

Cardiac Drug Development Guide

Edited by

Michael K. Pugsley

Cardiac Drug Development Guide Methods In Pharmacology And Toxicology

Franz J. Hock, Michael K. Pugsley



Cardiac Drug Development Guide Methods In Pharmacology And Toxicology:

Cardiac Drug Development Guide Michael K. Pugsley, 2008-02-06 Cardiac Drug Development Guide outlines in detail the therapeutics of cardiac medicine currently at the cutting edge of scientific research and development around the world. This volume integrates basic and clinical cardiac pharmacology by combining for the first time both classical and molecular aspects of therapeutic drug development. The chapters comprise a broad spectrum of therapeutic areas and hence involve a comprehensive discussion of molecular biochemical and electrophysiological concepts based on years of in vitro as well as in vivo pharmacological studies. In addition, the latter part of the book includes comprehensive clinical cardiac chapters that describe important topics in molecular medicine. These chapters also discuss current clinical therapeutic trends in medicine and provide an evaluation of the efficacy of novel drugs in these areas. Cardiac Drug Development Guide has many distinctive and outstanding features that set it apart from other cardiac pharmacology books. This book introduces topics in an easily understandable format for researchers in many varying disciplines by integrating and thereby simplifying concepts not usually discussed across a broad range of cardiac disciplines and in a highly technical field. Each chapter not only introduces and describes the physiology, pharmacology and pathophysiology of the disease but also overviews the clinical implications of drug development, what stages these areas are currently in and also reviews some of the methodologies involved in drug discovery and development. As a result, this book provides a comprehensive overview of the most advanced procedures in cardiac pharmacology today.

Phytotherapies Iqbal Ramzan, 2015-04-17 Covering fundamentals and new developments in phytotherapy, this book combines pharmaceutical sciences and chemistry with clinical issues. Helps readers better understand phytotherapy and learn the fundamentals of and how to analyze phytotherapeutic agents. Discusses phytotherapy in modern medicine, chemoprevention of disease and alternatives to western medicines for specific diseases. Chapters summarize the uses and applications of phytomedicines by type like Chinese, Greco-Arab, Indian, European and Ayurvedic. Includes international regulatory perspectives and discusses emerging regulations for various established and emerging markets.

A Comprehensive Guide to Toxicology in Nonclinical Drug Development Ali S. Faqi, 2016-11-03 A Comprehensive Guide to Toxicology in Nonclinical Drug Development, Second Edition, is a valuable reference designed to provide a complete understanding of all aspects of nonclinical toxicology in the development of small molecules and biologics. This updated edition has been reorganized and expanded to include important topics such as stem cells in nonclinical toxicology, inhalation and dermal toxicology, pitfalls in drug development, biomarkers in toxicology and more. Thoroughly updated to reflect the latest scientific advances and with increased coverage of international regulatory guidelines, this second edition is an essential and practical resource for all toxicologists involved in nonclinical testing in industry, academic and regulatory settings. Provides unique content that is not always covered together in one comprehensive resource, including chapters on stem cells, abuse liability, biomarkers, inhalation toxicology, biostatistics and more. Updated with the latest international

guidelines for nonclinical toxicology in both small and large molecules Incorporates practical examples in order to illustrate day to day activities and the expectations associated with working in nonclinical toxicology *Handbook of Toxicology, Third Edition* Michael J. Derelanko, Carol S. Auletta, 2014-03-07 The Handbook of Toxicology Third Edition provides an updated practical reference source for practicing toxicologists in the pharmaceutical and chemical industries contract laboratories regulatory agencies and academia Written by experts in their specific toxicology fields the chapters provide both fundamental and applied information Topics range from General Toxicology to Genetic Toxicology Human Clinical Toxicology Histopathology Clinical Pathology Metabolism and Toxicokinetics Risk Assessment and more New to this edition Completely rewritten chapters covering immunotoxicology endocrine toxicology and reproductive and developmental toxicology providing a fresh perspective on these topics Addition of new chapters on Chemical Toxicology Pharmaceutical Toxicology Juvenile Toxicology and Safety Pharmacology Updated information dealing with Inhalation Toxicology Neurotoxicology and Regulatory Toxicology which has been consolidated into single chapters for each specialty A separate glossary with toxicological terms presented both alphabetically and by toxicological subspecialty For nearly 20 years this handbook has remained the only reference book of its kind designed to facilitate easy access to information related to the various toxicology specialties This updated edition of a popular reference book reflects current practices and the state of the science of toxicology Optimization in Drug Discovery Zhengyin Yan, Gary W. Caldwell, 2008-02-06 Recent analyses of drug attrition rates reveal that a significant number of drug candidates fail in the later stage of clinical development owing to absorption distribution metabolism elimination ADME and toxicity issues Lead optimization in drug discovery a process attempting to uncover and correct these defects of drug candidates is highly beneficial in lowering the cost and time to develop therapeutic drugs by reducing drug candidate failures in development At present parallel synthesis combining with high throughput screening has made it easier to generate highly potent compounds i e hits However to be a potential drug a hit must have drug like characteristics in addition to potency which include optimal physicochemical properties reasonable pharmacokinetic parameters and good safety profiles Therefore research tools must be available in drug discovery to rapidly screen for compounds with favorable drug like properties and thus adequate resources can be directed to projects with high potential Optimization in Drug Discovery In Vitro Methods is a compilation of detailed experimental protocols necessary for setting up a variety of assays important in compound evaluation A total of 25 chapters contributed by many experts in their research areas cover a wide spectrum of subjects including physicochemical properties absorption plasma binding metabolism drug interactions and toxicity A good pharmacokinetic profile has long been recognized as an important drug like characteristic Pharmacokinetic parameters are affected by many properties of drug molecules such as physicochemical nature absorption metabolic stability and so on *A Comprehensive Guide to Toxicology in Preclinical Drug Development* Ali S. Faqi, 2012-11-02 A Comprehensive Guide to Toxicology in Preclinical Drug Development is designed for toxicologists who

need a thorough understanding of the drug development process This multi contributed reference will provide a detailed picture of the complex and highly interrelated activities of preclinical toxicology in both small molecules and biologics *In Vitro Neurotoxicology* Evelyn Tiffany-Castiglioni,2008-02-06 Well respected leaders in the field of in vitro neurotoxicology take a fresh look at their own and other s work critically and comparatively analyzing it across experimental systems and toxicants and synthesizing essential principles for in vitro neurotoxicity testing Neurotoxicants of significance to human health are emphasized especially those for which metabolism and dose responses are well well studied both in vivo and in vitro lead mercury organophosphorous insecticides polychlorinated biphenyls and dioxin ethanol and endogenous proteins The goal is to set out new concepts and research directions that will hasten significant improvement in the methods and systems for in vitro neurotoxicity testing **Handbook of Toxicology** Michael J. Derelanko,Carol S. Auletta,2014-03-07 The Handbook of Toxicology Third Edition provides an updated practical reference source for practicing toxicologists in the pharmaceutical and chemical industries contract laboratories regulatory agencies and academia Written by experts in their specific toxicology fields the chapters provide both fundamental and applied information Topics range from General Toxicology to Genetic Toxicology Human Clinical Toxicology Histopathology Clinical Pathology Metabolism and Toxicokinetics Risk Assessment and more New to this edition Completely rewritten chapters covering immunotoxicology endocrine toxicology and reproductive and developmental toxicology providing a fresh perspective on these topics Addition of new chapters on Chemical Toxicology Pharmaceutical Toxicology Juvenile Toxicology and Safety Pharmacology Updated information dealing with Inhalation Toxicology Neurotoxicology and Regulatory Toxicology which has been consolidated into single chapters for each specialty A separate glossary with toxicological terms presented both alphabetically and by toxicological subspecialty For nearly 20 years this handbook has remained the only reference book of its kind designed to facilitate easy access to information related to the various toxicology specialties This updated edition of a popular reference book reflects current practices and the state of the science of toxicology 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

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