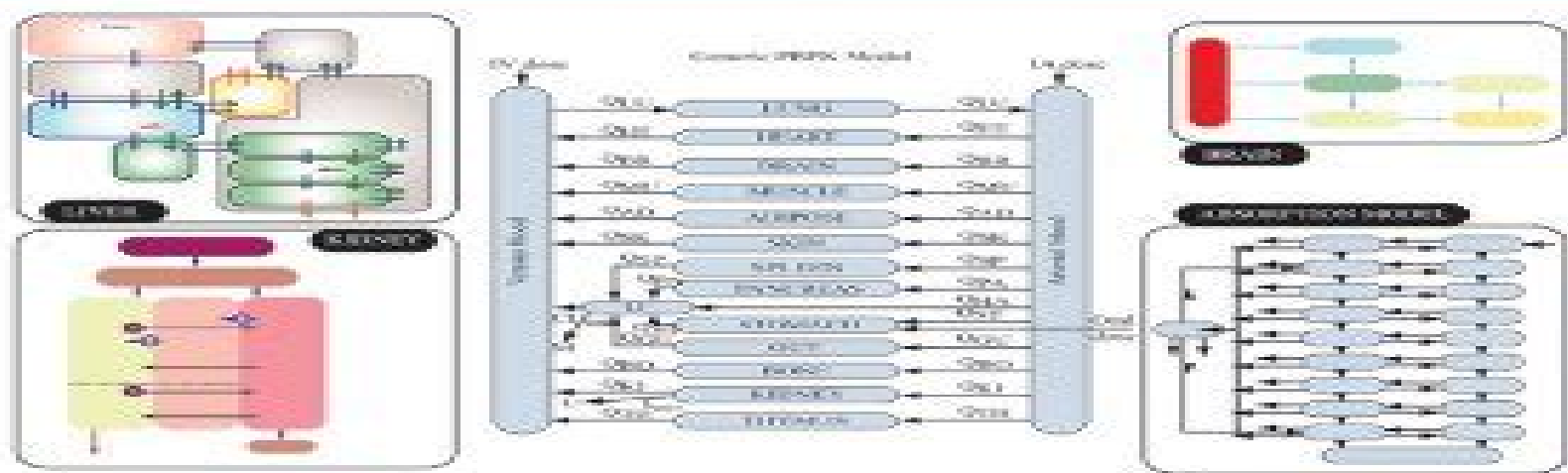


Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations

Principles, Methods, and Applications in the Pharmaceutical Industry

Sheila Annie Peters



Physiologically Based Pharmacokinetic Pbpk Modeling And Simulations Principles Methods And Applications In The Pharmaceutical Industry

Honghui Zhou, Frank-Peter Theil



Physiologically Based Pharmacokinetic Pbpk Modeling And Simulations Principles Methods And Applications In The Pharmaceutical Industry:

Physiologically Based Pharmacokinetic (PBPK) Modeling and Simulations Sheila Annie Peters, 2021-09-30 Physiologically Based Pharmacokinetic PBPK Modeling and Simulations The first book dedicated to the emerging field of physiologically based pharmacokinetic modeling PBPK Now in its second edition Physiologically Based Pharmacokinetic PBPK Modelling and Simulations Principles Methods and Applications in the Pharma Industry remains the premier reference book throughout the rapidly growing PBPK user community Using clear and concise language author Sheila Annie Peters connects theory with practice as she explores the vast potential of PBPK modeling for improving drug discovery and development This fully updated new edition covers key developments in the field of PBPK modelling and simulations that have emerged in recent years A brand new section provides case studies in different application areas of PBPK modelling including drug drug interaction genetic polymorphism renal impairment and pediatric extrapolation Additional chapters address topics such as model informed drug development MIDD and expose readers to a wide range of current applications in the field Throughout the book substantially revised chapters simplify complex topics and offer a balanced view of both the opportunities and challenges of PBPK modelling Providing timely and comprehensive coverage of one of the most exciting new areas of pharmaceutical science this book Describes the principles behind physiological modeling of pharmacokinetic processes inter individual variability and drug interactions for small molecule drugs and biologics Features a wealth of new figures and case studies of the applications of PBPK modelling along the value chain in drug discovery and development Reflects the latest regulatory guidelines on the reporting of PBPK modelling analysis Includes access to a new companion website containing code datasets explanations of case examples in the text and discussion of key developments in the field Contains a brief overview of the field end of chapter keywords for easy reference and an extensive bibliography Physiologically Based Pharmacokinetic PBPK Modeling and Simulations Principles Methods and Applications in the Pharmaceutical Industry Second Edition is an indispensable single volume resource for beginning and intermediate practitioners across the pharmaceutical sciences in both industry and academia **ADME and Translational Pharmacokinetics /**

Pharmacodynamics of Therapeutic Proteins Honghui Zhou, Frank-Peter Theil, 2015-10-26 With an emphasis on the fundamental and practical aspects of ADME for therapeutic proteins this book helps readers strategize plan and implement translational research for biologic drugs Details cutting edge ADME absorption distribution metabolism and excretion and PKPD pharmacokinetic pharmacodynamics modeling for biologic drugs Combines theoretical with practical aspects of ADME in biologic drug discovery and development and compares innovator biologics with biosimilar biologics and small molecules with biologics giving a lessons learned perspective Includes case studies about leveraging ADME to improve biologics drug development for monoclonal antibodies fusion proteins pegylated proteins ADCs bispecifics and vaccines Presents regulatory

expectations and industry perspectives for developing biologic drugs in USA EU and Japan Provides mechanistic insight into biodistribution and target driven pharmacokinetics in important sites of action such as tumors and the brain Mammalian Toxicology Mohamed Abou-Donia, 2015-05-04 Mammalian Toxicology surveys chemical agents and examines how such chemicals impact on human health emphasizing the importance in minimizing environmental exposure to chemical and physical hazards in our homes communities and workplaces through such media as contaminated water soil and air Starting with the basic principles on a wide range of toxic agents this textbook describes how they enter the body their mechanisms of action once inside and strategies for diagnosis prevention and treatment Topics covered include General principles of toxicology pharmacological and toxicological principles underpinning the study of toxicology risk assessments and mechanisms of cell death Disposition routes of chemical exposures entry into the body and various tissues storage metabolic biotransformation and elimination with examples from various toxicants Toxic agents the occurrences disposition in the body health effects toxic mechanisms antidotes and treatments of a range of agents including pesticides metals solvents gases nanomaterials food components and additives pharmaceuticals drugs of abuse natural toxins endocrine disruptors radiation and warfare weapons Toxic effects including neurotoxicity developmental toxicity immunotoxicity teratogenicity male and female reproductive toxicity mutagenicity carcinogenicity pulmonary toxicity cardiovascular toxicity hepatotoxicity gastrointestinal toxicity and cardiovascular toxicity Toxicology and society epidemiological studies of chemical induced diseases in human populations and a vision for toxicology in the 21st century Mammalian Toxicology is an essential primer for students of toxicology biochemistry biology medicine and chemistry It is also appropriate for professional toxicologists in research or regulatory affairs and anyone who needs to understand the adverse effects of toxic agents on the human body

Physico-Chemical Aspects of Dosage Forms and Biopharmaceutics Amit Kumar Nayak, Kalyan Kumar Sen, 2024-08-09 Physico Chemical Aspects of Dosage Forms and Biopharmaceutics Recent and Future Trends in Pharmaceutics Volume Two explores aspects of pharmaceutics with an original approach that focuses on technology novelties and future trends The field of pharmaceutics is highly dynamic and rapidly expanding day by day so it demands a variety of amplified efforts for designing and developing pharmaceutical processes and formulation strategies Readers will find practical information for conducting research in pharmaceutics that is ideal for researchers in academia and industry as well as advanced graduate students in pharmaceutics In addition the book discusses the most recent developments in biopharmaceutics including important and exciting areas such as solubility of drugs pharmaceutical granulation routes of drug administration drug absorption bioavailability and bioequivalence Provides extensive details on the most recent developments in biopharmaceutics Contains contributions from leading experts from academia research industry and regulatory agencies Includes high quality illustrations flow charts and tables for easier understanding of the concepts Discusses practical examples and research case studies Information Resources in Toxicology, Volume 1: Background, Resources, and Tools

,2020-05-16 This new fifth edition of Information Resources in Toxicology offers a consolidated entry portal for the study research and practice of toxicology Both volumes represents a unique wide ranging curated international annotated bibliography and directory of major resources in toxicology and allied fields such as environmental and occupational health chemical safety and risk assessment The editors and authors are among the leaders of the profession sharing their cumulative wisdom in toxicology s subdisciplines This edition keeps pace with the digital world in directing and linking readers to relevant websites and other online tools Due to the increasing size of the hardcopy publication the current edition has been divided into two volumes to make it easier to handle and consult Volume 1 Background Resources and Tools arranged in 5 parts begins with chapters on the science of toxicology its history and informatics framework in Part 1 Part 2 continues with chapters organized by more specific subject such as cancer clinical toxicology genetic toxicology etc The categorization of chapters by resource format for example journals and newsletters technical reports organizations constitutes Part 3 Part 4 further considers toxicology s presence via the Internet databases and software tools Among the miscellaneous topics in the concluding Part 5 are laws and regulations professional education grants and funding and patents Volume 2 The Global Arena offers contributed chapters focusing on the toxicology contributions of over 40 countries followed by a glossary of toxicological terms and an appendix of popular quotations related to the field The book offered in both print and electronic formats is carefully structured indexed and cross referenced to enable users to easily find answers to their questions or serendipitously locate useful knowledge they were not originally aware they needed Among the many timely topics receiving increased emphasis are disaster preparedness nanotechnology omics risk assessment societal implications such as ethics and the precautionary principle climate change and children s environmental health Introductory chapters provide a backdrop to the science of toxicology its history the origin and status of toxicoinformatics and starting points for identifying resources Offers an extensive array of chapters organized by subject each highlighting resources such as journals databases organizations and review articles Includes chapters with an emphasis on format such as government reports general interest publications blogs and audiovisuals Explores recent internet trends web based databases and software tools in a section on the online environment Concludes with a miscellany of special topics such as laws and regulations chemical hazard communication resources careers and professional education K 12 resources funding poison control centers and patents Paired with Volume Two which focuses on global resources this set offers the most comprehensive compendium of print digital and organizational resources in the toxicological sciences with over 120 chapters contributions by experts and leaders in the field

Human and Ecological Risk Assessment Dennis J. Paustenbach,2024-04-16 Understand the fundamentals of human risk assessment with this introduction and reference Human risk assessments are a precondition for virtually all industrial action or environmental regulation all the more essential in a world where chemical and environmental hazards are becoming more abundant These documents catalog potential environmental toxicological ecological or other

harms resulting from a particular hazard from chemical spills to construction projects to dangerous workplaces They turn on a number of variables of which the most significant is the degree of human exposure to the hazardous agent or process Human and Ecological Risk Assessment combines the virtues of a textbook and reference work to introduce and analyze these vital documents Beginning with the foundational theory of human health risk assessment it then supplies case studies and detailed analysis illustrating the practice of producing risk assessment documents Fully updated and authored by leading authorities in the field the result is an indispensable work Readers of the second edition of Human and Ecological Risk Assessment will also find Over 40 entirely new case studies reflecting the latest in risk assessment practice Detailed discussion of hazards including air emissions contaminated food and soil hazardous waste sites and many more Case studies from multiple countries to reflect diverse international standards Human and Ecological Risk Assessment is ideal for professionals and advanced graduate students in toxicology industrial hygiene occupational medicine environmental science and all related subjects

Comprehensive Medicinal Chemistry III, 2017-06-03 Comprehensive Medicinal Chemistry III Eight Volume Set provides a contemporary and forward looking critical analysis and summary of recent developments emerging trends and recently identified new areas where medicinal chemistry is having an impact The discipline of medicinal chemistry continues to evolve as it adapts to new opportunities and strives to solve new challenges These include drug targeting biomolecular therapeutics development of chemical biology tools data collection and analysis in silico models as predictors for biological properties identification and validation of new targets approaches to quantify target engagement new methods for synthesis of drug candidates such as green chemistry development of novel scaffolds for drug discovery and the role of regulatory agencies in drug discovery Reviews the strategies technologies principles and applications of modern medicinal chemistry Provides a global and current perspective of today's drug discovery process and discusses the major therapeutic classes and targets Includes a unique collection of case studies and personal essays reviewing the discovery and development of key drugs

Comprehensive Medicinal Chemistry II, Volume 5 John Bodenhayn Taylor, D. J. Triggle, 2007 This book comprises 8 volumes with all chapter sections available as PDF or HTML and includes bibliographical references and index

Physiologically Based Pharmacokinetic Modeling Micaela Reddy, R. S. Yang, Melvin E. Andersen, Harvey J. Clewell III, 2005-06-14 A definitive single source of information on PBPK modeling Physiologically based pharmacokinetic PBPK modeling is becoming increasingly important in human health risk assessments and in supporting pharmacodynamic modeling for toxic responses Organized by classes of compounds and modeling purposes so users can quickly access information this is the first comprehensive reference of its kind This book presents an overview of the underlying principles of PBPK model development Then it provides a compendium of PBPK modeling information including historical development specific modeling challenges and current practices for Halogenated Alkanes Halogenated Alkenes Alkene and Aromatic Compounds Reactive Vapors in the Nasal Cavity Alkanes Oxyhydrocarbons and Related Compounds Pesticides and Persistent

Organic Pollutants Dioxin and Related Compounds Metals and Inorganic Compounds Drugs Antineoplastic Agents Perinatal Transfer Mixtures Dermal Exposure Models In addition to pinpointing specific information readers can explore diverse modeling techniques and applications An authoritative reference for toxicologists ecotoxicologists risk assessors regulators pharmacologists pharmacists and graduate students in pharmacokinetics and toxicology Physiologically Based Pharmacokinetic Modeling compiles information from leaders in the field and discusses future directions for PBPK modeling *Physiologically Based Pharmacokinetic (PBPK) Modeling* Jeffrey W. Fisher, Jeffery M. Gearhart, Zhoumeng Lin, 2020-05-20 Physiologically Based Pharmacokinetic PBPK Modeling Methods and Applications in Toxicology and Risk Assessment presents foundational principles advanced techniques and applications of PBPK modeling Contributions from experts in PBPK modeling cover topics such as pharmacokinetic principles classical physiological models the application of physiological models for dose response and risk assessment the use of in vitro information and in silico methods With end of chapter exercises that allow readers to practice and learn the skills associated with PBPK modeling dose response and its applications to safety and risk assessments this book is a foundational resource that provides practical coverage of PBPK modeling for graduate students academics researchers and more Provides end of chapter exercises to teach hands on computational tools used in toxicology Supplies computer code and explanations and includes examples of applied models used in regulatory toxicology and research Authored by expert editors and contributors who are among the best PBPK modelers in the world **The Art and Science of Physiologically-Based Pharmacokinetics Modeling** Rodrigo Cristoforetti, Amin Rostami-Hodjegan, 2024-07-15 This state of the art text describes the science behind the system and drug dependent components of PBPK models its applications in translational and regulatory science e.g. guiding drug discovery and development and supporting precision medicine initiatives To incorporate state of the art knowledge each chapter is written by leaders in the field and illustrated by clear case studies Connecting basic and applied science this book explores the potential of PBPK modeling for improving therapeutics and is designed for a wide audience encompassing graduate students as well as biopharmaceutics scientists and clinical pharmacologists Features 1 Provides a basic understanding of the physiologically based pharmacokinetic modeling and its applications 2 Assists the reader in understanding product performance to allow for rapid product development and establish bioequivalence 3 Well constructed content and added value of real examples 4 Illustrates how using available resources via modeling and simulation leads to a reduction in the costs related to drug development which directly affects the costs to patients *Translational Physiologically-based Pharmacokinetic (PBPK) Modeling and Simulation to Support Drug Development and Pharmacotherapy*, 2018

Mechanistic Physiologically Based Pharmacokinetic (PBPK) Modeling of Renal and Systemic Disposition of Drugs and Metabolites Weize Huang, 2020 Physiologically based pharmacokinetic PBPK models integrate system specific anatomy and physiology information with drug specific physicochemical and pharmacokinetic properties to predict drug

disposition Such integration permits items events processes and pathways to communicate and influence each other interactively By taking advantage of such mechanistic nature of PBPK modeling drug dispositions under untested scenarios could be predicted by extrapolation from observed data in known conditions Renal clearance is one of the major pathways governing drug dispositions which has three main mechanisms unbound filtration passive reabsorption and active secretion In comparison to intestinal absorption and hepatic metabolism renal clearance has been relatively underappreciated Controlled clinical experiments that test renal clearance changes under altered conditions and mechanisms have been primarily focusing on drug drug interaction on active secretion However huge gaps in understanding renal clearance still exist in other areas such as altered urine pH and impaired renal function Further passive reabsorption has not been paid significant attention by the pharmaceutical field Therefore the overarching goal of this thesis is to leverage mechanistic PBPK modeling technique to understand and predict renal clearance of drugs and metabolites under altered urine pH and impaired renal function with a special focus on compounds undergoing significant renal passive reabsorption In Chapter 2 to predict the spatiodynamic process of renal passive reabsorption in human we developed a dynamic physiologically based mechanistic kidney model based on human data that can integrate drug permeability tubular surface area ionization status and drug concentration gradient between lumen and system to estimate renal passive reabsorption and predict renal clearance of drugs Using 46 test compounds with a variety of physicochemical properties the model successfully predicted the renal clearances of 87% compounds within 2 fold and 98% compounds within 3 fold Further by incorporating active secretion the model also successfully predicted the renal clearances of para aminohippuric acid PAH cimetidine salicylic acid and memantine In Chapter 3 to ensure the simulation output from PBPK models can be meaningfully compared to the arm vein plasma drug concentrations collected in clinical studies we developed a forearm model that captures the tissue distribution at the peripheral sampling site using human arm physiology data allowing for a better prediction of plasma drug concentrations that are comparable to observed data The model was successfully verified using arterial and venous concentrations of nicotine ketamine lidocaine and fentanyl simultaneously Further I demonstrated that use of a discrepant sampling site in PBPK modeling than observed clinical studies may lead to biased model evaluation erroneous model parameterization and misleading prediction in unstudied clinical scenarios In Chapter 4 to predict the altered renal excretion and systemic AUC of drug and metabolite when urine pH is changed the mechanistic kidney model developed and verified from Chapter 2 was integrated with the peripheral arm sampling and full body PBPK model developed from Chapter 3 The model was successfully verified with methamphetamine and amphetamine under varying urine pH statuses and showed feasibility to predict quantitatively and clinically significant changes in drug and metabolite disposition under comedications and diseases that can alter urine pH In Chapter 5 to predict renal clearance in patients with impaired renal function such as chronic kidney diseases physiological changes in tubular flow and urine flow observed in chronic kidney disease patients

were incorporated into the mechanistic kidney model developed and verified from Chapter 2. The model accounts for the adaptive renal tubular filtrate flows that decrease disproportionately with glomerular filtration rate and was successfully verified using three parent metabolite pairs, six non-permeable drugs, six permeable drugs and two secreted drugs. In conclusion, in this thesis I developed and verified a physiologically based mechanistic kidney model to translate drug properties such as plasma protein binding, transcellular permeability and active transport into renal clearance of drugs and metabolites. This mechanistic kidney model allows prediction of alterations in renal clearance of drugs and metabolites upon changes in urine pH and renal functions and can be incorporated into a full body PBPK model to predict alterations in systemic disposition of drugs and metabolites.

Advances in Pharmacokinetics and Pharmacodynamics Panos Macheras, 2023-05-26. This book provides a concise overview of recent advances in Pharmacokinetics (PK) and Pharmacodynamics (PD). The pharmacokinetics section covers the state of the art in Physiologically Based Pharmacokinetic (PBPK) modeling (Chapter 1) as well as the assessment of food effect on drug absorption using PBPK modeling (Chapter 2). Chapters 3 and 4 describe the recent development of Physiologically Based Finite Time Pharmacokinetic (PBFTP) models and their applications to pharmacokinetic data. The pharmacodynamics section focuses on PK/PD modeling (Chapter 5) which provides an overview of PK/PD modeling and simulation in clinical practice and studies. Chapter 6 deals with the subject physiology variability issue encountered in PK/PD studies while Chapter 7 reviews the influence of clinical pharmacology in the modernization of drug development and regulation. This book is an essential reference for pharmaceutical scientists.

Comparative Pharmacokinetics Jim E. Riviere, 2011-01-14. Now in a revised edition, *Comparative Pharmacokinetics: Principles, Techniques and Applications* presents the principles and techniques of comparative and veterinary pharmacokinetics in a detailed yet practical manner. Developed as a tool for ensuring that pharmacokinetics studies are properly designed and correctly interpreted, the book provides complete coverage of the conceptual basis of pharmacokinetics as used for quantifying biological processes from the perspectives of physiology and medicine. New chapters have been added on quantitative structure-permeability relationships and bioequivalence, and a number of existing chapters have been significantly revised and expanded to provide a current resource for veterinary and comparative pharmacokinetics.

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 (PD) 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 PD 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.

Physiologically Based Pharmacokinetic Modeling Jasmine Davda, 2009-08. This book describes the application of physiologically based pharmacokinetic PBPK modeling to characterize the disposition of therapeutic monoclonal antibodies (MAbs). These macromolecules exhibit distinctly different pharmacokinetic features compared with conventional small molecule drugs. A PBPK model was developed to characterize the biodistribution of the pancreatic carcinoma MAb CC49 in normal and neoplastic tissues of nude mice. The model included all the major processes involved in determining the disposition characteristics of MAbs. The applicability of the model was tested by predicting the disposition of di- and tetra-valent scFv constructs of CC49 in mice. Further, the model was applied to study the differences in disposition between MAbs labeled with ^{125}I and ^{177}Lu . Finally, the clinical utility of the model was tested by attempting to predict the disposition and tumor uptake of CC49 in patients. This model may be used to study the biodistribution and tumor localization of different combinations of radionuclides and engineered antibody fragments in an effort to establish the most effective approach to achieve the optimal therapeutic ratio for tumor therapy.

Applied Pharmacometrics Stephan Schmidt, Hartmut Derendorf, 2014-12-01. This comprehensive volume provides an update on the current state of pharmacometrics in drug development. It consists of nineteen chapters all written by leading scientists from the pharmaceutical industry, regulatory agencies, and academia. After an introduction of the basic pharmacokinetic and pharmacodynamic concepts of pharmacometrics in drug development, the book presents numerous examples of specific applications that utilize pharmacometrics with modeling and simulations over a variety of therapeutic areas including pediatrics, diabetes, obesity, infections, psychiatry, Alzheimer's disease, and dermatology, among others. The examples illustrate how results from all phases of drug development can be integrated in a more timely and cost-effective process. Applying pharmacometric decision tools during drug development can allow objective data-based decision making. At the same time, the process can identify redundant or unnecessary experiments as well as some costly clinical trials that can be avoided. In addition to cost saving by expedited development of successful drug candidates, pharmacometrics has an important economic impact in drug product selection. Unsuccessful drug candidates can be identified early and discontinued without expending efforts required for additional studies and allocating limited resources. Hence, pharmacometric modeling and simulation has become a powerful tool to bring new and better medications to the

patient at a faster pace and with greater probability of success *PB-PK* Derek Bruce Janszen,1992 **Physiologically**
Based Pharmacokinetic Modeling in Pediatric Drug Development and Research Feras Khalil,2014

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