

# Drug Metabolism and Pharmacokinetics in Drug Discovery: A Primer For Bioanalytical Chemists, Part II

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The first in this series of articles examined general aspects of drug metabolism (1). In Part II we will discuss the general pharmacokinetics principles and parameters and how some of those parameters can be estimated from the *in vitro* drug metabolism data we discussed in Part I.

Pharmacokinetics (PK) is the quantitative study of the time course of drug absorption, distribution, metabolism and elimination (ADME). This also includes the relationship of ADME to the intensity and time course of therapeutic and toxicological effects of drugs or chemicals. Pharmacokinetic data is very useful in optimization of the dosage form

*The rapidly evolving drug discovery process requires the analytical chemist to design new analytical procedures that maximize the efficiency of lead compound selection. Pre-clinical pharmacokinetics studies are an essential tool to weed out failures early on in the discovery process. Part I of this two-part series described the fundamentals of drug metabolism. This article, Part II of the series introduces the analytical chemist to the pharmacokinetics aspects and prediction of pharmacokinetic parameters from *in vitro* drug metabolism data.*

design and establishing the dosage interval. Pharmacodynamics (PD) of a drug describes the relationship between the dose and the pharmacological effect at the site of action.

When a drug is administered, it distributes rapidly from its administration site into the systemic blood circulation. The drug is distributed between plasma and red blood cells in the blood. Low molecular weight drugs can easily reach the extracellular fluid of every organ in the body rather quickly. Most lipophilic drugs cross cell membranes into the intracellular fluid and distribute in various tissues. Since distribution of a drug is rapid and reversible, changes in the concentration of a drug in plasma reflect the changes in the concentration of the drug in other tissues.

## Pharmacokinetic Profile

Intravenously administered drugs distribute very rapidly throughout the body without an absorption step. For other routes of administration,

absorption needs to be considered. When the drug reaches the systemic circulation it can undergo both elimination and distribution. Elimination can be by metabolism or by excretion. Elimination processes are irreversible and responsible for the removal of the drug from the body. Each of these processes is associated with a rate constant. Rate constants associated with distribution are much greater than the elimination rate constants. Rates of these processes govern the plasma drug concentrations at any given time. A plot of plasma drug concentration versus time is known as a pharmacokinetic profile. An example is shown in **Fig. 1**.

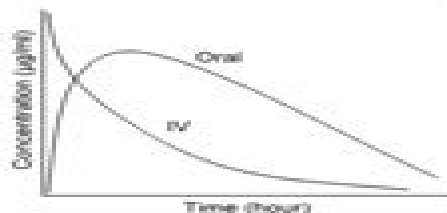
Elimination of a drug at equilibrium generally follows first order kinetics. The elimination rate decreases as the drug concentration decreases and this relationship is given by **Eq. 1**, where  $K$  is the first order rate constant.

$$dC_p/dt = -KC_p \quad (1)$$

Integration of **Eq. 1** gives

## Fig. 1

Schematic representation of pharmacokinetic profiles for intravenous and oral doses.



# Drug Metabolism Pharmacokinetics In Drug Discovery A

**Wen Xie**



## **Drug Metabolism Pharmacokinetics In Drug Discovery A:**

**Drug Metabolism and Pharmacokinetics Quick Guide** Siamak Cyrus Khojasteh,Harvey Wong,Cornelis E.C.A. Hop,2011-04-07 Drug Metabolism and Pharmacokinetics Quick Guide covers a number of aspects of drug assessment at drug discovery and development stages topics such as pharmacokinetics absorption metabolism enzyme kinetics drug transporters drug interactions drug like properties assays and in silico calculations It covers key concepts with useful tables on physiological parameters eg blood flow to organs in x species expression and localization of enzymes and transporters chemical structure nomenclature and moieties leading to bioactivation with examples Overall it includes a number of key topics useful at the drug discovery stage which would serve as a quick reference with several examples from the literature to illustrate the concept New Horizons in Predictive Drug Metabolism and Pharmacokinetics Alan G E Wilson,2015-11-20 Drug metabolism pharmacokinetics and toxicokinetics as determinants of drug attrition and the safety of xenobiotics are critically important This book presents a comprehensive treatise on the current issues and challenges facing drug metabolism and pharmacokinetics Readers will find a thorough exploration of their predictive role in impacting drug discovery and development and in improving the success rate and safety assessment of pharmaceuticals and industrial or occupational chemicals Chapters not only focus on the current state of art with distinct examples but on future needs and approaches likely to improve our prediction of potential human risk Discussions of critical properties that are determinants of a compound s metabolic and pharmacokinetic fate follow introductory chapters The Drug Discovery process increasingly incorporates pharmacokinetics and drug metabolism screening and focus has shifted towards in silico computational and systems biology approaches Core chapters reflect this and the recent interest and need to assess the role of transporters along with drug metabolizing enzymes as potential determinants of pharmacokinetic behaviour toxicity and drug drug interactions Lastly chapters cover the issues and factors involved in translating pharmacokinetics from in silico to in vivo and from animal models to man and postulate future directions and opportunities Leading experts from academia industry and regulatory bodies across the globe contribute their knowledge to this book which scientists involved in many aspects of the drug discovery process as well as regulators and postgraduate students will find a useful resource **Pharmacokinetics and Metabolism in Drug Design** Dennis A. Smith,Charlotte Allerton,Amit S. Kalgutkar,Han van de Waterbeemd,Don K. Walker,2012-09-13 In this new edition of a bestseller all the contents have been brought upto date by addressing current standards and best practices in the assessment and prediction of ADMET properties Although the previous chapter layout has been retained substantial revisions have been made with new topics such as pro drugs active metabolites and transporters covered in detail in a manner useful to the Drug Discovery scientist The authors discuss the parameters and processes important for the absorption distribution and retention of drug compounds in the body plus the potential problems created by their transformation into toxic byproducts While aimed at all those dealing professionally with the development

and application of pharmaceutical substances the readily comprehensible style makes this book equally suitable for students of pharmacy and related subjects Uniquely comprehensive the book relates physicochemistry and chemical structure to pharmacokinetic properties and ultimately drug efficacy and safety

**Pharmacokinetics in Drug Development** Peter L. Bonate, Danny R. Howard, 2011-02-21 The topics chosen for this volume were selected because they are some of the current development or technological issues facing drug development project teams They regard the practical considerations for assessment of selected special development populations For example they include characterization of drug disposition in pregnant subjects for measuring arrhythmic potential for analysis tumor growth modeling and for disease progression modeling Practical considerations for metabolite safety testing transporter assessments Phase 0 testing and development and execution of drug interaction programs reflect current regulatory topics meant to address enhancement of both safety assessment and early decision making during new candidate selection Important technologies like whole body autoradiography digital imaging and dried blood spot sample collection methods are introduced as both have begun to take a more visible role in pharmacokinetic departments throughout the industry

**Pharmacokinetics and Metabolism in Drug Design** Dennis A. Smith, Han van de Waterbeemd, Don K. Walker, 2006-05-01 In this new edition of a bestseller all the contents have been updated and new material has been added especially in the areas of toxicity testing and high throughput analysis The authors all of them employed at Pfizer in the discovery and development of new active substances discuss the significant parameters and processes important for the absorption distribution and retention of drug compounds in the body plus the potential problems created by their transformation into toxic byproducts They cover everything from the fundamental principles right up to the impact of pharmacokinetic parameters on the discovery of new drugs While aimed at all those dealing professionally with the development and application of pharmaceutical substances the readily comprehensible style makes this book equally suitable for students of pharmacy and related subjects

**Evaluation of Drug Candidates for Preclinical Development** Chao Han, Charles B. Davis, Binghe Wang, 2010-01-19 Emphasizes the integration of major areas of drug discovery and their importance in candidate evaluation It is believed that selecting the right drug candidate for development is the key to success In the last decade pharmaceutical R D departments have integrated pharmacokinetics and drug metabolism pharmacetics and toxicology into early drug discovery to improve the assessment of potential drug compounds Now Evaluation of Drug Candidates for Preclinical Development provides a complete view and understanding of why absorption distribution metabolism excretion toxicology ADMET plays a pivotal role in drug discovery and development Encompassing the three major interrelated areas in which optimization and evaluation of drug developability is most critical pharmacokinetics and drug metabolism pharmacetics and safety assessment this unique resource encourages integrated thinking in drug discovery The contributors to this volume Cover drug transporters cytochrome P 450 and drug drug interactions plasma protein binding stability drug formulation preclinical safety assessment

toxicology and toxicokinetics Address developability issues that challenge pharma companies moving beyond isolated experimental results Reveal connections between the key scientific areas that are critical for successful drug discovery and development Inspire forward thinking strategies and decision making processes in preclinical evaluation to maximize the potential of drug candidates to progress through development efficiently and meet the increasing demands of the marketplace Evaluation of Drug Candidates for Preclinical Development serves as an introductory reference for those new to the pharmaceutical industry and drug discovery in particular It is especially well suited for scientists and management teams in small to mid sized pharmaceutical companies as well as academic researchers and graduate students concerned with the practical aspects related to the evaluation of drug developability

**Pharmacokinetics in Drug Development** Peter L. Bonate,2005-12-05 These volumes are designed to be the most complete guide to pharmacokinetics PK and its role in drug development They fill a gap between the academic science and the practical application of that knowledge in drug development Volume 1 discusses the role that PK plays in selected clinical study designs Volume 2 details the key regulatory and development paradigms in which PK supplements decision making during drug development

**Drug Metabolism and Pharmacokinetics** Liang Shen,WuXi AppTec DMPK,2025-07-09 Practical state of the art pharmacokinetic research methods ideas advancements applications and strategies Drawing on a wealth of extensive practical experience and theoretical research Drug Metabolism and Pharmacokinetics encapsulates the most recent advancements and illustrative applications in the field Sixty eight relatively independent yet interconnected articles are included each offering a unique perspective and providing in depth interpretation Readers can either read systematically or select specific topics of interest from the table of contents Basic concepts frontier advancements DMPK research strategies and technical methods are covered for novel drug modalities and therapeutics in different disease areas The book encompasses a wide range of application and validation cases for DMPK research including studies in in vitro ADME in vivo pharmacokinetics metabolite profiling and identification radiolabeled ADME and bioanalysis Case studies showing the application of topics covered are included throughout along with valuable insights into problem solving and critical thinking Written by a team of scientists specializing in DMPK research from the DMPK Department of WuXi AppTec Drug Metabolism and Pharmacokinetics discusses sample topics including ADME properties metabolite identification and bioanalytical strategies for oligonucleotide drugs Strategies and challenges in the determination of drug to antibody ratio DAR values of antibody drug conjugates ADCs Breaking barriers in CNS drug development with intrathecal and intracerebroventricular administration Application and detection techniques of biomarkers in drug development Flux dialysis method for assessing plasma protein binding of high protein binding drugs Drug Metabolism and Pharmacokinetics is an essential forward thinking reference on the subject for pharmacy students pharmaceutical industry researchers and DMPK scientists especially those exploring novel drug modalities

**Drug Metabolism in Drug Design and Development** Donglu Zhang,Mingshe Zhu,William G. Humphreys,2007-11-16 The

essentials of drug metabolism vital to developing new therapeutic entities Information on the metabolism and disposition of candidate drugs is a critical part of all aspects of the drug discovery and development process Drug metabolism as practiced in the pharmaceutical industry today is a complex multidisciplinary field that requires knowledge of sophisticated analytical technologies and expertise in mechanistic and kinetic enzymology organic reaction mechanism pharmacokinetic analysis animal physiology basic chemical toxicology preclinical pharmacology and molecular biology With chapters contributed by experts in their specific areas this reference covers Basic concepts of drug metabolism The role of drug metabolism in the pharmaceutical industry Analytical techniques in drug metabolism Common experimental approaches and protocols Drug Metabolism in Drug Design and Development emphasizes practical considerations such as the data needed the experiments and analytical methods typically employed and the interpretation and application of data Chapters highlight facts common protocols detailed experimental designs applications and limitations of techniques This is a comprehensive hands on reference for drug metabolism researchers as well as other professionals involved in pre clinical drug discovery and development

**A Handbook of Bioanalysis and Drug Metabolism** Gary Evans, 2021-10-08 Recent years have seen a greater industrial emphasis in undergraduate and postgraduate courses in the pharmaceutical and chemical sciences However textbooks have been slow to adapt leaving the field without a text reference that is both instructional and practical in the industrial setting until now A Handbook of Bioanalysis and Drug Metabolism is a stimulating new text that examines the techniques methodology and theory of bioanalysis pharmacokinetics and metabolism from the perspective of scientists with extensive professional experience in drug discovery and development These three areas of research help drug developers to optimize the active component within potential drugs thereby increasing their effectiveness and to provide safety and efficacy information required by regulators when granting a drug license Professionals with extensive experience in drug discovery and development as well as specialized knowledge of the individual topics contributed to each chapter to create a current and well credentialed text It covers topics such as high performance liquid chromatography protein binding pharmacokinetics and drug drug interactions The unique industrial perspective helps to reinforce theory and develop valuable analytical and interpreting skills This text is an invaluable guide to students in courses such as pharmaceutical science pharmacology chemistry physiology and toxicology as well as professionals in the biotechnology industry

**Pharmacokinetics in Drug Discovery and Development** Ronald D. Schoenwald, 2002-03-06 Pharmacokinetics has evolved from its origin into a complex discipline with numerous subspecialties and applications in patient management drug development and regulatory issues This expansion has made it difficult for any one individual to become a full fledged expert in all areas Fulfilling the need for a wide ranging guide to the many existing subspecialties in this field Pharmacokinetics in Drug Discovery and Development details the different areas in the field providing the ideal comprehensive quick access text and reference After an introduction of basic principles the book is divided into sections that cover industrial and regulatory

applications clinical applications and research applications The following sections cover such topics as PK PD approaches clinical pharmacokinetic monitoring population pharmacokinetics linear systems approaches and more Fourteen authors each an expert in his her area of expertise provide an extensive background into the subspeciality with emphasis on the section s theme Covering the many sub disciplines and providing pharmacokinetic concepts terminology and approaches Pharmacokinetics in Drug Discovery and Development serves as a resource for professionals throughout this field

Introduction to Drug Disposition and Pharmacokinetics Stephen H. Curry, Robin Whelpton, 2016-12-08 The application of knowledge of drug disposition and skills in pharmacokinetics are crucial to the development of new drugs and to a better understanding of how to achieve maximum benefit from existing ones The book takes the reader from basic concepts to a point where those who wish to will be able to perform pharmacokinetic calculations and be ready to read more advanced texts and research papers The book will be of benefit to students of medicine pharmacy pharmacology biomedical sciences and veterinary science including those who have elected to study the topic in more detail such as via electives and special study modules It will be of benefit to those involved in drug discovery and development pharmaceutical and medicinal chemists as well as budding toxicologists and forensic scientists who require the appropriate knowledge to interpret their findings and as an introductory text for clinical pharmacologists Early chapters describe the basic principles of the topic while the later ones illustrate the application of those principles to modern approaches to drug development and clinical use Full colour illustrations facilitate the learning experience and supporting material for course leaders and students can be found on the Companion Web Site Another book on PK Yes and there should be and it should be DD PK It is good unique and does fill a currently unmet need for those working in the xenobiotic arena DD PK is just like the perfect mystery novel the one you just can t put down However unlike a mystery novel which requires only one reading to find the answer the reader of DD PK will learn more than an answer to a single question The reader will find many solutions to a wide variety of mysterious problems associated with the time course and actions of xenobiotics International Journal of Toxicology John A Budny PhD President PharmaCal Ltd 2018 This book has many innovations that make a welcome addition to the bookshelves of a wide range of pharmaceutical scientists The effective use of figures and tables to summarize and clarify a wide range of issues is to be commended as are the learning objectives at the start of the chapter coupled with the summary at the end providing a succinct way in understanding the objectives of the chapter and together with links to a website provides accessibility for all from the neophyte pharmacokineticist to the consultant physician A book all in the Pharma industry should be aware of Int J of Pharmacokinetics Howard M Hill ResolvPharma 2018 Overall Introduction to Drug Disposition and Pharmacokinetics offers its readership an in depth view of classic pharmacokinetic concepts This book would be an excellent choice for a pharmacokinetics elective or as an adjunctive text for an introductory course This book reviews a wide array of clinically relevant topics and encourages the reader to apply the knowledge gained to all medi cations A robust and varied amount of

online material is provided to enhance understanding and encourage discussion It is likely that all readers novice or experienced pharmacists would find value in this textbook Currents in Pharmacy Teaching and Learning Milena McLaughlin Midwestern University Chicago College of Pharmacy 2018 In summary this is an excellent textbook for students new to the field of pharmaceuticals and medical pharmacy and veterinary students particularly those who envision a career in drug development research in either academia or industry Veterinary Pathology Review John K Amory University of Washington 2018 Drug Metabolism in Diseases Wen Xie,2016-09-12 Drug Metabolism in Diseases is a comprehensive reference devoted to the current state of research on the impact of various disease states on drug metabolism The book contains valuable insights into mechanistic effects and examples of how to accurately predict drug metabolism during these different pathophysiological states Each chapter clearly presents the effects of changes in drug metabolism and drug transporters on pharmacokinetics and disposition This is a unique and useful approach for all those involved in drug discovery and development and for clinicians and researchers in drug metabolism pharmacology and clinical pharmacology Written and edited by leaders in drug metabolism from academia and industry Covers important topics such as pharmacogenomics drug metabolism in transplant patients xenobiotic receptors drug metabolism in geriatric and pediatric populations and more Highlights topics of importance in drug discovery and development and for safe and effective drug use in the clinic

Metabolism, Pharmacokinetics and Toxicity of Functional Groups Dennis A Smith,2010-04-09 Until now the area of drug metabolism and pharmacokinetics has been lacking in texts written for the Medicinal Chemist This outstanding book aimed at postgraduate medicinal chemists and those working in industry fills this gap in the literature Written by medicinal chemists and ADMET scientists with a combined experience of around 300 years this aid to discovering drugs addresses the absorption distribution metabolism excretion and toxicity ADMET issues associated with drugs The book starts by describing drug targets and their structural motifs before moving on to explain ADMET for the medicinal chemist It is the functional groups which most profoundly influence the drug molecules of which they form a part They characterise the pharmacology are essential to the activity and alter the ADMET characteristics of each drug Their effects follow a pattern thus allowing medicinal chemists to predict and overcome potential challenges For this reason the Editors have taken the unique approach of dividing the remainder of the book into chapters which each focus on a different functional group They describe drugs containing the functional group under consideration explain why the group is there and outline its physicochemical properties before going on to detail the ADMET issues Where possible prodrugs and bioisosteres which may give alternative ADMET outcomes are described The chapters cross refer where similar matters are covered but individual chapters can be used in a stand alone manner The book ends with a discussion of future targets and chemistry needs *Mass Spectrometry in Drug Metabolism and Disposition* Mike S. Lee,Mingshe Zhu,2011-03-16 This book examines the background industrial context process analytical methodology and technology of metabolite identification It emphasizes the applications of



metabolite identification in drug research While primarily a textbook the book also functions as a comprehensive reference to those in the industry The authors have worked closely together and combine complementary backgrounds to bring technical and cultural awareness to this very important endeavor while serving to address needs within academia and industry It also contains a variety of problem sets following specific sections in the text

**Applications of Pharmacokinetic Principles in Drug Development** Rajesh Krishna,2012-12-06 This volume is an important advancement in the application of pharmacokinetic PK and pharmacodynamic PO principles to drug development The series of topics presented deal with the application of these tools to everyday decisions that a pharmaceutical scientist encounters The ability to integrate these topics using PK and PO methods has optimized drug development pathways in the clinic New technologies in the areas of in vitro assays that are more predictive of human absorption and metabolism and advancement in bioanalytical assays are leading the way to minimize drug failures in later more expensive clinical development programs of Pharmacokinetics and pharmacodynamics have become an important component understanding the drug action on the body and is becoming increasingly important in drug labeling due to its potential for predicting drug behavior in populations that may be difficult to study in adequate numbers during drug development The ability to correlate drug exposure to effect and model it during the drug development value chain provides valuable insight into optimizing the next steps to derive maximum information from each study These principles and modeling techniques have resulted in an expanded and integrated view of PK and PO and have led to the expectations that we may be able to optimally design clinical trials and eventually lead us to identifying the optimal therapy for the patient while minimizing cost and speeding up drug development There is wide utility for the book both as a text and as a reference

Drug Metabolism, Pharmacokinetics and Bioanalysis Hye Suk Lee,Kwang-Hyeon Liu,2019-06-12 Drug metabolism pharmacokinetics and drug interaction studies have been extensively carried out in order to secure the druggability and safety of new chemical entities throughout the development of new drugs Recently drug metabolism and transport by phase II drug metabolizing enzymes and drug transporters respectively as well as phase I drug metabolizing enzymes have been studied A combination of biochemical advances in the function and regulation of drug metabolizing enzymes and automated analytical technologies are revolutionizing drug metabolism research There are also potential drug drug interactions with co administered drugs due to inhibition and or induction of drug metabolic enzymes and drug transporters In addition drug interaction studies have been actively performed to develop substrate cocktails that do not interfere with each other and a simultaneous analytical method of substrate drugs and their metabolites using a tandem mass spectrometer This Special Issue has the aim of highlighting current progress in drug metabolism

pharmacokinetics drug interactions and bioanalysis

**Pharmacokinetics and Metabolism in Drug Design, Volume 13** Dennis A. Smith,Han van de Waterbeemd,Don K. Walker,2001 The medical benefits of a drug are not only dependent on its biological effect but also on its life cycle within the organism from its absorption into the blood distribution to tissue until its

eventual breakdown or excretion by the liver and kidneys This book explains in readily comprehensible terms the problems that may arise and how these may be taken into account at an early stage in drug development *Enzyme Inhibition in Drug Discovery and Development* Chuang Lu, Albert P. Li, 2010-01-26 The science and applied approaches of enzyme inhibition in drug discovery and development Offering a unique approach that includes both the pharmacologic and pharmacokinetic aspects of enzyme inhibition *Enzyme Inhibition in Drug Discovery and Development* examines the scientific concepts and experimental approaches related to enzyme inhibition as applied in drug discovery and drug development With chapters written by over fifty leading experts in their fields *Enzyme Inhibition in Drug Discovery and Development* fosters a cross fertilization of pharmacology drug metabolism pharmacokinetics and toxicology by understanding the good inhibitions desirable pharmacological effects and bad inhibitions drug drug interactions and toxicity The book discusses The drug discovery process including drug discovery strategy medicinal chemistry analytical chemistry drug metabolism pharmacokinetics and safety biomarker assessment The manipulations of drug metabolizing enzymes and transporters as well as the negative consequences such as drug drug interactions The inhibition of several major drug target pathways such as the GPCR pathway the NFkB pathway and the ion channel pathway Through this focused single source reference on the fundamentals of drug discovery and development researchers in drug metabolism and pharmacokinetics DMPK will learn and appreciate target biology in drug discovery discovery biologists and medicinal chemists will also broaden their understanding of DMPK **Overcoming Obstacles in Drug Discovery and Development** Kan He, Paul F. Hollenberg, Larry C. Wienkers, 2023-05-18 *Overcoming Obstacles in Drug Discovery and Development* uses real world case studies to illustrate how critical thinking and problem solving skills are applied in the discovery and development of drugs It also shows how developing critical thinking to overcome issues plays an essential role in the process Modern drug discovery and development is a highly complex undertaking that requires scientific and professional expertise to be successful After the identification of a molecular entity for treating a medical condition challenges inevitably arise during the subsequent development to understand and characterize the biological profile feedback from scientists is used to fine tune the molecular entity to obtain an effective and safe product In this process the discovery team may identify unexpected safety issues and new medical disorders for treatment by the molecular entity Invariably inherent in this complex undertaking are miscues mistakes and unexpected problems that can derail development and throw timetables into disarray potentially leading to failure in the development of a medically useful drug Addressing critical unexpected problems during development often requires scientists to utilize critical thinking and imaginative problem solving skills *Overcoming Obstacles in Drug Discovery and Development* will be essential to young scientists to help learn the skills to successfully face challenges learn from mistakes and further develop critical thinking skills It will also be beneficial to experienced researchers who can learn from the case studies of successful and unsuccessful drug development Provides real world case studies in drug discovery and the

development of drugs Illustrates the use of critical thinking and problem solving in approaching preclinical and clinical problems in drug discovery and development Illustrates and analyses examples of successes and failures in drug discovery and development that have not previously been reported

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