.

7. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.

**1.2.5 QUALITY ASSURANCE TECHNIQUES – II** **Practical (6 hrs/wk.)**

**EXPERIMENTS BASED ON FOLLOWING CONCEPTS**

1. Validation of equipments, Autoclave, hot air oven, membrane filter.
2. Validation of process, Mixing drying and compression.
3. Validation of an analytical method.

**RECOMMENDED BOOKS**

1. J. F. Despautz, Automation and validation of information in Pharmaceutical Processing Marcel and Dekker.
2. F.J. Carleton and J.P. Agalloco validation of aseptic Pharmaceutical processes Marcel and Dekker.
3. J.R. Berry and R.A. Nash pharmaceutical process validation Marcel and Dekker.
4. S.H. Will and J.R. Stoker Good manufacturing Practices for Pharmaceuticals Marcel and Dekker.
5. R.F. Brewer, Design of Experiments for process improvement and quality Assurance, Narosa.
6. S. N. Katju Law and drugs, Law Publishers (I) Pvt. Ltd.

**1.2.2 QUALITY ASSURANCE TECHNIQUES – III** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| **1. Validation of instruments :** | 08 | 20 – 28 |
| HPLC, UV and IR spectrophotometer and dissolution test apparatus. | | |
| 2. **Validation of Analytical Method :** | 08 | 20 – 28 |
| Validation parameters, accuracy, precision, ruggedness, statistical design and statistical consideration. | | |
| 3. **Current good manufacturing Practices.** | 08 | 20 – 28 |
| 4. **Biostatistics :** | 15 | 30 – 40 |
| Probability distribution, normal, binomial and polynomial distributions, continuous data distribution, fiducial limits, probit and logit analysis. Linear regression and correlation, method of least squares, significance of correlation and regression. Parametric tests, testing hypothesis, types of errors test of significance based on normal distribution, test of significance for correlation coefficients. Non parametric test. Experimental Designs. Randomization completely randomized and Latin square designs, and factorial design. Statistical Quality Control. | | |
| 5. **Guidelines and technique for experiments on animals.** | 06 | 10 – 16 |

**RECOMMENDED BOOKS**

1. D.A. Berry, statistical methodology in the Pharmaceutical Science: Marcel and Dekker Vol.104.

2. S.W. Bergman and JC Gittins statistical methods for Pharmaceutical Research and planning Marcel and Dekker.

3. S. C. Chowand J.P. Liu statistical Design and Analysis in Pharmaceutical Sciences. Marcel, Dekker.

## *SYLLABUS FOR M. PHARM (PHARMACEUTICAL CHEMISTRY)*

### 1.1.1 ADVANCED PHARMACEUTICAL ANALYSIS — Theory (3 hrs/wk.)

| | Hrs | Marks |
|---|---|---|
| 1. **Spectroscopic Methods:** Introduction application and Structure Elucidation using UV, IR, NMR, Mass Spectroscopy with examples.<br><br>**Electron Spin Resonance (ESR) Spectroscopy:** Introduction, principles, instrumentation and application in detection of free radical reactions in chemical and biological systems. | 10 | 20-25 |
| 2. **Separation Techniques:** Theory, instrumentation, Applications of GLC, HPLC, HPTLC, Chiral Chromatography, lon Pair Chromatography, Affinity chromatography ,Electro kinetic chromatography & Capillary Electrophoresis. | 10 | 20-25 |
| 3. **Thermal Analysis:** Theory, Instrumentation and Applications of Thermogravimetric Analysis, Differential Thermal Analysis, Differential Scanning Calorimeter. | 04 | 10-15 |
| 4. **Immunochemical Techniques:** lmmunoelectrophoresis, Immuno- precipitation, ELISA, Radioimmuno assays. | 05 | 10-15 |
| 5. **X-Ray diffraction**: Introduction, Principle, instrumentation and pharmaceutical applications. | 05 | 10-15 |
| 6. Basic principles, classification of laser. | 03 | 10-15 |
| 7. **Reference standards:** Source, preparation, characterization, usage, storage and records preparation of reference standards of diclofenac sodium, losartan and chloramphenicol. | 05 | 10-15 |
| 8. **Introduction to Quality Assurance Techniques:** Validation of equipments, processes, products, etc. | 03 | 10-15 |

**1.1.5 ADVANCED PHARMACEUTICAL ANALYSIS** **Practical (6 hrs/wk.)**

1. Experiments based on UV-Vis, FT-IR, HPLC, & GC.
2. Interpretation of UV & IR Spectra of some Chemicals & drugs.
3. ELISA Test / LAL Test.
4. Estimation of drugs in biological fluids.
5. Validation of analytical methods.
6. Analysis of OTC Analgesics by High Performance Chromatographic methods.
7. Demonstration of Reverse Phase HPLC by Internal standard method.

**Reference Books:**


1. Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2. M.Orchin and H.H-Jaffe - Theory and applications of ultra violet spectroscopy (John Wiley Md Sons, N.Y.)
3. Silverstein. Basseler, Moiril – Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4. Willard, Merritt, Dean - Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5. J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentice Hall, London)
6. CN. R. Rao - Chemical applications of IR spectroscopy (Academic press, N.Y.)
7. Higuchi : Instrumental Methods of Analysis (CBS Publishers)
8. Analytical Chemistry by open learning series
9. Wim Kok : Capillary Electrophoresis : Instrumentation and Operation
10. R. J. Hamilton - Introduction to High Performance Liquid chromatography, (Chapman and Hall, London)
11. Ewing - Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

**1.1.2 ADVANCED PHARMACEUTICAL CHEMISTRY – I** **I** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Molecular basis of drug action:** Receptor, Drug Receptor Interaction. | 12 | 25-35 |
| 1.Types of receptors<br>2. Drug target binding forces.<br>3. Receptor structure and signal transduction.<br>4. Changes in receptor shape.<br>5. Design of agonist and antagonist.<br>6. Above concepts with special reference to Opioid, Histaminergic, Adrenergic and GABA nergic receptors.<br>7. Recent advances & trends in the drugs acting on above mentioned categories of receptors. | | |
| 2. **Enzyme Inhibition:** | 14 | 30-40 |
| 1. Enzyme Inhibitors - Reversible, irreversible, Kcat inhibitors. Transition state analogs and their application with respect to drug design.<br>2. Enzyme Inhibitors of - ACE, leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, DNA Polymerase Inhibitors, HIV - Protease / Reverse Transcriptase, Integrase and Cytochrome P-450 Inhibitors, purine, pyrimidine inhibitors, DHFR inhibitors as drugs.<br>3. Recent advances & trends in the above mentioned categories of drugs. | | |
| 3. **Design and application of prodrugs:** | 07 | 15-25 |
| 1. Prodrug concept.<br>2. Prodrugs of various functional groups like carbonyl, hydroxy. amide, amines.<br>3. Application of Prodrug approach to: | | |

i. Improvement of bioavailability

ii. Prevent first pass metabolism

iii. Reduction of side effects

iv. Prolong duration of action

v. Site specific delivery

4. PDEPT (Polymer-Directed Enzyme Prodrug Therapy); ADEPT (Antibody-Directed Enzyme Prodrug Therapy); GDEPT/VDEPT (Gene-Directed Enzyme Prodrug Therapy/Virus-Directed Enzyme Prodrug Therapy);

4. **Synthon approach:** 12 30-40

- Definition of terms - disconnection, synthon, functional group interconversion (FGI).
- Basic rules in Disconnection.
- Use of synthon approach in synthesis of following compounds

Trimethoprim, Terfenadine, Ibuprofen, Propanolol, Fentanyl, Cimetidine, Ciprofloxacin, Piroxicam, Rosiglitazone, Diclofenac, Captopryl, Nifedipine, Losartan.

- Recent advances & trends in the above mentioned categories of drugs.

**Reference Books:**

1. Graham and Patrick An Introduction To Medicinal Chemistry.
2. Foye's: Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer: Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens: Medicinal Chemistry Series
5. Ellis and West: Progress in Medicinal Chemistry Series
6. Bunerworther Progress in Medicinal Chemistry Series
7. Wilson & Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren: Organic Synthesis- The Disconnection, approach (John Wiley & Sons)
9. Stuart Warren : Designing Organic Syntheses: A Programmed Introduction to the Synthon Approach
10. Comprehensive Medicinal Chemistry - Series –I – VI (Academic Press)
11. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)

**1.1.2 ADVANCED PHARMACEUTICAL CHEMISTRY – I** **Practical (6 hrs/wk.)**

1. Study and applications of enzymes Kinetics, Inhibition and Immobilization.
2. Determination of partition coefficient.
3. Synthesis of drugs mentioned in the theory using basic operations like Molecular distillation, fractional crystallization, and purification by column chromatography, preparative TLC.
4. Synthesis of drugs using synthon approach.
5. Structure confirmation by spectroscopic studies.
6. Mixture analysis of 2/3 organic compounds.

**Reference Books:**

1. Organic Synthesis; Fieser and William Son (CBS Publishers)
2. Mann and Saunders. Practical Organic Chemistry (Orient Longman)
3. A. l. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

**1.2.1 ADVANCED PHARMACEUTICAL CHEMISTRY – II** **Theory (3 hrs/wk.)**

| | | Hrs | Marks |
|---|---|---|---|
| 1. | **Combinatorial Chemistry:** Introduction, combinatorial approaches, small molecule libraries, applications, methodology, combinatorial organic synthesis, screening of combinatorial libraries, introduction to high throughputs screening (HTS). | 11 | 25-35 |
| 2. | **Chiral Technology:** Introduction to Chirality and Techniques used asymmetric synthesis of Diltiazem, Timolol, Vitamin C, Ampicillin, Dextrapropoxyphen, Thienamycin, Citrenalol, Propranolol, Atenolol, and Naproxen. | 10 | 20-30 |
| 3. | **Bioconversions in Drug Synthesis and Development:** Bio conversions of drugs like steroids, prostaglandin, antibiotics, enzyme immobilization Techniques. Chiral bioconversion of NSAID's using esterases. | 10 | 20-30 |
| 4. | Agents used in Neurodegenerative diseases: like Alzheimer's and Parkinsonism. Therapeutic targets for their treatment. Recent advances and trends. | 06 | 15-20 |
| 5. | Agents used in treatment of AIDS: Life cycle of HIV and various therapeutic targets for their treatment with examples. Recent Advances and Trends. | 08 | 20-25 |

**Reference Books:**


1. Graham and Patrick An Introduction To Medicinal Chemistry.
2. Foye's: Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer: Organic Drug synthesis Vol. 1,2,3,4 (John Wiley &. Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold: Text book of Medicinal Chemistry (J.B. Lippincot )
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Academic Press)
10. Burger: Medicinal Chemistry (John Wiley & Sons N.Y.)

**1.2.1 ADVANCED PHARMACEUTICAL CHEMISTRY – II** **Practical (6 hrs/wk.)**

1. Asymmetric synthesis.

2 Application of partition coefficient, pKa, Stearic factor, electronic factors in QSAR studies with examples. Use of statistical regression analysis.

3 Microbial conversion for drug synthesis.

4 Resolution of racemic mixture.

5 Synthesis of compounds using 3/4 steps, structure confirmation by spectroscopic methods.

6 Synthesis of drugs by combinatorial approach.

7. Multi-component synthesis approach.

8. Synthesis based on Solvent free reactions and reactions involving water as a solvent.

**Reference Books:**

1. Organic Synthesis; Fieser and William Son (CBS Publishers)

2. Mann and Saunders. Practical Organic Chemistry (Orient Longman)

3. A. l. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)

**1.2.2 ADVANCED PHARMACEUTICAL CHEMISTRY – III** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Drug Discovery:** | 09 | 20-28 |

1. Historical perspective.

2. Drug Discovery Strategies in Direct Drug Design (Structure based) and indirect drug design. advantages and limitations of both.

3. Target selection and lead identification

i. Natural product sources

ii. Fermentation / Microbial sources

iii. Synthetic

4. Structure activity relationships - Binding role of –OH groups, $-NH_2$ groups, aromatic rings, double bonds, ketones and amides.

5. Bioinformatics in drug discovery.

| | | |
|---|---|---|
| 2. **Pharmacogenomics and informatics:** Genomics – types of genomics, bioinformatics, chemoinformatics, proteomics, barriers to progress of pharmacogenomics progress. | 09 | 20-28 |
| 3. **QSAR:** | 09 | 20-28 |

1. Parameters - Lipophilicity, electronic, Stearic factors.

2. Quantitative Models:

i. Hansch analysis.

ii. Free Wilson Analysis.

iii. Mixed approach.

3. Other QSAR Approaches.

4. Applications of Hansch Analysis, Free Wilson Analysis.

| | | |
|---|---|---|
| 4. **Molecular Modeling in Drug Design:** Introduction to Molecular Modeling: Concepts and Methods. | 09 | 20-28 |

1. Molecular Mechanics - force fields (Potential energy function).

2. Energy Minimization Methods - Steepest, descent. Conjugate gradients, Newton methods (Non mathematical).

3. Conformational Analysis

i) Systematic search.

ii) Monte Carlo simulations.

iii) Molecular dynamics simulations.

4. Ligand design based on 3D structure of receptor /enzyme.

5. Computer assisted drug design.

5. **Proteins and Peptide drugs:** Chemistry, structure and stability, Reactivity of proteins and peptides. Different ways to synthesize these drugs - study of Insulin, Relaxin, Somatostatin, DNAse Interferon. Peptides in molecular biology. 09 20-28

**Reference Books:**

1. Graham and Patrick An Introduction To Medicinal Chemistry.
2. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol I.
3. Poul Krogsgaand Larsen: A textbook of Drug Design and Development First Edi.
4. Thomas J. Penim, C.L-Propst - Computer Aided Drug Design.
5. Pandi Veerapandian - Structure Based Drug design.
6. Paul S. Charifson - Practical Applications of Computer Aided Drug Design (Marcel & Dekkar Inc. New York)
7. Paul Leff-Receptor Based Drug Design.
8. Bernard Testa, Walter Fuh rer – Perspectives in-Medicinal Chemistry.
9. C. Hansch Comprehensive Medicinal Chemistry Vol.-IV.

## List of Elective Subjects for Semester I

1. Drug Design
2. Bulk Drug Technology
3. Toxicology
4. Biopharmaceutics & Pharmacokinetics
5. Medicinal Plant Biotechnology
6. Clinical Research
7. Advances in Drug Delivery
8. Product Development
9. Industrial Pharmacy & Production Management
10. Quality Assurance

## List of Elective Subjects for Semester II

11. Cosmeticology
12. Phytopharmaceuticals
13. Sterile Product Formulation & Technology
14. Fermentation Technology
15. Quality Control
16. Immunopharmacology & Immunoassays
17. Polymer Technology
18. Clinical Pharmacy
19. Therapeutic Drug Monitoring

# Electives

**1. DRUG DESIGN** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Introduction to drug design:** Drug design, Molecular modification, Rational approach of drug design, QSAR and drug design, drug design methodologies, challenges of drug design. | **06** | **15-20** |
| 2. **Recent developments in Histamine receptor antagonists and antiulcer therapy:** Theory of histamine receptors, Design of H1 antagonists (Non sedating / Second generation analogs) and H2 antagonists (Ranitidine analogs, analogs for prolonged action viz. cimetidine), Design of proton pump inhibitors. | **07** | **15-20** |
| 3. **The basis of drug design and recent advances in Cardiovascular and CNS agents:**<br><br>**Antihypertensive agents - ACE inhibitors**-The ACE active site, specificity for decrease in angiotensin-II formation, Actions of ACE inhibitors to inhibit kinase-II to potentiate bradykinin, **Angiotensin-II receptor antagonists –** angiotensin receptor subtypes, and design of nonpeptide angiotensin-II receptor antagonists and **Calcium channel antagonists –** Chemical subtypes of antagonists with reference to mechanism of action**.**<br><br>**Antipsychotic agents -** Development of dopamine selective legents viz.domperidone, isoxazole, pyrazole analogs. Different types of 5HT receptors and designing of protein kinase C activator. Design of serotonin blocking agents viz. Clozapine analogs. Designing of clonazepam analogs as Gaba agonists. | **10** | **25-30** |
| 4. **The basis of drug design and recent advances in Chemtherapeutic agents:**<br><br>a. **Antineoplastic agents –** Origin of neoplasm and Design of drugs for various therapeutic targets.<br>b. **Anti-AIDS agents –** Life cycle of HIV and Design of drugs for various therapeutic targets.<br>c. **Chemistry of β-lactam antibiotics –** Design of β-lactamase resistant and acid resistant analogs. | **08** | **15-25** |

5. **Molecular modelling in Drug Design:** **07 15-20**

- Molecular mechanics and Quantum Mechanics
- Known receptor sites: Defination, Characterisation of sites, design of ligands, manually assisted three dimentional databases & calculation of affinity.
- Unknown receptor sites: Searching for similarity, Pharmacophore models, molecular comparisons, finding common patterns.

6. **Structural variations for drug design and drug target interactions:** **07 15-25**

a. Drug design, variation of substituents.

b. Extention of structure, chain extensions / contraction.

c. Ring expansion / contractions.

d. Ring variations.

e. Ring fusions.

f. Isosters.

g. Simplification and rigidification of structures.

h. Conformation blockers.

i. A case study of oxamniquine.

**Reference Books:**

1. Ariens – drug design Vol. – II.
2. Annual Reports in medicinal chemistry (Academic press Inc.).
3. Smith - William – Introduction to the principles of drug design.
4. Woodridge – Progress in pharmaceutical Research.
5. Medicinal Chemistry – Monographs series (Academic Press).
6. Burgers - Medicinal Chemistry & Drug Discovery.

| 2. | **BULK DRUG TECHNOLOGY** | **Theory** | **(3 hrs/wk. )** |
|---|---|---|---|
| | | **Hrs** | **Marks** |
| 1. | **Stoichiometry and its importance in the manufacture of drugs**<br>**Discussion on the following processes** (reaction types in relation to manufacturing of drugs<br>Acetylation, Nitration, Sulphonation, chlorosulphonation, Oxidation, Reduction, alkylation, Halogenation, Carboxylation, Decarboxylation, Esterification, Addition, epoxidation and important rearrangements. | 07 | 16 – 24 |
| 2. | **Unit processes:** Study of the following chemical processes (with reference to reagents, mechanisms, equipments. and manufacture of drugs given below): Acylation, Esterification, alkylation, amination, Halogenation, hydrolysis, nitration, oxidation, reduction. | 08 | 18 – 24 |
| 3. | **Further discussion on (unit operation important to drug synthesis)**<br>e. g. mixing, distillation, drying, filteration and centrifugation, evaporation, crystallization, Counter current extraction, Effluent treatment and Pollution Control. | 07 | 15 – 22 |
| 4. | **Principles and design of the reactors-**<br>Factors to be considered (including material selection) construction of flow diagrams- selection of Equipment | 08 | 18 – 24 |
| 5. | **Detailed manufacturing aspects, inclusive of processes and operations involved-for :**<br>Aspirin, Adrenaline, Aneurine, Barbitones, Benzocaine, Chloramphenicol, Sulphathiazole | 07 | 15 – 22 |
| 6. | Safety and Hazards concepts. | 08 | 18 – 24 |

**Reference Books:**


1. M. Giarians : Fundamentals of Chemicals Engineering Operations
2. W. J. Badger and Banchero : Introduction to chemical engineering (McGraw Hill Services)
3. L. Lachman - the theory and practice of Industrial Pharmacy (Varghese Publishing)
4. Ganderton G ; Unit processes in Pharmacy
5. Groggin P. K. : Unit processes in Organic synthesis (McGraw Hill Publication London)
6. Marshall Sitting : Organic Chemical Processes
7. Dryden C. L.: Outlines of chemical Technology (Affiliated East-West Press Pvt. Ltd. )

**3. TOXICOLOGY** **Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| **1. Fundamental Principles:** | 08 | 20-20 |
| • Introduction, Toxicological Evidence, Common household poisons, description of sub disciplines of toxicology, qualitative and quantitative aspects of toxic effects. | | |
| • Biotransformation: detoxication and bioactivation. | | |
| • Absorption, distribution and elimination of xenobiotics. | | |
| • Toxicokinetics ; quantitative aspect. | | |
| • Dose time – effect relationships. | | |
| **2.** Molecular aspects of toxicology :- Cytotoxicity – Molecular Mechanism of cell death, Genetic toxicology<br>Introduction to carcinoensis. | 05 | 10-10 |
| **3. Organ toxicology :-** | 32 | 70-110 |
| • Cytopathology general response patterns and Morphological aspects Necrosis and apoptossis: irreversibility of cell damage and cell death. | | |
| • Dermatotoxicology: Toxicological, pathology and methodological aspects. | | |
| • Raspiratory toxicology: Toxicological pathophysilogy, toxicological pathology and mechanisms of toxicity. | | |
| • Gastrointstinal toxicology: toxicological pathology and source of intestinal toxicity. | | |
| • Hepatotoxicology: Mechanisms of liver toxicity and methodology aspects. | | |
| • Nephotoxicology : toxicologycal pathology and biochemical toxicology. | | |
| • Cardiovascular toxicology; toxicological pathology and methodological aspects. | | |
| • Toxicology of blood: Pathophysiology, Toxicological pathology and mechanisms of toxicity. | | |
| • Immunoxicology: determination of immunotoxic effects and immunotoxicity mechanisms. | | |

- Endocrine toxicology.
- General reproductive toxicology.
- Functional neurotoxicology.
- Neurobehavioural toxicology.
- Food, nutritional toxicology.
- Medical and clinical toxicology.
- Ecotoxicology.
- Occupational toxicology.
- Carcinogencity mutagenicity ; Teratogenicity.

**Reference Books:**

1. Niesink R. J. M. de Vries J and Hollingers M. A. Toxicology, Principal and Applications, CRC Press 1996
2. Amdur M. O Doul J and Klassen C. D. Casarett and Doull's Toxicology
3. Gupta P, K and Salunkhe D. K. Modern toxicology Vol. -I, II and III (Metropolitan, New Delhi).

**4. BIOPHARMACEUTICS & PHARMACOKINETICS Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| 1. **Introduction to Biopharmaceutics and clinical pharmacokinetics** | 05 | 10 – 15 |
| Definition of Biopharmaceutics, Pharmacokinetic, clinical Pharmacokinetic and its importance | | |
| 2. **Basic concepts** | 06 | 15 – 20 |
| Definition and introduction to absorption rate constant, bioavailability, volume of distribution, elimination half-life, elimination rate constant. Clearance, extraction ratio, area under curve, protein binding and tissue binding. | | |
| Calculation of parameters from plasma and urine data. | | |
| 3. **Compartment modelling: -** | 08 | 20 – 30 |
| *a. One compartment open model :* | | |
| I. V. route of administration; Disposition viewed from plasma ($t_{1/2}$, V, 1st order examination, fraction of dose remaining) total clearance, renal clearance, disposition viewed from urine only and estimation of pharmacokinetic parameters. | | |
| E. V. route of administration, kinetics of absorption, body level time relationship and assessment of pharmacokinetic parameters. | | |
| *b. Multi compartment modeling :* | | |
| 2 compartment and 3 compartment models, determination of compartment models. | | |
| 4. **Absorption of drugs** | 06 | 15 – 20 |
| a. GI absorption of drugs | | |
| b. Cell membrane structure and physiology | | |
| c. Mechanism of drug absorption | | |
| d. Factors influencing drug absorption and bioavailability. | | |
| e. Concepts and kinetics of physiological parameters of absorption. | | |
| 5. **Distribution of drugs :-** | 05 | 10 – 15 |
| *a) Factors affecting distribution of drugs.* | | |

1) Tissue permeability of drugs

   Physicochemical properties of drugs.

   Physiological barriers to diffusion of drugs.

2) Organ / Tissue size and perfusion rate.

3) Binding of drugs to blood components and tissue. Factors affecting it.

4) Miscellaneous factors ( Age, Pregnancy, Obesity etc)

*b) Volume of distribution*

*Clinical concepts and kinetics of physiological parameters of distribution.*

6. **Elimination of drug: -** 05 10 – 15

   a. Concept of clearance

   b. Hepatic metabolism: chemical pathways and factors affecting it

   c. Renal excretion: principle processes and factors affecting It

   d. Non renal excretion:

   e. Concepts and kinetics of physiological parameters of elimination

7. **Bioavailability:** 06 15 – 20

   - Objective of bioavailability studies, determination bioavailability parameters of bioavailability rate of absorption extent of absorption, relative bioavailability, determination of AUC (using planimeter, counting squares trapezoidal rule and cutting and weighing studies)
   - Drug dissolution rate and bioavailability

     Theories of dissolution in-vitro drug dissolution testing models invitro - invivo correlation
   - Invitro and insitu absorption studies

     Various Invitro & insitu models – selection of animals

     Correlation between invitro & invivo studies.

8. **Non linear Pharmacokinetics** 06 15 – 20

   Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, mixed drug elimination, time dependent pharmacokinetics, bioavailability of drug that follow non linear pharmacokinetics, non linear pharmacokinetics due to protein binding (e. g. phenytoin)

**Reference Books:**


1. Applied Biopharmaceutics & Pharmacokinetics – Leon Shargel.
2. Biopharmaceutics - Swarbrick, Lea & Febiger book publication
3. Biopharmaceutics & P'cokinetics - an introduction - Robert E. Notary.
4. Biopharmaceutics & P'cokinetics - Milo Gibaldi , Lea & Febiger book publication
5. Biopharmaceutics & Pharmacokinetics - P. L. Madan
6. Biopharmaceutics & Pharmacokinetics. A treatise - D. M. Brahmankar S B. Jasiwal
7. Clinical Pharmacokinetics - concept & application - Malcolm Rowland & Thomas N. Tozer, Lea & Febiger book.
8. Handbook of clinical p'cokinetics- Gibaldi & Pancot
9. Introduction to Biopharmaceutics. - G. P. -Shriwastav
10. Pharmacokinetics - Milo Gibaldi & Donald Perrier
11. Remington's pharmaceutical sciences

**5. MEDICINAL PLANT BIOTECHNOLOGY Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| 1. **Introduction to plant Genetic structure & Molecular Biology** | 05 | 10-16 |
| 2. **Plant gene Mapping & molecular maps of plant genomes** | 05 | 12-18 |
| 3. **Methods of quality improvement of plants** | 05 | 12-18 |
| a. Chemodemes | | |
| b. Hybridization | | |
| c. Mutation | | |
| d. Polyploidy | | |
| 4. **Gene transfer in plants** | 06 | 14-20 |
| a. Using Vectors of *Agrobacterium* Ti, co-integrative, Intermediate plasmid | | |
| b. DNA mediated gene transfer | | |
| Electroporation, Microprojectiles, Micro and macro injection, Liposomes Ultrasonication | | |
| 5. **Localization of transferred gene in genetically modified plants** | 06 | 14-20 |
| a. Plant chromosome analysis | | |
| b. Gene mapping | | |
| c. Use of markers | | |
| d. DNA hybridization | | |
| 6. **Applications of transgenic plants** | 06 | 14-18 |
| a. Resistance to herbicides, insects, fungus and virus, physiological stress | | |
| b. Edible vaccines | | |
| 7. **Plant tissue Culture** | 12 | 24-30 |
| a. Totipotency | | |
| b. Culture media | | |
| c. Types of cultures | | |
| d. Cell suspension, Organogenesis, Embryogenesis, Protoplast culture | | |

e. Cell Immobilization
f. Biotransformation
g. Generation and production of secondary metabolites
h. Germplasm conservation

**Reference Books:**

1. Elements of Biotechnology: P. K. Gupta
2. Molecular biology and biotechnology: J. M. Walter, E. D. Gingo
3. Essentials of molecular biology: Dovid F. A. , George M . M.
4. An introduction to plant tissue culture : A. Razdan
5. Plant biotechnology: Samtel
6. Plant tissue culture: Narayanswamy, S. ; Tata McGraw-Hill Publishing Company, Ltd. , New Delhi
7. Plant tissue culture: Angela Stafford, Open University press, Buckingham. 1991.
8. Plant tissue culture: Dixon (47)
9. Pharmaceutical Biotechnology: Vyas, Dixit, CBS Publishers, New Delhi. 1998
10. Pharmacognosy: Trease W. C. , Evans G. E. , Baillerie & Tindall, 15th Edi.

**6. CLINICAL RESEARCH** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Discovery of new pharmaceutical entities** | 4 | 05 – 10 |
| Introduction, market needs, historical aspects of new drug discovery, Impact of pharmacogenomics, proteomics and bioinformatics in new drug discovery, concepts of high through put screening and combinatorial chemistry | | |
| 2. **Characterization of new drug molecules** | 6 | 10 – 15 |
| Solubility studies, spectroscopic characterization (UV-Vis, IR, NMR, Mass, and other techniques), thermal analysis, X ray diffraction, optimization of synthetic procedure, impurity profile, scale up. | | |
| 3. **Pre clinical studies** | 8 | 10 – 15 |
| Introduction, risk benefit assessment, Good laboratory Practices, experimental design, single dose and repeated dose studies, safety pharmacological studies, teratogenicity and oncogenicity studies, animal pharmacokinetic studies and invitro screening tests for safety and efficacy | | |
| 4. **Phase studies** | 12 | 30 – 40 |
| Introduction, study design, conduct, monitoring of phase I, II, III and IV studies | | |
| 5. **Regulatory aspects of clinical trials** | 15 | 45 – 60 |
| Historical aspects of clinical trails, declaration of Helsinki, Belmont report, Nuremberg code, Tuskgee trial. Composition, functions & operations of IRB/IEC ethics of clinical trials in developed and developing countries, ICH GCP, WHO guide lines, USFDA guidelines, UK drug regulatory procedure, CDSCO/ICMR guidelines, schedule Y, regulatory and clinical trails system in Japan, Australia and Canada | | |

**Reference Books:**

1. John P. Griffin, John O'Grady. Pharmaceutical medicine. 2003, British Medical Journal, UK

2. Francis L. S. Tse, James M. Jaffe. Preclinical Drug disposition.1987, Marcel Dekker Inc.

3. Andrew J. Fletcher, Lionel D. Edwards, Anthony W. Fox, Peter Stonier, Pharmaceutical medicine. 2002, John Wiley & Sons, Ltd.

4. Cocchetto, Nardi. Managing the Clinical Drug Development Process, 1987, Marcel Dekker Inc.

5. Lelia Duley Barbara. Clinical Trials. 2002, Viva Books Pvt. Ltd.

**Web resources**

6. www.fda.gov/cder/handbook/preclin

7. www.cato.com/biotech/bio-prod-cro

8. www.niaid.nih.gov/hivvaccines/preclinrd

9. www.qservegroup.com/consulatancy/services/pre_clinical

10. www.pharmahungary.com

| 7. | ADVANCES IN DRUG DELIVERY | Theory | (3 hrs/wk.) |
|---|---|---|---|
| | | Hrs | Marks |
| 1. | **Protein & peptide drug delivery system: -** | 06 | 16-22 |
| | Physical aspects, biochemistry of protein drug (structure, properties & stability) general methods of analysis of protein' & peptide drugs, barrier to transport &pharmacokinetics, different route of delivery, practical considerations. Importance of Preformulation & formulation considerations, toxicity immunogenicity, 'stability & regulatory perspective. | | |
| 2. | **Mucosal drug delivery models: -** | 04 | 08-14 |
| | Buccal, rectal: & vaginal drug delivery. Mechanisms of transports of drugs trough mucosal routes | | |
| 3. | **Occular Drug Delivery: -** | 04 | 08-14 |
| | Occular delivery mechanisms & development of Occular controlled release system | | |
| 4. | **Transdermal drug delivery system: -** | 05 | 12-14 |
| | Permeation through skin including mechanism, permeation enhancers, invitro skin permeation, technologies for developing Transdermal drug delivery system & evaluation thereof. | | |
| 5. | **Oral & Parenteral controlled release system: -** | 05 | 12-14 |
| | Scope, terminology & techniques used, injectable controlled release formulation. Long acting contraceptive formulations. Implantable drug delivery, microspheres liposomes, & nanoparticles & quality control. | | |
| 6. | **Site specific drug delivery system: -** | 05 | 12-14 |
| | Active & passive targeting, resealed erythrocyte, monoclonal antibodies drug targeting particulate carrier system, specific drug delivery to targeted organs like brain & colon, freeze drying of Parenteral, environmental controlled Parenteral manufacturing. | | |
| 7. | **Intrauterine drug delivery system: -** | 04 | 08-12 |
| | Medicated IUDs„ 'Copper lUDs, Harmone released lUDs | | |
| 8. | **Regulatory considerations in controlled release modification: -** | 04 | 08-12 |
| | Requirements to demonstrate safety, efficiency & controlled release nature, Bioavailability, assurance, WHO & Indian condition. | | |

| | | | |
|---|---|---|---|
| **9.** | **Methods of enhancing bioavailability: -**<br>Solubilisation, Prodrugs, and enhancement of dissolution characteristics, bioavailability enhancer | 04 | 08-12 |
| **10.** | **Fundamental polymer sciences: -**<br>Use of polymers, hydrogels biodegradable & other polymers in preparation of NDDS | 04 | 08-12 |

**Reference Books:**


1. Remington's pharmaceuticals sciences
2. Novel drug delivery system – Marcel Dekker N. Y.
3. Controlled drug delivery system- Vincent H. L, Marcel Dekker
4. Bentley's textbook of pharmaceuticals – E. A**.** Rawlin
5. Novel and controlled drug delivery systems - N. K. Jain.

**8. PRODUCT DEVELOPMENT** **Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| 1. **Preformulation studies:** | 05 | 15 – 20 |

Characterisation of fundamental & derived properties of drug molecules. Study of particle morphology, particle size, shape, surface area, solubility, ageing and polymorphism. Particle Characterization by optical and electron microscopy, spectroscopy, chromatography, thermal techniques.

| | | |
|---|---|---|
| 2. **Design of experiments and optimization:** | 04 | 10 – 15 |

Design of experiment, Terminologies in experimental design. Product, process and response variables. Optimization methodologies with special reference to factorial design, central composite design and mixture designs. Response surface analysis.

| | | |
|---|---|---|
| 3. **Dosage form development:** | 08 | 30 – 40 |

Types, components, manufacturing and evaluation of tablets (coated, uncoated, layered and immediate release), capsules (HGC, SGC, microcapsules), liquids like suspension (coarse suspension, nano suspension), emulsion (conventional, multiple, microemulsion, nanoemulsion) and self emulsifying drug delivery system (SEDDS). cGMP as followed in the manufacturing of above dosage forms.

| | | |
|---|---|---|
| 4. **Validation:** | 04 | 10 – 15 |

Concept and need of validation, types of validation, process validation, equipment validation and cleaning validation, validation master plan.

| | | |
|---|---|---|
| 5. **5. Packaging of pharmaceuticals:** | 04 | 15 – 20 |

Types of primary and secondary packaging materials for pharmaceuticals. Studies on types and suitability evaluation of glass, plastic and rubber as a primary packaging for non-sterile and sterile dosage forms. Regulatory requirements for pharmaceutical packaging.

| | | |
|---|---|---|
| 6. **Basics of statistics in product development** | 04 | 10 – 15 |

Data collection, summarizing data, proposing hypothesis, statistical models like linear and multiple regression analysis, significance testing using ‘t’ test, ‘z’ test, and ‘chi square’ test. Analysis of variance (one way and two way ANOVA, ‘F’ test)

7. **Drug regulatory affairs:** 04 10 – 15

   Need of harmonization in pharmaceutical sector, Regulatory requirements of US, UK, domestic and other markets. Concept of NDA and ANDA with the process of patent filing.

**Reference Books:**


1. N. G. Stanley – Wooed; Enlargement and compaction of particle solids; Butterworths.
2. D. M. Parikh; Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
3. H. G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
4. A. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
5. J. T. Cartensen; Drug Stability; Marcel Dekker.
6. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7. A. Martin, P. Bustamante and A. H. Chun; Physical Pharmacy; Waverly.
8. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.
9. M. N. Rubinstein; Pharmaceutical Technology, Drug stability, John Wiley and sons.
10. Martin Rhodes; Principles of Powder Technology, John Wiley and sons.
11. James J. Wells; Pharmaceutical Preformulation, Ellis Harwood Ltd.
12. P. J. Tarcha; Polymer for Controlled Drug Delivery, CRC Press.
13. P. H. List and P. C. Schmidt; Pharmaceutical Technology, CRS Press.
14. Robinson; Novel Drug Delivery Systems, Marcel Dekker.
15. N. K. Jain; Pharmaceutical product development, CBS publishers and distributors.

| 9. | **INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT** | **Theory Hrs** | **(3hrs/wk.) Marks** |
|---|---|---|---|
| 1. | **Pilot plant scale – up pilot plant design:** tablets, capsules, liquid orals. Parenterals and semisolid preparations.<br><br>Basic requirements for design of product, facility, equipment selection. Personnel, Pharmaceutical process validation for various products. | 5 | 10 – 15 |
| 2. | **Quality Assurance:** GMP considerations, quality assurance and process control. Total quality management and productivity. ISO 9000 Salient features. | 6 | 15 – 20 |
| 3. | **Optimization Techniques:** Optimization parameters, classical optimization, statistical design and applied optimization methods. | 6 | 10 – 15 |
| 4. | **Production Planning:** Plant site selection, layout and organization of pharmaceutical industrial. Vendor development capacity (plant, machine, human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix. | 6 | 15 – 20 |
| 5. | **Drugs and Cosmetics Act:** Requirement related to manufacturing and sale of drugs. | 4 | 10 – 15 |
| 6. | **Machinery Engineering:** Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handing for various pharmaceutical products. | 4 | 10 – 15 |
| 7. | **Safety:** Industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals, monitoring and preventive system. | 4 | 10 – 10 |
| 8. | **Effluent Testing and Treatment:** Pharmaceutical industry. | 4 | 10 – 15 |
| 9. | **Automation:** Flexible manufacturing system. Computer control systems: data acquizition, distribution control and centralized control system. Typical models for solid and liquid manufacturing. | 6 | 10 – 15 |

**Reference Books:**


1. A. Jaiswal: Management of quility control and standardization: Kanishka Pubisher, New Delhi.

2. B. Rothery: ISO 14000 and ISO 9000; Gower.

3. D. H. Stamatis: Understanding ISO 9000 and implementing the basics to quality: Marcel Dekker.

4. G. C. Cole: Pharmaceutical production facilities, design and application: Taylor and Francis.

5. J. F. Despautz: Automation and validation of information in Pharmaceutical processing: Marcel Dekker.

6. J. M. Juran and A. B. Godfrey: Juraris quality handbook: McGraw Hill.

7. J. R. Berry and R. A. Nashi Pharmaceutical process validation: Marcel Dekker.

8. P. Gilson. G. Green halgh and K. Kerr: Manufacturing management: Chapman and Hall.

9. P. R. Watt: Tablet machine instruments in pharmaceuticals; John Wiley and Sons.

10. R. F. Brewer: Design of Experiments for process improvement and quality Assurance: Narosa.

11. S. Bolton: Pharmaceutical statistical: Marcel Dekker.

12. S. H. Will and J. R. Stoker; Good Manufacturing Practices for Pharmaceutical: Marcel Dekker.

13. S. N. Katju's; Law and drugs: Law publishers (I) Pvt. Ltd.

14. S. S. Rao: Optimization theory and applications: Wiley Eastern Limited.

**10. QUALITY ASSURANCE Theory (3 hrs/wk. )**

| | | Hrs | Marks |
|---|---|---|---|
| 1. | Interpretations of current good manufacturing regulations | 4 | 08 – 10 |
| 2. | Auditing function in the Total control of Quality. | 4 | 08 – 10 |
| 3. | Process validation and control of components, containers & closures. | 5 | 10 – 15 |
| 4. | Production and process controls. | 5 | 10 – 15 |
| 5. | Packaging & Labelling control. | 3 | 07 – 10 |
| 6. | Laboratory controls. | 3 | 07 – 10 |
| 7. | Records and reports. | 3 | 07 – 10 |
| 8. | Returned and Salvaged Drug products. | 3 | 07 – 10 |
| 9. | Repacking and Re-labeling. | 3 | 07 – 10 |
| 10. | Recalls. | 3 | 07 – 10 |
| 11. | Problem Analysis and Corrective action Report. | 3 | 07 – 10 |
| 12. | Quality control of Biological -international Biological standards. | 3 | 07 – 10 |
| 13. | Safety testing, of Pharmaceutical Quality control of Antibiotics, Evaluation of sustained release products. | 3 | 07 – 10 |

**Reference Books:**


1. B. Othery. ISO 14000 and ISO 9000 Gower.
2. D. H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
3. J. Swarbrick Boylan, encyclopedia of pharmaceutical technology, Marcel and Dekker.
4. J. R. Berry and R. A. Nash, Pharmaceutical process validation. Marcel and Dekker.
5. R. F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
6. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
7. S. H. Will and J. R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.

**11. COSMETICOLOGY Theory (3 hrs/wk. )**

| | | Hrs | Marks |
|---|---|---|---|
| 1. | **Physiological Consideration:** Skin, hair, nail and eye- in relation to cosmetic application. | 4 | 10 – 15 |
| 2. | **Rheology of cosmetics:** Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, hair products, creams and lotions. | 4 | 10 – 15 |
| 3. | **Manufacturing techniques:** cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics. | 8 | 15 – 20 |
| 4. | **Evaluation of cosmetics: Performance**, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and anti-aging products. | 6 | 10 – 15 |
| 5. | **Clinical safety testing:** Irritation, sensitization, photoirritation, photoallergy, ocular irritation and protocols for the same. | 3 | 10 – 15 |
| 6. | **Regulatory requirements: Manufacturing** and sale of cosmetics. | 3 | 10 – 10 |
| 7. | **Herbal cosmetics:** Formulation development. | 4 | 10 – 15 |
| 8. | **Packaging:** Package development and design for cosmetics including aerosol packs. | 5 | 10 – 15 |
| 9. | **Advance in cosmetics:** Liposomes, multiple and micromulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses. | 8 | 15 – 20 |

**Reference Books:**


1. J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology Elsevier science publisher.
2. J. B. Wilkinson and R. J. Moore; Harry's cosmetology; Longman science and Technical.
3. S. N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
4. E. G. Thomssen; Modern cosmetics; Universal Publishing Corporation.
5. M. S. Balsam and E. Sagarin; Cosmetics, science and technology; John Wiley and Sons.
6. R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox.
7. H. R. Moskowitz; Cosmetic Product Testing; Marcel Dekker.
8. W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.
9. C. G. Gebelein, T. C. Cheng and V. C. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
10. L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
11. W. A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3 Chapman and Hall
12. Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

**12. PHYTOPHARMACEUTICALS Theory (3 hrs/wk. )**

| | | Hrs | Marks |
|---|---|---|---|
| | **Source**, phytochemistry (isolation, identification, chemical nature) and physiological activities of following phytopharmaceuticals. | | |
| 1. | **Anticancer:** Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide. | 12 | 26 – 36 |
| 2. | **Nervous system activities:** Hypericin, Valepotriates, Gingkolides. | 07 | 14 – 20 |
| 3. | **CVS activities:** Colenol, Streptokinase. | 05 | 12 – 16 |
| 4. | **Anti-inflammatory:** Curcuminoids, Guggulipids, Boswellic acid, Serratioptidase. | 08 | 18 – 24 |
| 5. | **Miscellaneous:** Silymarin, Artemisinin, Omega-3 fatty acids. | 06 | 14 – 20 |
| 6. | Charantin and momordicosides, Resveretrol, Protamine sulphate, prostaglandins. | 07 | 16 – 24 |

**Reference Books:**


1. Pharmacognosy : Trease and Evans, Bailliere & Tindall. 14th edth.
2. Pharmacognosy : Kokate, Puruhit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Biochemistry : Delvin.
4. Alkalods Edited by J. R. F. Manske.
5. Various Research Journals on Natural products and therapeutics.

## 13. STERILE PRODUCT FORMULATION AND TECHNOLOGY — Theory (3 hrs/wk. )

| | | Hrs | Marks |
|---|---|---|---|
| **A)** | **FORMULATIONS:** | | |
| 1. | **Preformulation:** Physico-chemical properties of materials used in perenteral formulations. Selection of polymeric components. Selection of packaging components. | 6 | 10 – 15 |
| 2. | **Formulation of SVP and LVP:** Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals. | 6 | 10 – 15 |
| 3 | **Ophthalmic Products:** Ocular anatomy and physiology relevant to ocular drug delivery, ocular pharmacokinetics, conventional products, ocular inserts, particulate and liposomal drug delivery, protein and prptide delivery. | 8 | 20 – 25 |
| 4 | **Sustained Release Parenterals: -** Liposomes, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes. | 12 | 30 – 40 |
| **B.** | **TECHNOLOGY: Manufacturing** | | |
| | **of Parenterals:** | | |
| 5. | Environmental control: Temperature and humidity control, air handing systems and their validation. | 4 | 10 – 15 |
| 6. | Industrial sterilization: Large scale sterilization processes, process selection, specifications, development and validation of process and equipment. | 4 | 10 – 15 |
| 7. | Guidelines: Overview of GMP and regulatory guidelines. | 5 | 10 – 15 |

**Reference Books:**

1. K. E. Avis, H. A. Liberman and Lanchman; Pharmaceutical dosage forms: Parenteral Medications: Vol. 1, 2, 3, Marcel Dekker.

2. S. J. Turco; Sterile dosage forms: their preparation and clinical application; Lee and Febiger.

3. N. K. Jain; Controlled and novel drug delivery: CBS Publication.

4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.

5. F. J. Carleton and J. P. Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.

6. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.

7. N. A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.

**14. FERMENTATION TECHNOLOGY Theory (3 hrs/wk. )**

| | | Hrs | Marks |
|---|---|---|---|
| 1. | **Industrial Microorganisms:** Source, characteristics, growth and genetics. | 5 | 10 – 20 |
| 2. | **Development of Industrial Fermentation Processes:** Screening, detection and assay of fermentation products, stick cultures, fermentation media, inoculum preparation, scale up of fermentations, increasing product yields, fermentation economics. | 10 | 20 – 30 |
| 3. | **Industrial Fermentor:** Batch and continuous operation, requirements and design of Fermentor, control mechanisms for temperature, pH and foam. Sterilization of fermentation equipment. Tank agitators, spargers, heating and cooling equipment. Materials for construction. | 10 | 20 – 30 |
| 4. | **Typical Fermentation Processes:**<br>• Antibiotic fermentation: Properties, Biosynthesis and Fermentation of Antibacterial antibiotics –Penicillin, tetracyclines, aminoglycosides, chloramphenicol and macrolides.<br>• Antifugals – Griseofulvin. Antiviral – Bacitracin, hamycin. Antibiotic Production by immobilized living cells.<br>• Enzyme Fermentation: Amylases, Proteolytic enzymes. Other Fermentation: Acetonebutanol, citric acid, glycerol, industrial alcohol, yeast and Vitamins. | 10 | 25 – 30 |
| 5. | **Downstream Processing :** Unit operations in downstream processing<br>• Harvesting: Sedimentation, centrifugation, filtration.<br>• Cell Disintegration: Nonmechanical method such as wet milling, high pressure homogenization, treatment extrusion and sonification.<br>• Clarification of crude extract.<br>• Product Entrichment: precipitation, ultrafiltration, extraction.<br>• Chromatography: Gel filtration, ion exchange, hydrophobic and affinity type | 10 | 25 – 30 |

**Reference Books:**

1. E. J. Vandamme; Biotechnology of Industrial Antibiotics; Marcel and Dekker.
2. H. J. Rahm and G. Reed : Biotechnology : Verlag Chaemie.
3. L. E. Casida: Industrial Microbiology: Wiley Eastern Limited.
4. G. REED: Prescott and Dunn's Industrial Microbiology: The AVI Publications.
5. Petal: Industrial Microbiology.

**15. QUALITY CONTROL Theory (3 hrs/wk. )**

| | | Hrs | Marks |
|---|---|---|---|
| 1. | Concept of Therapeutic equivalence and Pharmaceutical equivalence, General steps in Conduct and Analysis of Bioavailability and Bioequivalence Studies. | 3 | 09 – 10 |
| 2. | The basic concepts of Quality Assurance (QA), Good Manufacturing Practices (GMP), and quality control (QC), their relationships and their fundamental importance to the production and control of drugs. | 3 | 09 – 10 |
| 3. | Quality Risk Management: Introduction to Quality Risk Management (QRM), Scope, Principles of QRM, Risk management methodology, applications of QRM. | 2 | 06 – 10 |
| 4. | Pharmaceutical Quality System (PQS): ICH Quality Roadmap, Quality by Design (QbD), Introduction and scope, Management responsibility, Continual improvement of Process performance & Product quality, Continual improvement of PQS. | 5 | 15 – 20 |
| 5. | Stability testing of API and pharmaceutical products. Evaluation of stability data and stability data package for registration applications. | 4 | 12 – 15 |
| 6. | General considerations for clinical trials, Protection of clinical trial subjects, Scientific approaches in design and analysis, development methodology. | 3 | 09 – 10 |
| 7. | In-process quality control tests, introduction to Process Analytical Technology (PAT) as a framework for innovative pharmaceutical manufacturing and QA. | 3 | 09 – 15 |
| 8. | Evaluation of pharmaceutical container closure systems. Labeling for Human Prescription Drugs and Biological Products. Prescribing information, information necessary for the safe and effective use of a prescription drugs. Development of 'Package inserts' and 'Drug information leaflets. | 5 | 15 – 20 |
| 9. | Comparison of QC and QA aspects in International and National Pharmacopoeias. | 3 | 09 – 15 |
| 10. | Statistics in drug product development and regulatory approval processes. | 3 | 09 – 15 |

**Reference Books:**


1. Design and Analysis of Bioavailability and Bioequivalence studies by Shein-Chung Chow, Jen-Pei Liu, Biostatistics, New York, Marcel Dekker, 2000.

2. A WHO guide to good manufacturing practice (GMP) requirements, World Health Organization, Geneva, 1997.

3. Risk Assessment and Risk Management in the Pharmaceutical Industry Clear and Simple, James L. Vesper, PDA book store.

4. Pharmaceutical Quality Systems by Oliver Schmidt, Interpharm Press Inc, US.

5. Drug Stability: Principles and Practices (Drugs and the Pharmaceutical Sciences) by Jens T. Carstensen (Editor), Christopher Rhodes, M. Dekker, New York.

6. Principles of Clinical Research, by G. Ignazio, Routledge; 1 edition (March 30, 2001).

7. Guide to Clinical Trials, by Bert Spilker, Lippincott Williams & Wilkins; 1st edition 1991.

8. Process Analytical Technology: Books: Edited by Katherine A. Bakeev.

9. Introduction: Process Analytical Technology, http://www. fda. gov /cder/ OPS/PAT. htm.

10. Patient Package Insert as a Source of Drug Information Edited by M. Bogaert, R. v. d. Stichele, J. -M. Kaufman, R. Lefebvre, Excerpta Medica.

11. New Drug Approval Process, Fourth Edition, by Richard Guarino, Informa Healthcare, USA.

**16. IMMUNOPHARMACOLOGY AND IMMUNOASSAYS Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| **1. Basic Principles:** | 04 | 10-10 |
| ¾ Cells of the immune system. | | |
| ¾ Non specific immunity | | |
| ¾ The specific immunologic response Antigens and antigen-binding body | | |
| ¾ Immunologlobulines | | |
| ¾ The humoral immune response | | |
| ¾ The cellular immune response | | |
| ¾ The control of immune response | | |
| ¾ The complement system | | |
| **2. Pharmacological aspects of clinical conditions involving immunological mechanism** | 08 | 20-20 |
| ¾ Hypersensitivity | | |
| ¾ Delayed hypersensitivity | | |
| ¾ Immunomodulators | | |
| **3. Current concepts in therapy and research of drugs for:** | 16 | 30-50 |
| ¾ Acquired Immuno Deficiency Syndrome (AIDS) | | |
| ¾ Tissue transplantation (Immunosuppresants and immunoenhancers) | | |
| ¾ Cancer | | |
| ¾ Vaccines and sera | | |
| ¾ Antifertility drugs and vaccine | | |
| ¾ Drug allergy | | |
| **4. Methods for (invitro and invivo) evaluation of influencing immune system drugs** | 04 | 10-20 |
| **5. Immuno assays** | 08 | 20-30 |
| ¾ Radioimmunoassay (RIA), | | |
| ¾ Enzyme multiplied Immuno assay techniques (EMIT) | | |
| ¾ fluorescence polarization Immunoassay (FPIA) | | |

- ¾ Enzyme linked Immunosorbent Assay (ELISA)
- ¾ Apoenzyme - Reactivation Immunoassay (NIIA)
- ¾ Substrate labeled fluorescence immunoassay (SLFIA)
- ¾ Prosthetic group labeled Immunoassay (PGLI)
- ¾ Immunomodulators of Indigenous origin (plants)

**6. FcReceptors** 05 10-10

- ¾ Introduction, structure and function of antibodies, conformation of antibodies, Fc8R family,
- ¾ Proteins, transcripts and genes: Gene, structure and actions of high affinity Fc receptor *for* immunoglobulin E.
- ¾ Fc - receptor mediated killing
- ¾ Fc - receptor on T and B lymphocytes
- ¾ Immunoglobulin binding factors

**Reference Books:**

1. Kirkwood E and Catriona L. Understanding Medical Immunology (John Wiley and Sons New York)

2. Humphrey J. H. and White R. G. Immunology for students of Medicine (Blackwell Scientific Publication London)

3. Goodman and Gilmans. The pharmacological Basis of Therapeutics (9th Ed) McGraw Hill 1996.

**17. POLYMER TECHNOLOGY Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| 1. **General Study of Polymer Science:** | 10 | 25 – 35 |

Classification of polymers, Macromolecules: structure and properties (molecular mass, molecular weight distribution, conformation and configuration), Major strategies for synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsions polymerizations with examples. Methods of polymer modification, Solid state properties of polymers, flow characteristics, crystallinity.

| | | |
|---|---|---|
| 2. **Evaluation of Polymers in Solution**: | 05 | 15 – 25 |

Polymers in solutions: Solubility of polymers, methods of polymer characterization in solution (thermodynamics of polymer solutions), Viscosity and viscoelasticity of polymers, polyelectrolytes and polyampholytes, cross-linked polymers and polymer complexes.

| | | |
|---|---|---|
| 3. **Therapeutic Applications of Polymers:** | 07 | 20 – 25 |

Polymers for therapeutic applications, biocompatible and biodegradable polymers, biodegradability and biodegradability testing of polymers, applications of biodegradable polymers in parenterals and surgicals, polymer-drug conjugates, self-assembled polymeric carriers (polymeric micelles, polymer-coated liposomes, nanoparticles, microspheres, etc.)

| | | |
|---|---|---|
| 4. **Biointeractions of Polymers:** | 07 | 20 – 25 |

Interactions of polymers with tissues and cells, Pharmacokinetics of polymer therapeutics, targeted polymer therapeutics, passive targeting of polymeric drugs, enhanced permeation and retention effect (EPR), functional excipients and biological response modifiers, polymeric immunoadjuvants and immunomodulators, stimuli responsive systems and intracellular drug delivery.

| | | |
|---|---|---|
| 5. **Polymer Drugs** | 03 | 10 – 15 |

Prospects of polymer drugs and challenges in polymer therapeutics

| | | |
|---|---|---|
| 6. **Regulatory Issues Of Polymer Therapeutics** | 02 | 10 – 15 |

**Reference Books:**


1. J. Brandrup, E. H. Immergur; Polymer Handbook ;John wiley and Sons
2. L. H. Sperling, Introduction to Polymer Science, Wiley, NY, 1992.
3. H. Morawetz, Macromolecules in Solution (2nd ed. ), Wiley-Interscience, NY, 1975
4. C. Tanford, Physical Chemistry of Macromolecules, John Wiley, NY, 1961.
5. F. W. Billmeyer, Jr. , Textbook of Polymer Science, 3rd Ed. , J. Wiley, New York, 1984.
6. B. D. Ratner, A. S. Hoffman, F. J. Schoen, J. E. Lemons, Biomaterials Science. An Introduction to Materials in Medicine, Academic Press, San Diego, 1996.
7. Biomedical Polymers and Polymer Therapeutics, Eds. E. Chiellini et. al. , KluwerCharles G. Gebelein. T. C. Chin and V. C. Yang; Cosmetic and Pharmaceutical Applications of Polymers; Plenum Press, New work.
8. D. S. Soane; Polymer Applications for Biotechnology ; Prentice Hall Inc.
9. J. R. Robinson and V. H. Lee: Controlled Drug Delivery – Fundamentals and Application; Marcel Dekker.
10. N. K. Jain; Controlled and Novel Drug Delivery; CBS publications.
11. P. J. Tarcha; Polymers for controlled Drug Delivery; CRC Press.
12. A. F. Kydonieus; Controlled Release Technologies: Methods, Theory and Application, Vol-I & II; CRC Press Inc.
13. Academic/Plenum Publishers, NY, 2001.
14. Self-Assembling Complexes for Gene Delivery. From Laboratory to Clinical Trial. A. V. Kabanov,
15. P. L. Felgner, L. W. Seymour, Eds. , John Wiley & Sons: New York, 1998.

**18. CLINICAL PHARMACY** **Theory (3 hrs/wk.)**

| | Hrs | Marks |
|---|---|---|
| 1. **Introduction to Clinical Pharmacy** | 3 | 05 – 10 |
| • Scope objective & goals in healthcare | | |
| • Practice of Clinical Pharmacy in hospitals & community | | |
| 2. **FUNDAMENTALS OF DISEASES** | 510 | – 15 |
| • Symptoms & disease identification | | |
| • General Systemic effects of disease. | | |
| • CVS & other systemic effects of disease & injury. | | |
| • Endocrine & metabolic responses to disease & trauma. | | |
| • Nervous system involvement in disease. | | |
| • Communicable disease prevention | | |
| 3. **THERAPEUTIC USE OF MEDICINE** | 10 | 20 – 25 |
| *A. Drug Selection & Administration* | | |
| • Problems associated with concomitant therapy | | |
| • Patient sensitivities, allergies. | | |
| • Precautions during the use | | |
| • Diet control | | |
| *B. Reasons for noncompliance : -* | | |

- Poor standards of labeling, social isolation, complex therapeutic regimens, nature of medication, side effects.
- Lack of doctor / pharmacist / patient rapport
- Inadequate patient education.

*C. Strategies for Improving Compliance*

- Supplementary labeling, simplification of therapeutic regimens, patient counseling, use of warning cards, patient education, patient – package inserts.

*D. Use of drugs in Geriatric, Pediatric patients & in Pregnancy.*

4. **MONITORING THE PATIENT IN HEALTH & ILLNESS** 510 – 15

A.

- Fluid & electrolyte imbalance.
- Cardio-pulmonary dysfunction
- Metabolic disorders
- Patient follow-up.
- Discharge interview for hospitalized patients

B. Precautions & Directions during use of medication.

C. Pharmacological & biochemical examinations, their significance.

D. Supervision of therapeutic success, side effects & adverse effects.

5. **DRUG INFORMATION** 510 – 10

- Introduction to information resources available, development of drug information services, drug literature utilization, selection, evaluation & immunization

- Physician - Pharmacist interaction
- Pharmacist - patient interaction

6. **Therapeutic management of following diseases** 7 15 – 20

   a. *Cardiovascular diseases*

      i. Myocardial ischemia.

      ii. Miocardial infraction.

      iii. Conjestive cardiac failure

      iv. Cardiac arrhythmias

      v. Hypertension

      vi. Hyperlipidema

   b. *Renal disorders*

      i. Acute renal failure

      ii. Chronic renal failure

   c. *Respiratory disorders*

      i. Bronchial asthma

      ii. Chronic obstructive lung disease

7. **Clinical testing of drugs** 5 10 – 15

   Introduction, various phases, ICH guidelines, regulatory affairs.

8. **Statistical methods in pharmacy** 5 10 – 15

Mean, statistical analysis of data including various, standard derivation student 't' test ANOVA, of Non-parametric analysis, correlation of data & its interpretations. Bio-statistics for clinical trials.

9. **Examples: Based on above** 10 – 15

**Reference Books:**


1. Clinical pharmacy practice; C.W. Blissit
2. Clinical pharmacy & therapeutics; Walker Edwards, Churchill Livingston
3. Analysis drug treatment
4. TB of clinical pharmacology; James M. Ritter, Lionel D.
5. Drugs in Pregnancy & lactation; 4th Ed; Gerald, G Briggs, Roger K. Freeman, Williams & Wilkins.
6. Pharmaceutical & Medicine Information Management; Principles & Practice; Andrew S. Robson, Churchill - Livingston.
7. Computer & bio statistics: Paradkar
8. Handbook of Pharmacy Healthcare Diseases & Patient Advice; Ed; R.J. Harman, Pharmaceutical Press; London.
9. Patient care in community practice; R.J. Harman; Pharmaceutical Press, London.
10. Applied therapeutics for clinical pharmacists; Koda Kimble M.N, Applied Therapeutic Inc. San, Fransico.

**19. THERAPEUTIC DRUG MONITORING Theory (3 hrs/wk. )**

| | Hrs | Marks |
|---|---|---|
| **1. Fundamentals of diseases and drug therapy** | 05 | 05 – 10 |
| Symptoms and diseases identification, ADRs, prevention of communicable diseases, drug selection and administration, patient non compliance, strategy to improve the compliance | | |
| **2. Monitoring the patient in health and illness** | 04 | 10 – 15 |
| Fluid and electrolyte imbalance, cardio-pulmonary dysfunction, metabolic disorders, precautions and directions during used of medication, pharmacological and biochemical examinations | | |
| **3. Therapeutic management of diseases** | 06 | 10 – 15 |
| Cardiovascular, renal, respiratory and metabolic disorders | | |
| **4. INTRODUCTION TO THERAPEUTIC DRUG MONITORING** | 06 | 10 – 15 |
| ¾ Definition & introduction. | | |
| ¾ Indication for TDM & clinical applications. | | |
| ¾ Monitoring plasma drug levels. | | |
| ¾ Role of Clinical pharmacist in TDM. | | |
| **5. TECHNIQUES USED IN TDM** | 05 | 10 – 15 |
| a) Physical methods | | |
| HPLC, HPTLC, GC | | |
| b) Immuno assays. | | |
| RIA, ELISA, EMITH, NIIA | | |
| **6. IMPORTANCE OF TDM WITH REFERENCE TO ADVERSE DRUG REACTION** | 03 | 10- 10 |
| **7. VARIATION OF CLINICAL LABORATORY TESTS DUE TO DRUGS** | 06 | 10– 15 |
| **TESTS:** - | | |
| Serum Creatinine, blood urea, nitrogen, plasma, glucose, creatine kinase, phosphatase, amylase, bilirubin, serum proteins, globulines, complete blood count & differential blood count | | |

**8. TDM OF SPECIFIC DRUGS** 09 30 – 40

Clinical pharmacokinetics, general guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reactions & drug interactions, techniques used for estimation, importance of

| | | |
|---|---|---|
| 1. Digoxin | 2. Lithium | 3. Phenobarbitone |
| 4. Gentamicin. | 5. Theophylline | 6. Carbamazepine |
| 7. Lidocaine | 8. Phenytoin | 9. Valproic acid |

**9. Futuristic application of TDM** 02 05 – 10

TDM of antiretroviral and anti tubercular drugs

**Reference Books:**


1. Clinical pharmacy practice - C. W. Blissit.
2. Therapeutic drug monitoring - B. Widdop
3. TDM & Clinical biochemistry – Mike Hallworth
4. Textbook of therapeutics, Drug & disease management - 7th edition - Eric T. Herfindel, Dick. R. Gourley.
5. Recent developments in TDM & Clinical toxicology – I. Sunshine - Marcel – Dekker – 1992.
6. Handbook of TDM. – Simkin
7. TDM – Abbot

**Journal references**

8. Therapeutic drug monitoring
9. AIDS
10. Clinical pharmacology
11. New England Journal of Medicine