# C. U. SHAH UNIVERSITY

## With Effect from June 2014

**Faculty**: - Pharmaceutical Sciences
**Department**: All Discipline
**Semester: I**
**Name of Subject**: Modern Analytical Techniques (Theory)
**Subject Code**: 5PS01MAT2

**TEACHING & EVALUATION SCHEME:-**

| Sr. No | Branch Code | Subject Code | Subject Name | Teaching hours/ week | | | | Credit | Evaluation Scheme/ Semester | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Theory | | | | Practical | | | Total |
| | | | | Th | Tu | Pr | Total | | Sessional Exam | | University Exam | | Internal | | University | |
| | | | | | | | | | Marks | Hrs | Marks | Hrs | Pr | TW | Pr | |
| 1 | 5 | 5PS01MAT2 | Modern Analytical Techniques | 6 | - | 6 | 12 | 9 | 20 | 1 | 70 | 3 | 20 | -- | 70 | 200 |
| | | | | | | | | | 10 (CEC) | -- | | | 10 (CEC) | -- | | |

**OBJECTIVES:-**

- To make students familiar with the principles of modern analytical techniques and its application in pharmacy
- To give training in use of the technique & its applications in day to day practice
- To build on the basics learned at UG level & give latest advances in the area
- To give more stress on application based knowledge than instrumentation based one
- To give hands on training on use of as many different sophisticated instruments as possible

**PREREQUISITES:-**

- Minimum two UG level courses in Pharmaceutical analysis
- A B. Pharm. Degree from any AICTE approved institution or its equivalent

**COURSE OUTLINE:-**

| Sr. No. | Course Content | Hours |
|---|---|---|
| 1 | **UV – Visible spectroscopy:** Theory, chromophores and their interaction with EMR, solvent effects, instrumentation (components and their function) & applications including multi-component assay and derivative spectra. Woodward-Fieser and Fieser-Kuhn rules for calculating absorbance maximum and interpretation of spectra. | 10 |
| 2 | **Infrared spectroscopy:** Introduction, basic principles, instrumentation (components and their function), sampling techniques, interpretation of spectra and applications. Theory and applications of FTIR, ATR and NIR. | 10 |
| 3 | **Nuclear Magnetic Resonance Spectroscopy:** Fundamental principle and theory of proton NMR, instrumentation, solvents, chemical shift, spin-spin coupling, coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT- NMR, 2D-NMR, applications in pharmacy and interpretation of spectra.<br>13C NMR Spectroscopy: Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling and its structural applications. | 12 |
| 4 | **Mass Spectroscopy:** Basic principle and instrumentation, ion formation and | 10 |

| | | |
|---|---|---|
| | type, fragmentation process and fragmentation pattern, chemical ionization mass spectroscopy (CIMS), field ionization MS (FIMS), Fast atom bombardment MS (FAB-MS), matrix assisted laser desorption/ ionization MS (MALDI-MS), Interpretation of spectra and application in pharmacy, Surface Ionization MS(SIMS). | |
| 5 | **Flourimetry:** Principle Instrumentation and Application. | 02 |
| 6 | **X-Ray Diffraction & Optical Rotary Dispersion:** X-ray diffraction, Braggs Law, Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD. | 04 |
| 7 | **Thermal Methods of Analysis**: Thermo analytical techniques: Differential Scanning Colorimetry (DSC), Thermogravitry (TG), Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy. | 05 |
| 8 | **Chromatographic techniques:** Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation. Principles, elution techniques, instrumentation, derivatization and application of GC, HPLC, HPTLC. Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, Size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC),UPLC, GC-MS, short column chromatography, flash chromatography, medium pressure LC and LC-MS. | 22 |
| 9 | **Radio analytical techniques used in pharmaceuticals:** Isotopic dilution methods, Radioimmunoassay, ELISA etc. | 05 |
| 10 | **Electrophoresis:** Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications. | 04 |
| 11 | Application of Transmittance Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM). | 04 |
| 12 | Interpretation Problem based on Spectral Data | 02 |
| | Total | 90 |

# C. U. SHAH UNIVERSITY

## With Effect from June 2014

**Faculty**: - Pharmaceutical Sciences
**Department**: All Discipline
**Semester: I**
**Name of Subject**: Modern Analytical Techniques (Practical)
**Subject Code**: 5PS01MAT2

**Module-1:** UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures and isosbestic point in case of mixtures.
**Module-2:** Effect of solvents and pH on UV spectrum of drugs
**Module-3:** Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g. Vitamins, Oral antidiabetics, NSAIDs, Antimicrobials, Antihistamines, Antihypertensive etc.
**Module-4:** Experiments based on the application of derivative spectroscopy.
**Module-5:** Experiments based on HPLC (Isocratic and Gradient elution) techniques.
**Module-6:** Interpretation of drugs by IR spectra
**Module-7:** Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of few compounds
**Module-8:** Separation of protein drug substances by electrophoresis
**Module-9:** Use of fluorimeter for analysis of Pharmacopoieal compounds.
**Module-10:** Experiments of Chromatography. (a) Thin Layer Chromatography, (b) Paper Chromatography.
**Module-11:** Any other relevant experiments based on theory.

**LEARNING OUTCOMES:-**

- At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

**TEACHING & LEARNING METHODOLOGY:-**

- Faculty member/s shall explain in a class room using black board and multimedia projector.

**BOOKS RECOMMENDED:-**


1. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers Delhi
2. Chromatographic Analysis of Pharmaceuticals, A. John, Adamovics, Cytogan Corporation, Princeton, NJ.
3. Clarke's Analysis of Drugs and Poisons, A.C. Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press.
4. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
5. Handbook of Instrumental techniques for analytical chemistry, Frank Settle,1st edition, Pearson education, Singapore.
6. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
7. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, 2nd Edition, P. D. Sethi, CBS Publishers and Distributers, New Delhi.
8. Instrumental Methods of Analysis – Willard, Merritt, Dean, CBS, Delhi.

9. Instrumental Methods of Chemical Analysis, B.K. Sharma, Goel Publication House, Meerut, India.
10. Instrumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill Book Co, NY.
11. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
12. Modern Methods of Pharmaceutical Analysis, Vol 1, 2, RE Schirmer, Franklin Book Co, PA.
13. NMR spectroscopy (Basic Principles, concepts and application in Chemistry) Herald Gunther (John Wiley and Sons), NY..
14. Organic Spectroscopy – William Kemp, 3rd Edition.
15. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical formulations (VBS Publishers, Delhi).
16. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson 2001.
17. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th edition.
18. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
19. Remington's Pharmaceutical Sciences, J. P. Remington, Mack Pub. Co., Pennsylvania.
20. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morril (John Wiley and Sons. N.Y).
21. Spectroscopic identification of organic compounds. John Dyer, Willy, NY.
22. Spectroscopy of Organic Compounds by P. S. Kalsi.
23. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
24. Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.
25. United States Pharmacopoeia-27(NF-22), 2004, United State of Pharmacoppeal convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
26. British Pharmacopoeia, 2004, The British Pharmacopoeia commission office, Market Tower, Nine Elms Lane, London.
27. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission, Sector-23, Raj Nagar, Ghaziabad.

**E-RESOURCES:-**

1. www.jascoinc.com/
2. www.ssi.shimadzu.com
3. www.perkinelmer.com
4. www.phenomenex.com

# C. U. SHAH UNIVERSITY

## With Effect from June 2014

**Faculty**: - Pharmaceutical Sciences
**Department**: All Discipline
**Semester: I**
**Name of Subject**: Biostatistics (Theory)
**Subject Code**: 5PS01BST2

**TEACHING & EVALUATION SCHEME:-**

| Sr. No | Branch Code | Subject Code | Subject Name | Teaching hours/ week | | | | Credit | Evaluation Scheme/ Semester | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Theory | | | | Practical | | | |
| | | | | | | | | | Sessional Exam | | University Exam | | Internal | | University | Total |
| | | | | Th | Tu | Pr | Total | | Marks | Hrs | Marks | Hrs | Pr | TW | Pr | |
| 1 | 5 | 5PS01BST2 | Biostatistics | 4 | - | - | 04 | 4 | 15 | 1 | 35 | 2 | -- | -- | -- | 50 |

**OBJECTIVES:**

- To explain students with various Statistical Techniques used to draw conclusions in Experimental Research.
- To emphasize the use of these Techniques to address the problems and issues arising in the discipline of Pharmacy and to find their solutions using Statistical Software.

**PREREQUISITES:-**

- 10 + 2 level mathematics knowledge.
- B. Pharm. Degree from any institution approved by AICTE or its equivalent.

**COURSE OUTLINE:**

| Sr. No | COURSE CONTENTS | Hours |
|---|---|---|
| 01 | **Introduction:**<br>Relevance and the scope of Statistics.<br>Difference between 'Descriptive' and 'Inferential' Statistics; Relationship between them | 04 |
| 02 | **Test of hypothesis**<br>Concepts of hypothesis testing and types of errors. Point and interval estimation including fiducial limits, t-test, Chi square tests, f-test, Z-test.<br>**Non parametric test like:** Sign test, Mann-Whitney U test, Wilcoxon sign rank test, Kruskal wallis test | 22 |
| 03 | **Correlation and regression:**<br>Introduction and Theory, different method of correlation (graphical method, Person's product moment, correlation coefficients, Spearman rank correlation.<br>**Regression**:<br>Regression line, Determination of Regression coefficients, Multiple regression analysis | 14 |
| 04 | **ANOVA**<br>Introduction, One Way ANOVA, Two way ANOVA and it's statistical inferences | 08 |

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|---|---|---|
| 05 | **Experimental design in clinical trials;** Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies | 08 |
| 06 | Introduction to common software | 04 |
| | Total | 60 |

**LEARNING OUTCOMES:**

- Students will able to identify, analyze and solve problems related to biostatistics using statistical software.
- Students can apply biostatics application in order to understand various pharmaceutical process variables, understand significance effect on parameters in clinical trials

**TEACHING & LEARNING METHODOLOGY:**

- Lectures will be taken in class room with the aid of multi-media presentations / black board or mix of both.
- Assignments based on the course content will be given at the end of the topic.

**BOOKS RECOMMENDED:-**

1. Stanford Bolton, Charles Bon (2004), Pharmaceutical Statistics, Practical and Clinical Applications (Fourth rev. ed) Marcel Dekker, Inc
2. Dowdy, S., and Wearden, S. (1991), Statistics for Research (2nd ed.), New York: John Wiley.
3. Freund, R. J., and Wilson, W. J. (1997), Statistical Methods (rev. ed.), San Diego, CA: Academic Press
4. Miller, R. G., Efron, B., Brown, B. W., and Moses, L. E. (eds.) (1980), Biostatistics Casebook, New York: John Wiley.
5. Steel, R. G. D., and Torrie, J. H. (1980), Principles and Procedures of Statistics: A Biometrical Approach (2nd ed.), New York: McGraw-Hill.
6. Woolson, R. F. (1987), Statistical Methods for the Analysis of Biomedical Data, New York: John Wiley.
7. Wackerly DD, Mendenhall W, Schaeffer RL. Mathematical Statistics with Applications, 7th edition, 2008, Duxbury Press, USA
8. Piantadosi S. (2005), Clinical Trials a Methodological Perspective, 2nd edition. John Wiley & Sons.
9. Senn S. Cross-over trials in clinical research, 2nd edition. Wiley, 2002.
10. Jennison C. and B.W. Turnbull. Group sequential methods with applications to clinical trials. Chapman & Hall, 1999.

# C. U. SHAH UNIVERSITY

## With Effect from June 2014

**Faculty**: - Pharmaceutical Sciences
**Department**: Pharmaceutics & Pharmaceutical Technology
**Discipline**: 1) Pharmaceutics 2) Pharmaceutical Technology
**Semester: I**
**Name of Subject**: Fundamental of Formulation & Product Development (Theory) (Specialization-I)
**Subject Code**: 5PS01FPD2

**TEACHING & EVALUATION SCHEME:-**

| Sr. No | Branch Code | Subject Code | Subject Name | Teaching hours/ week | | | | Credit | Evaluation Scheme/ Semester | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Theory | | | | Practical | | | Total |
| | | | | | | | | | Sessional Exam | | University Exam | | Internal | | University | |
| | | | | Th | Tu | Pr | Total | | Marks | Hrs | Marks | Hrs | Pr | TW | Pr | |
| 1 | 5 | 5PS01FPD2 | Fundamental of Formulation & Product Development | 6 | - | 6 | 12 | 9 | 20 | 1 | 70 | 3 | 20 | -- | 70 | 200 |
| | | | | | | | | | 10 (CEC) | -- | | | 10 (CEC) | -- | | |

**OBJECTIVE:**

- To understand formulation development concept, like preformulation, excipients, stability and dissolution in order to develop safe, effective and stable dosages form.
- To give training at advanced level in preformulation studies of drugs & other requisite aspects.
- To give practical training to students in these aspects.

**PREREQUISITES**:-

1. Basic knowledge in Pharmaceutics.
2. B. Pharm. Degree from any institution approved by AICTE or its equivalent.

**COURSE OUTLINE:**

| Sr. No | COURSE CONTENTS | Hours |
|---|---|---|
| 01 | **Preformulation & dosages form design aspects:** Introduction, goals of preformulation, Detailed study of physical, chemical and pharmaceutical parameters influencing formulation of drugs. Compatibility tests. Significance and methods for evaluation of drug-excipient, excipient -excipient and drug containers/closures interactions and incompatibilities. | 09 |
| 02 | **Polymorphism in pharmaceutical solids:** Application of phase rule to the characterization of polymorphic systems, structural aspect of polymorphism, hydrates and solvents, generation of polymorphs, hydrates, solvates and amorphous solids, methods for the characterization of polymorphs and solvates, effect of polymorphism on solubility and dissolution rate, effect of pharmaceutical processing on drug polymorphs and solvates, impact of polymorphism on quality of lyophilized products. | 08 |
| 03 | **Partition Coefficient** Pharmaceutical significance of partition coefficient, correlation with in- | 08 |

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| | vivo performance, techniques to estimate log P values, shake flask method, choice of solvent systems, chromatographic determination, theoretical computation using Hansch & Leo/Rekker principle, effect of various variants like temperature, pH, etc. on partition coefficient. | |
| 04 | **Excipients:**<br>General considerations of excipients used in formulations and factors governing selection.<br>**Compatibility issues regarding Excipients:** drug-excipients and excipients - excipient, excipients-package interactions<br>**Safety and regulatory issues of excipients**<br>**International patented excipients.** Implication of quantitative selection of each excipient in product development.<br>**Study of novel Excipients:**<br>Superdisintegrants, directly compressible and spray dried diluents, film coating materials, solubilizing agents like surfactants, Cyclic Glucose Polymers, polymeric Excipients for controlled release applications, Improved excipients functionality by co processing, Standardization of excipients | 12 |
| 05 | **Biomaterials:**<br>Types, applications of biomaterials in pharmaceutical formulations & medicine, safety considerations of biomaterials, mechanism of biodegradation. | 06 |
| 06 | **Solubility and Solubilization**<br>Development of theoretical relationships of prognostic relevance, techniques of solubilization of drugs including surfactant systems, co-solvents, solid dispersions, complexation, inclusion complexes with reference to cyclodextrins, types of cyclodextrins, their pharmaceutical applications and chemical modifications. | 12 |
| 07 | **Dissolution & it's testing:**<br>**(a)** Importance, objectives, equipments,<br>**(b)** Biological classification system (BCS); its significance on dissolution study and application in dosage form development.<br>**(c)** Selection of dissolution media and conditions.<br>**(d)** Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods. | 12 |
| 08 | **Stability of drug & dosage forms:**<br>Degradation of drug in solid state & solid dosage forms, stabilization methods, importance of stability indicating assay in stability evaluation, stability evaluation of disperse systems.<br>Brief introduction to FDA and WHO guidelines. Detail study of ICH guidelines (Q1A, (R2), Q1B, Q1C, Q1D, Q1E, Q1F, Q5C).<br>Kinetic principles applied for stability evaluation and their applications in predicting shelf life and half life of pharmaceutical formulations. Importance of accelerated stability study. | 12 |
| 09 | **Herbal Product Development**<br>Background and present scenario, formulation considerations, major hurdles and challenges, future prospects. | 04 |

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|---|---|---|
| 10 | **Documentation**<br>Importance of documentation, statutory requirements and procedure for documentation, critical examination of documents. | 07 |
| | Total | 90 |

# C. U. SHAH UNIVERSITY

## With Effect from June 2014

**Faculty**: - Pharmaceutical Sciences
**Department**: Pharmaceutics & Pharmaceutical Technology
**Discipline**: 1) Pharmaceutics 2) Pharmaceutical Technology
**Semester: I**
**Name of Subject**: Fundamental of Formulation & Product Development (Practical) (Specialization-I)
**Subject Code**: 5PS01FPD2

**Detailed Syllabus (Practical):** To illustrate the topics included under theory

**LEARNING OUTCOME:**

- To develop the ability to effectively apply knowledge of excipients, dosage forms, preformulation, quality improvements, and documentation of pharmaceutical products and drug delivery systems.

**TEACHING & LEARNING METHODOLOGY:**

- Through discussion in a class-room, and performing experiments related to Product development studies.

**BOOKS RECOMMENDED:-**


1. Drug Stability, J. T. Carstensen, Marcel Dekker, New York
2. Theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publication, Bombay.
3. Modern Pharmaceutics, G.S. Banker and C.T. Rhodes, Marcel Dekker, NY.
4. Physical Characterization of Pharmaceutical Solids, H. G. Brittain, Marcel Dekker, NY.
5. Physical Pharmacy, A. Martin, Lea and Febiger, Philadelphia.
6. Pharmaceutical dissolution testing, U.V. Banaker, Marcel Dekker, Inc., New York.
7. Pharmaceutical Dosage Forms: Parenteral Medications, Avis K. E., Leon Lachman and H. Lieberman, Marcel Dekker, New York
8. Pharmaceutical Dosage Forms : tablets, Lieberman H. A. and Leon Lachman, , Marcel Dekker, New York
9. Oral lipid based formulations; D.J. Hauss, Informa Healthcare, New York
10. Polymorphism in Pharmaceutical solids: H.G. Britain, Marcel Dekker, New York
11. Biodegradable polymers as drug delivery systems, edited by M. Chasin, R. langer, Marcel Dekker, New York.
12. Handbook of Preformulations, S. K. Niazi, Informa Healthcare, New York.
13. Pharmaceutical Preformulations & Formulation, edited by Marks Gibson, Interpharm/CRC, Boca Raton, Florida, USA.


**E-RESOURCES:-**

1. www.fda.gov.org
2. On line journals

# C. U. SHAH UNIVERSITY

## With Effect from June 2014

**Faculty**: - Pharmaceutical Sciences
**Department**: Pharmaceutics & Pharmaceutical Technology
**Discipline**: 1) Pharmaceutics 2) Pharmaceutical Technology
**Semester: I**
**Name of Subject**: Biopharmaceutics, Pharmacokinetics & Methods in Drug Evaluation (Theory) (Specialization-II)
**Subject Code**: 5PS01BPM2

**TEACHING & EVALUATION SCHEME:-**

| Sr. No | Branch Code | Subject Code | Subject Name | Teaching hours/ week | | | | Credit | Evaluation Scheme/ Semester | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | Theory | | | | Practical | | | |
| | | | | | | | | | Sessional Exam | | University Exam | | Internal | | University | Total |
| | | | | Th | Tu | Pr | Total | | Marks | Hrs | Marks | Hrs | Pr | TW | Pr | |
| 1 | 5 | 5PS01BPM2 | Biopharmaceutics, Pharmacokinetics & Methods in Drug Evaluation | 6 | - | - | 06 | 6 | 20<br>10 (CEC) | 1<br>-- | 70 | 3 | -- | -- | -- | 100 |

**OBJECTIVES:-**

- To Study the absorption, metabolism, distribution and excretion of drugs. The primary goal of the course related to pharmacokinetics is to provide a conceptual and quantitative background in pharmacokinetic theory and applications. This will be indispensable to pursue studies in clinical pharmacokinetics and which in terns help in drug delivery system design and development of pharmaceutical formulations.
- To familiar students about evaluation of drugs by various methodology in pharmacy.

**PREREQUISITES:-**

- B. Pharm. degree from any AICTE approved institution or its equivalent

**COURSE OUTLINE:**

| Sr. No | COURSE CONTENTS | Hours |
|---|---|---|
| 01 | **ADME Characteristics of drug:**<br>• Drug Absorption: General consideration, absorption / drug transport mechanisms, role of sorption promoters, factors affecting absorption, absorption of drug of through routes other then oral, in-vitro, in-situ, in-vivo and cell line (Caco – 2) study methods of determining absorption.<br>• Drug Distribution: Factors affecting drug distribution, protein & tissue binding, Apparent volume of drug distribution<br>• Drug Metabolism (Biotransformation): Biotransformation, factors affecting biotransformation, Phase I & Phase-II reactions<br>• Drug Excretion: Glomerular filtration, tubular secretion, tubular reabsorption, Factors affecting drug excretion. | 12 |
| 02 | **Pharmacokinetics:**<br>• One compartment and two compartments open model: i.v. bolus administration, i.v. infusion, extra vascular administration<br>• Multicompartment model<br>• Application of Pharmacokinetics: new drug development, Design of | 12 |

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|---|---|---|
| | dosage forms and novel drug delivery systems, Case studies based on pharmacokinetic principles<br>• Determination of various pharmacokinetic parameters<br>• Absorption rate constant, elimination rate constant, biological half life, % drug<br>• metabolized, apparent volume of distribution, excretion rate constant, Clearance ( including the concept of renal & non-renal clearance), Kinetics of protein binding and other Pharmacokinetic parameters<br>• Softwares used for determination of pharmacokinetic parameters<br>**Pharmacokinetics of Multiple Dosing:**<br>• Adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring, Kinetics of sustained release | |
| 03 | **Non-linear Pharmacokinetics:**<br>Causes of non-linearity, estimation of various parameters and bioavailability of drugs that follow non-linear kinetics | 04 |
| 04 | **Bioavailability & Bioequivalence:**<br>Objectives of bio-availability & bioequivalence studies, Measurements of bio-availability, Concept of Bioequivalence, Experimental Designs in Bioequivalence study (Cross over, Latin Square, Balance incomplete block design etc), Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems | 09 |
| 05 | **In-vitro In-vivo Correlation (IVIVC):**<br>Concept, Methods of establishing IVIVC, Factors effecting IVIVC. Application of IVIVC for biowaivers of immediate release dosage forms. IVIVC for Sustain Release and controlled release dosage forms | 10 |
| 06 | Guideline for the use and care of laboratory animals. | 04 |
| 07 | **Toxicological evaluation of new chemical entities:**<br>Acute, sub acute and chronic toxicity studies, teratogenicity, mutagenicity and carcinogenic studies. | 04 |
| 08 | Techniques in the estimation of enzyme and the endogenous substances in the body fluids in physiological and pathological condition. | 04 |
| 09 | **Biological evaluation of following classes of drugs**:<br>(Development of models for disease: in vivo models / in vitro models / cell line studies). Analgesic, anti-inflammatory, antiepileptic, antidiabetic, antifertility, antihypertensive, antidyslipidaemic, anticancer, antiasthmatic, antiviral, antibacterial, antifungal, antiparasitic, antiulcer, hepatoprotective, immunomodulatory. | 20 |
| 10 | **Bioassay of various hormones.** New approach in drug discovery (High throughput Screening-HTS). | 05 |
| 11 | Good Clinical Practice (GCP): ICH guidelines (E6R1) | 06 |
| | Total | 90 |

**LEARNING OUTCOMES:**

- Students will be able to predict the effects of various physicochemical, biochemical, physiological and pathological processes on the kinetics and extent of drug absorption, distribution, and elimination.

- Student will be able to learn the basic techniques to evaluate drugs using various animal models for different pathological conditions.

**TEACHING & LEARNING METHODOLOGY:**

- Faculty member/s shall explain in a class room using black board and multimedia projector

**BOOKS RECOMMENDED:-**

1. Pharmacokinetics, M Gibaldi, Marcel Dekker, Inc., New York.
2. Remington's Pharmaceutical Sciences, Mack publishing company, Pennsylvania.
3. Biopharmaceutics and Pharmacokinetics- A Treatise, D.M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi.
4. Clinical Pharmacokinetics, Concepts and Applications, M. Rowland and T. N. Tozer, Lippincott Williams & Wilkins, Philadelphia
5. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; Robert. E. Notari, Marcel Dekker Inc, New York
6. Encyclopedia of Pharmaceutical Technology, James Swarbrick and C.Boylan, Marcel Dekker Inc, New York,
7. Pharmaceutical dissolution testing, U.V. Banaker, Marcel Dekker, Inc., New York.
8. The United States Pharmacopoeia-27 (NF-22),2004, United State of Pharmacopeial convention, INC, 12601 Twinbrook Parkway, Rockville, MD 20852.
9. Applied Biopharmaceutics and pharmacokinetics, Leon Shargel, Mc Graw Hill,
10. Pharmacokinetics, Welling and Tse, Marcel Dekker, Inc., New York.
11. Biopharmaceutics and Clinical Pharmacokinetics, Niazi, Prentice Hall, London
12. Dose finding in Drug Development, N. Ting, Springer, U.K.
13. Drug disposition & Pharmacokinetics, S.H. Curry, Pharma Med Press , Hyderabad
14. Introduction of Biopharmaceutics & Pharmacokinetics, H. P. Tipnis and M. S. Nagarsenkar, Nirali Prakashan, Pune.
15. Textbook of Biopharmaceutics & Pharmacokinetics, Javed Ali, R. K. Khar and Alka Ahuja, Birla Publication, Delhi.
16. Biopharmaceutics & Pharmacokinetics, Venkateshwarlu, India
17. Drug discovery and evaluation: Pharmacological assays, H. Gerhard Vogel, 2nd edition, 2002.
18. Screening methods in pharmacology Vol-1 & 2, Robert Arnold Turner, 1971, Academic Press.
19. Fundamental of experimental pharmacology, M.N. Ghosh, 971, Scientific Book Agency.
20. Quality control of herbal drugs: an approach to evaluation of botanicals, Pulok K. Mukherjee, 2002, Business horizons.
21. Relevant articles from journals.
22. Drug Bioscreening: Drug evaluation techniques in Pharmacology, Emmanuel B. Thompson, 1990, VCH publisher.
23. Drug absorption studies: in situ, in vitro and in silico models, By Carsten Ehrhardt, Kwang-Jin Kim, 2008.

**E-RESOURCES:-**

1. www.fda.gov
2. http://www.ich.org