Dissolution Test Of Tacrolimus Capsule Quality Effects Of

O tacrolimus é uma lactona macrolídea, derivada do Streptomyces tsukubaensis. É um fármaco imunossupressor usado na prevenção da rejeição de transplante de órgãos, tais como fígado, rim, coração, intestino delgado, pâncreas e medula óssea. É também indicado para tratamento de dermatite atópica, lupus eritematoso, psoríase e vitiligo. Encontra-se comercialmente disponível na forma de cápsulas, injetáveis e pomadas. Poucos métodos estão descritos na literatura para quantificação do tacrolimus nas formas disponíveis. Neste trabalho foram desenvolvidos e validados métodos espectrofotométricos para determinaçãoquantitativa do fármaco em cápsulas. Um dos métodos utilizou reação com ácido sulfúrico concentrado (98%), com detecção em 295 nm. O outro se baseou na reação de complexo de transferência de carga com iodo 0,01M, com detecção em365 nm. Os métodos desenvolvidos apresentaram linearidade (r>0,99), precisão (0,2%) e exatidão (99%) adequadas. Realizou-se, igualmente, estudo preliminar para avaliação do perfil de dissolução in vitro do fármaco. Diferentes meios dedissolução (tampão fosfato pH 6,8, tampão acetato pH 5,5 and HCl 0,1M) e diferentes velocidades de rotação (75 e 100 rpm) foram avaliados para definir as condições para o teste de dissolução, empregando o aparato cesta. Asporcentagens dissolvidas do fármaco foram determinadas através de método por cromatografia líquida de alta eficiência descrito na literatura. As percentagens dissolvidas foram superiores a 85% em 60 minutos.

As the generic pharmaceutical industry continues to grow and thrive, so does the need to conduct adequate, efficient bioequivalence studies. In recent years, there have been significant changes to the statistical models for evaluating bioequivalence. In addition, advances in the analytical technology used to detect drug and metabolite levels have made bioequivalence testing more complex. The second edition of Handbook of Bioequivalence Testing has been completely updated to include the most current information available, including new findings in drug delivery and dosage form design and revised worldwide regulatory requirements. New topics include: A historical perspective on generic pharmaceuticals New guidelines governing submissions related to bioequivalency studies, along with therapeutic code classifications Models of noninferiority Biosimilarity of large molecule drugs Bioequivalence of complementary and alternate medicines Bioequivalence of biosimilar therapeutic proteins and monoclonal antibodies New FDA guidelines for bioanalytical method validation Outsourcing and monitoring of bioequivalence studies The cost of generic drugs is rising much faster than in the past, partly because of the increased costs required for approval—including those for bioequivalence testing. There is a dire need to re-examine the science behind this type of testing to reduce the burden of development costs—allowing companies to develop generic drugs faster and at a lower expense. The final chapter explores the future of bioequivalence testing and proposes radical changes in the process of biowaivers. It suggests how the cost of demonstrating bioequivalence can be reduced through intensive analytical investigation and proposes that regulatory agencies reduce the need for bioequivalence studies in humans. Backed by science and updated with the latest research, this book is destined to spark continued debate on the efficacy of the current bioequivalence testing paradigm.

This volume is intended to provide the reader with a breadth of understanding regarding the many challenges faced with the formulation of poorly water-soluble drugs as well as in-depth knowledge in the critical areas of development with these compounds. Further, this book is designed to provide practical guidance for overcoming formulation challenges toward the end goal of improving drug therapies with poorly water-soluble drugs. Enhancing solubility via formulation intervention is a unique opportunity in which formulation scientists can enable drug

therapies by creating viable medicines from seemingly undeliverable molecules. With the ever increasing number of poorly water-soluble compounds entering development, the role of the formulation scientist is growing in importance. Also, knowledge of the advanced analytical, formulation, and process technologies as well as specific regulatory considerations related to the formulation of these compounds is increasing in value. Ideally, this book will serve as a useful tool in the education of current and future generations of scientists, and in this context contribute toward providing patients with new and better medicines.

"A to Z Drug Facts" is an alphabetically organized drug reference that integrates successful drug therapy and patient care. Monographs are divided into pharmacological and patient-care considerations and include indications, dosages, and side effects. Includes up-to-date information on more than 4,500 new and orphan drugs and uses icons and second color for ease of use.

The field of encapsulation, especially microencapsulation, is a rapidly growing area of research and product development. The Handbook of Encapsulation and Controlled Release covers the entire field, presenting the fundamental processes involved and exploring how to use those processes for different applications in industry. Written at a level comp

For over 100 years, Remington has been the definitive textbook and reference on the science and practice of pharmacy. This Twenty-First Edition keeps pace with recent changes in the pharmacy curriculum and professional pharmacy practice. More than 95 new contributors and 5 new section editors provide fresh perspectives on the field. New chapters include pharmacogenomics, application of ethical principles to practice dilemmas, technology and automation, professional communication, medication errors, re-engineering pharmacy practice, management of special risk medicines, specialization in pharmacy practice, disease state management, emergency patient care, and wound care. Purchasers of this textbook are entitled to a new, fully indexed Bonus CD-ROM, affording instant access to the full content of Remington in a convenient and portable format.

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This comprehensive reference provides an in-depth discussion on state-of-the-art regulatory science in bioequivalence. In sixteen chapters, the volume explores a broad range of topics pertaining to bioequivalence, including its origin and principles, statistical considerations, food effect studies, conditions for waivers of bioequivalence studies, Biopharmaceutics Classification Systems, Biopharmaceutics Drug Disposition Classification System, bioequivalence modeling/simulation and best practices in bioanalysis. It also discusses bioequivalence studies with pharmacodynamic and clinical endpoints as well as bioequivalence approaches for highly variable drugs, narrow therapeutic index drugs, liposomes, locally acting gastrointestinal drug products, topical products and nasal and inhalation products. FDA Bioequivalence Standards is written by FDA regulatory scientists who develop regulatory policies and conduct regulatory assessment of bioequivalence. As such, both practical case studies and fundamental science are highlighted in these chapters. The book is a valuable resource for scientists who work in the pharmaceutical industry, regulatory agencies and academia as well as undergraduate and graduate students looking to expand their knowledge about bioequivalence standards.

A suitable drug delivery system is an essential element in achieving efficient therapeutic responses of drug molecules. With this desirability in mind, the book unites different techniques through which extremely small-sized particles can be utilized as a successful carrier for curing chronic as well as life-threatening diseased conditions. This is a highly informative and prudently organized book, providing scientific insight for readers with an interest in nanotechnology. Beginning with an overview of nanocarriers, the book impetuses on to explore other essential ways through which these carriers can be employed for drug delivery to varieties of administrative routes. This book discusses the functional and significant features of nanotechnology in terms of Lymphatic and other drug targeting deliveries. The book is presenting depth acquaintance for various vesicular and particulate nano-drug delivery carriers, utilized successfully in Pharmaceutical as well as in Cosmeceutical industries along with brief information on their related toxicities. In addition, the work also explores the potential applications of nanocarriers in biotechnology sciences for the prompt and safe delivery of nucleic acid, protein, and peptide-based drugs. An exclusive section in the book illuminates the prominence and competent applicability of nanotechnology in the treatment of oral cancer. The persistence of this book is to provide basic to advanced information for different novel carriers which are under scale-up consideration for the extensive commercialization. The book also includes recent discoveries and the latest patents of such nanocarriers. The cutting-edge evidence of these nanocarriers available in this book is beneficial to students, research scholars, and fellows for promoting their advanced research.

This book provides a critical overview of the advances being made towards overcoming biological barriers through the contribution of nanosciences and nanotechnologies. Overcoming these barriers is of primary importance for solving the problems of many current drugs and vaccines and it is also especially relevant for the commercial exploitation of new therapeutic strategies i.e. gene and cellular therapies. Despite important information that has been covered in recently published books related to nanomedicine (mainly oriented to technologies and applications), there is still an important

gap related to the relationship between the chemical properties of nanobiomaterials and their interaction with the biological environment. Thus, this comprehensive new book that is presented with a clear and organised structure dedicated to the different biological barriers relevant for drug delivery applications will focus on (i) mechanistic issues related to the interaction between drug delivery systems and biological barriers and (ii) the analysis of the critical factors determining the efficacy of nanobiomaterials for specific applications. Moreover, this field has become highly multidisciplinary over the last decade, leading to the development of new products, as well as to significant advances from the regulatory point of view. Moreover, this book will also provide an up-to-date view on the clinical relevance of nanomedicine and on its possible impact on global health.

This volume offers a comprehensive guide on the theory and practice of amorphous solid dispersions (ASD) for handling challenges associated with poorly soluble drugs. In twenty-three inclusive chapters, the book examines thermodynamics and kinetics of the amorphous state and amorphous solid dispersions, ASD technologies, excipients for stabilizing amorphous solid dispersions such as polymers, and ASD manufacturing technologies, including spray drying, hot melt extrusion, fluid bed layering and solvent-controlled micro-precipitation technology (MBP). Each technology is illustrated by specific case studies. In addition, dedicated sections cover analytical tools and technologies for characterization of amorphous solid dispersions, the prediction of long-term stability, and the development of suitable dissolution methods and regulatory aspects. The book also highlights future technologies on the horizon, such as supercritical fluid processing, mesoporous silica, KinetiSol®, and the use of non-salt-forming organic acids and amino acids for the stabilization of amorphous systems. Amorphous Solid Dispersions: Theory and Practice is a valuable reference to pharmaceutical scientists interested in developing bioavailable and therapeutically effective formulations of poorly soluble molecules in order to advance these technologies and develop better medicines for the future.

Providing methodologies that can serve as a reference point for new formulations, the second volume covers uncompressed solids, which include formulations of powders, capsules, powders ready for reconstitution, and other similar products.Highlights from Uncompressed Solid Products, Volume Two include:the fundamental issues of good manufacturin

This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such

drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.

Pharmaceutics: Drug Delivery and Targeting focuses on what pharmacy students really need to know in order to pass exams, providing concise, bulleted information, chapter overviews, hints, key points, mind maps and an all-important self-assessment section which includes MCQs. This FASTtrack book systematically reviews important concepts and facts relating to the delivery and targeting of drugs. Relevant examples of delivery systems are given throughout the book with a focus on delivery systems that have actually reached clinical reality. Information is presented concisely with self assessment questions/answers and mindmaps to aid learning. The text has been updated for the new edition based on student feedback.