

# Drug Metabolism & Pharmacokinetics in Drug Discovery: A Primer for Bioanalytical Chemists, Part I

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*In the face of advancing technology in combinatorial synthesis and high throughput screening, the drug discovery process continues to evolve. Preclinical drug metabolism and pharmacokinetics studies play a key role in lead identification and optimization. This fast-paced development process has imposed an enormous burden on the analytical chemist to design faster and more sensitive assay techniques to aid the drug discovery and development. This article, Part I of a two-part series introduces the analytical chemist to the fundamentals of drug metabolism. Part II of this series will discuss the pharmacokinetics aspects and how drug metabolism data can be used to predict pharmacokinetic parameters.*

Technological innovation and the pressures of competition have caused enormous changes in the drug discovery process. Progress in molecular biology and the Human Genome Project has contributed to the remarkable advances made in identification of new therapeutic targets. The drug discovery process is rapidly evolving due to the technological developments in target identification along with automation of combinatorial synthesis and high throughput screening (HTS). In light of these advances, improving effi-

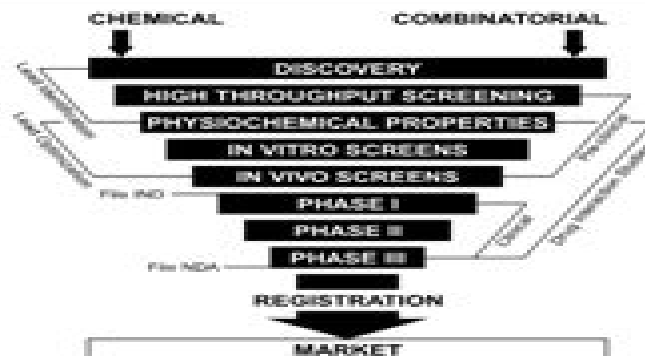
ciency in the optimization of desired pharmacological activity in humans while decreasing the reliance on animal studies has become a challenge. New chemical entities (NCEs) enter the drug discovery pipeline through combinatorial synthesis and rational drug design where information about the target of action is used to design the lead compound. HTS helps the identification of the leads that provide the required effect at high concentrations. In the secondary screening stage physicochemical properties such as solubility,

lipophilicity and stability are determined by measuring the octanol-water partition coefficient and  $pK_a$ . These measurements are useful in predicting the protein binding, tissue distribution and absorption in the gastrointestinal tract (1).

The selected leads are further screened using *in vitro* tests during lead optimization. The goal of lead optimization is to select compounds with required biological activity in humans. Relevant pharmacokinetic parameters such as tissue penetration, stability, intestinal absorption, metabolism, and elimination are obtained using *in vitro* systems. These *in vitro* systems include microsomes, hepatocytes or tissue slices for metabolite identification and evaluation of metabolic pathways and rates, and caco-2 cell lines for evaluating transcellular absorption. Cytotoxicity data can be obtained by using organ-specific cell lines. Knowledge of the toxic potential of these early leads and their possible metabolites is essential for successful drug discovery. Most drug candidates fail at this stage and only a few will be judged sufficiently safe and efficacious to proceed further into development. Both *in vitro*

## F1

Drug development process (IND, Investigational New Drug, NDA, New Drug Application)



# Drug Metabolism Pharmacokinetics In Drug Discovery A

**Raymond G Hill, Duncan Richards**



## **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 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 **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 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      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      **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

*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 pharmacokinetics 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 pharmacokinetics 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

**Drug Discovery and Evaluation: Safety and Pharmacokinetic Assays** Franz J. Hock, Michael K. Pugsley, 2024-10-21 Many aspects of drug safety have become an outstanding and even persistent issue and may occur during the process of both drug discovery and development Until 15 years ago drug discovery and evaluation was primarily a sequential process starting with the selection of the most pharmacologically active compound from a series of newly synthesized small molecule chemical series by means of distinctive pharmacological assays Safety aspects were addressed by evaluation of the selected compound at high doses in a series of specific studies directed at indications other than the intended indication of the new compound These tests are then followed by pharmacokinetic studies which are primarily conducted to confirm whether the selected compound possesses a suitable half life for sufficient

exposure and efficacy and whether it has the desired properties specificity to the intended route of administration Safety aspects relied predominantly on the conduct of single and repeat toxicologydose studies which inform changes in organ structure rather than organ function Both toxicological and pharmacokinetic studies are adapted to the progress of studies in clinical pharmacology and clinical trials The new edition of this well and broadly accepted reference work contains several innovative and distinguished chapters This sequential strategy has been abandoned with this new version of the book for several reasons Of the possible multitude of negative effects that novel drugs may impart on organ function e g ventricular tachy arrhythmia many are detected too late in non clinical studies to inform clinicians On the other hand negative findings in chronic toxicity studies in animals may turn out to be irrelevant for human beings New scientific approaches e g high throughput screening human pluripotent stem cells transgenic animals knock out animals in silico models pharmaco genomics and pharmaco proteomics as well as Artificial Intelligence AI methods offered new possibilities There are several examples that show that the druggability of compounds was considerably underestimated when the probability of success of a new project was assessed The success rate in the pharmaceutical industry and the introduction of new chemical entities to the market per year dropped dramatically whereas the development time for a new compound increased sometimes exceeding the patent protection Research and development scientists involving the following changes therefore adopted a change of strategy Parallel instead of sequential involvement of the various disciplines multidimensional compound optimization The term Safety Pharmacology was coined The International Conference on Harmonization ICH founded a Safety Pharmacology Working Group and the Safety Pharmacology Society SPS was launched The discipline provided for evaluation development and validation of a multitude of safety tests outlined in the Core Battery of Studies Characterizing the exposure profile of a drug by conducting pharmacokinetic studies that evaluates the absorption distribution metabolism and excretion should to be investigated at an early stage of development as results contribute to the selection of a compound for further development Advancements in Toxicology were achieved by the introduction of new methods e g in silico methods genetic toxicology computational toxicology and AI The book is a landmark in the continuously changing world of drug research and developments As such it is essential reading for many groups not only for all students of pharmacology and toxicology but also for industry scientists and physicians especially those involved in clinical trials of drugs and for pharmacists who must know the safety requirements of drugs The book is essential for scientists and managers in the pharmaceutical industry who are involved in drug discovery drug development and decision making in the development process In particular the book will be of use to government institutions and committees working on official guidelines for drug evaluation worldwide , 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 *Using Mass Spectrometry for Drug Metabolism Studies* Walter A.

Korfmacher,2004-12-17 Mass spectrometry MS is fast becoming the premier tool for analyzing various drug metabolism samples in the early phases of drug discovery and research Introducing the newer more powerful MS equipment and exploring new applications for using them this book provides a state of the art look at this promising field *Using Mass Spectrometry* 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 **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

**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. 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.

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.

Drug Discovery and Development E-Book Raymond G Hill, Duncan Richards, 2021-05-16 With unprecedented interest in the power that the modern therapeutic armamentarium has to combat disease, the new edition of Drug Discovery and Development is an essential resource for anyone interested in understanding how drugs and other therapeutic interventions are discovered and developed through to clinical research, registration, and



market access The text has been thoroughly updated with new information on biopharmaceuticals and vaccines as well as clinical development and target identification Drug discovery and development continues to evolve rapidly and this new edition reflects important changes in the landscape Edited by industry experts Raymond Hill and Duncan Richards this market leading text is suitable for undergraduates and graduates undertaking degrees in pharmacy pharmacology toxicology and clinical development through to those embarking on a career in the pharmaceutical industry Key stages of drug discovery and development Chapters outline the contribution of individual disciplines to the overall process Supplemented by specific chapters on different modalities Includes coverage of Oligonucleotide therapies cell and gene therapy Now comes with online access on StudentConsult

**Handbook of Drug Metabolism, Third Edition** Paul G. Pearson, Larry C. Wienkers, 2019-05-20 This book continues to be the definitive reference on drug metabolism with an emphasis on new scientific and regulatory developments It has been updated based on developments that have occurred in the last 5 years with new chapters on large molecules disposition stereo selectivity in drug metabolism drug transporters and metabolic activation of drugs Some chapters have been prepared by new authors who have emerged as subject area experts in the decade that has passed since publication of the first edition

**Drug Metabolism Handbook** Ala F. Nassar, Paul F. Hollenberg, JoAnn Scatina, Soumen Kanti Manna, Su Zeng, 2022-11-18 A comprehensive explanation of drug metabolism concepts and applications in drug development and cancer treatment In the newly revised second edition of Drug Metabolism Handbook Concepts and Applications in Cancer Research a distinguished team of researchers delivers an incisive and robust exploration of the drug metabolism system and a well illustrated and detailed explanation of the latest tools and techniques used in the research pharmacology and medicine The book discusses the creation of new molecular entities drug development troubleshooting and other highly relevant concepts guiding readers through new applications in pharmaceutical research development and assessment The latest edition offers updated content on metabolism basics and the application of a variety of new techniques to cancer treatment including mass spectrometry imaging metabolomics and immunotherapy It also offers in depth case studies highlighting the role of metabolism in drug development Readers will also benefit from A thorough introduction to drug metabolism including a historical perspective factors affecting metabolism and biotransformations in drug metabolism Comprehensive discussions of technologies for in vitro and in vivo studies including mass spectrometry and accelerating metabolite identification with mass spectrometry In depth explorations of drug interactions including discussions of enzyme inhibition and the characterization of cytochrome P450 mechanism based inhibition Fulsome treatments of drug toxicity including the role of drug metabolism in toxicity and allergic reactions to drugs Perfect for medicinal chemists pharmaceutical scientists and toxicologists Drug Metabolism Handbook Concepts and Applications in Cancer Research Second Edition will also earn a place in the libraries of analytical chemists and drug discovery professionals

**Trends in Drug Research II** H. van der Goot, 1998-01-16 This volume of Pharmacochemistry

Library comprises the text of invited lectures presented at the 11th Noordwijkerhout Camerino Symposium Trends in Drug Research held in Noordwijkerhout The Netherlands from 11-15 May 1997. In the programme attention has been given to the generation of new biological target systems and the generation of new lead molecules with presentations on e.g. combinatorial chemistry, compound libraries, database search, high throughput screening and molecular biology. Other topics discussed were the perspectives for new medicines for the gastro intestinal tract, the major developments in the search for effective anti HIV drugs and new aspects in synthetic approaches. In a special session three topics which currently draw much attention were discussed: How to deal with the major problem of resistance against antimicrobial agents, Can the apoptosis mechanism be used as a drug target, Is the newly observed phenomenon of inverse agonism a general principle and has it consequences for drug development and use.

## Unveiling the Magic of Words: A Overview of "**Drug Metabolism Pharmacokinetics In Drug Discovery A**"

In a world defined by information and interconnectivity, the enchanting power of words has acquired unparalleled significance. Their power to kindle emotions, provoke contemplation, and ignite transformative change is really awe-inspiring. Enter the realm of "**Drug Metabolism Pharmacokinetics In Drug Discovery A**," a mesmerizing literary masterpiece penned by a distinguished author, guiding readers on a profound journey to unravel the secrets and potential hidden within every word. In this critique, we shall delve into the book is central themes, examine its distinctive writing style, and assess its profound impact on the souls of its readers.

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