

Dissolution Test Usp

Handbook of Pharmaceutical Wet
GranulationIntegrative PsychiatryOral Drug
AbsorptionDissolution Shelf Life of PrednisoneApplied
Physical PharmacyBentley's Textbook of
Pharmaceutics - E-BookModern PharmaceuticsShelf
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based Shelf Life Computer ProgramLong Acting
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Dissolution TestingIn Vitro Drug Release Testing of
Special Dosage FormsTheory and Practice of Physical
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Pharmacokinetics, Sixth EditionDissolution,
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Process Scale-Up
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Testing
Nonclinical Statistics for Pharmaceutical and
Biotechnology Industries
Issues in National, Regional,
and Environmental Health and Medicine: 2011
Edition
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Handbook of Pharmaceutical Wet Granulation

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an

Integrative Psychiatry

The USP-NF is a combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. USP-NF standards are enforceable by the U.S. Food and Drug Administration for medicines manufactured and marketed in the United States. Learn more about USP-NF. Highlights & Features: * More than 4,500 monographs with specifications for identity, strength, quality, purity, packaging, and

labeling for substances and dosage forms. View a sample USP-NF monograph (100KB). * Over 230 General Chapters providing clear, step-by-step guidance for assays, tests, and procedures * Focus-specific charts and a combined index helps you find the information you need * Helpful sections on reagents, indicators, and solutions, plus reference tables * Published annually in an official English edition (print, CD, and new USB flash drive formats) and an official Spanish edition (print).

Oral Drug Absorption

The highly experienced authors here present readers with step-wise, detail-conscious information to develop quality pharmaceuticals. The book is made up of carefully crafted sections introducing key concepts and advances in the areas of dissolution, BA/BE, BCS, IVIC, and product quality. It provides a specific focus on the integration of regulatory considerations and includes case histories highlighting the biopharmaceutics strategies adopted in development of successful drugs.

Dissolution Shelf Life of Prednisone

"Completely revised and expanded throughout. Presents a comprehensive integrated, sequenced approach to drug dosage formulation, design, and evaluation. Identifies the pharmacodynamic and physicochemical factors influencing drug action through various routes of administration."

Applied Physical Pharmacy

Bentley's Textbook of Pharmaceutics - E-Book

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in September, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery company specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Nottingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. Iain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the development of in vitro-in vivo

relationships for ER products. The original idea went back approximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development.

Modern Pharmaceuticals

The US Food and Drug Administration's Report to the Nation in 2004 and 2005 indicated that one of the top reasons for drug recall was that stability data did not support existing expiration dates. Pharmaceutical companies conduct stability studies to characterize the degradation of drug products and to estimate drug shelf life. Illustrating how stability studies play an important role in drug safety and quality assurance, *Statistical Design and Analysis of Stability Studies* presents the principles and methodologies in the design and analysis of stability studies. After introducing the basic concepts of stability testing, the book focuses on short-term stability studies and reviews several methods for estimating drug expiration dating periods. It then compares some commonly employed study designs and discusses both fixed and random batch statistical analyses. Following a chapter on the statistical methods for stability analysis under a linear mixed effects model, the book examines stability analyses with discrete responses, multiple components, and frozen drug products. In addition, the author provides statistical methods for dissolution testing and explores current issues and recent developments in stability studies. To ensure the safety of consumers, professionals in

the field must carry out stability studies to determine the reliability of drug products during their expiration period. This book provides the material necessary for you to perform stability designs and analyses in pharmaceutical research and development.

Shelf Life Estimation of USP 10mg Prednisone Calibrator Tablets in Relation to Dissolution & New Windows-based Shelf Life Computer Program

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.

Long Acting Injections and Implants

Updated and expanded second edition covers all aspects of capsule technology, including history, standards, methods and equipment used in manufacture, filling, printing, weighing, cleaning and inspecting of both hard and soft capsules.

Developing Solid Oral Dosage Forms

Statistics in Drug Research

A comprehensive textbook on the theoretical and practical applications of biopharmaceutics and pharmacokinetics The field's leading text for more than three decades Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition provides you with a basic understanding of the principles of

biopharmaceutics and pharmacokinetics and applies these principles to drug product development, drug product performance and drug therapy. The revised and updated sixth edition is unique in teaching basic concepts that relate to understanding the complex issues associated with safe and efficacious drug therapy. Written by authors who have both academic and clinical experience, *Applied Biopharmaceutics & Pharmacokinetics* will help you to: Understand the basic concepts in biopharmaceutics and pharmacokinetics. Use raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, and elimination Critically evaluate biopharmaceutic studies involving drug product equivalency and unequivalency Design and evaluate dosage regimens of drugs, using pharmacokinetic and biopharmaceutic parameters Detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them Practical problems and clinical examples with discussions are included in each chapter to help you apply these principles to patient care and drug consultation situations. Chapter Objectives, Chapter Summaries, and Frequently Asked Questions along with additional application questions appear within each chapter to identify and focus on key concepts. Most of the chapters have been revised to reflect our current understanding of drug product performance, bioavailability, bioequivalence, pharmacokinetics, pharmacodynamics, and drug therapy.

Handbook of Dissolution Testing

This book serves as a reference text for regulatory, industry and academic statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxicology sciences, and the Chemistry, Manufacturing and Controls sciences. Drug discovery and development is a long and costly process. Most decisions in the drug development process are made with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory guidance, current statistical practice, and further research directions.

In Vitro Drug Release Testing of Special Dosage Forms

A core subject in pharmaceuticals, physical pharmacy is taught in the initial semesters of B. Pharm. The methodical knowledge of the subject is required, and is essential, to understand the principles pertaining to design and development of drug and drug products.

Theory and Practice of Physical Pharmacy is unique as it fulfils the twin requirements of physical pharmacy students: the authentic text on theoretical concepts and its application including illustrative exercises in the form of practicals. Covers all the topics included in various existing syllabi of physical pharmacy Provides an integrated understanding of theory and practical applications associated with physicochemical concepts Explore the latest developments in the field of pharmaceutics Reviews the relevance of physicochemical principles in the design of dosage form Ensures proper recapitulation through sufficient end-of-chapter questions Provides valuable learning tool in the form of multiple choice questions Multiple choice questions section especially useful for GPAT aspirants

Theory and Practice of Physical Pharmacy - E-Book

Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition

Dissolution, Bioavailability & Bioequivalence

Designed as the core textbook for the required physical pharmacy or pharmaceutics course within the pharmacy school curriculum. With a focus on examples from pharmacy practice, this book presents the chemical and physical chemical principles

fundamental to the development of medication dosage forms. Numerous case studies present relevant examples of physical chemical principles in current pharmacy practice.

Pharmacopoeia of the People's Republic of China

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, prefomulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

Dosage Form Design Considerations

1. Evolution of dissolution testing 5; 2. Theory of dissolution 11; 3. Theoretical concepts for the release of a drug from dosage forms 37; 4. Effect of the physicochemical properties of the drug on dissolution rate 53; 5. Factors affecting the rate of dissolution of solid dosage forms 73; 6. Effects of storage and packaging on the dissolution of drug formulations 107; 7. Factors relating to the dissolution apparatus 115; 8. Effect of the test parameters on dissolution rate 145; 9. Dissolution of suspensions 173; 10. Dissolution of topical dosage forms (creams, gels, and ointments) 189; 11. Dissolutions of suppositories 205; 12. Dissolution characteristics of controlled-release systems 215; 13. Methods for enhancement of the drug-dissolution characteristics 265; 14. Developing a new dissolution method 285; 15. Bioavailability, definitions and historical perspective 297; 17. In vitro modeling for drug absorption 315; 18. Pharmacokinetic considerations in bioavailability studies 335; 19. Bioavailability and variations in drug blood levels 367; 20. Bioavailability and the biologic response 385; 21. Measurements of bioavailability 399; 22. General issues to be considered in conducting bioavailability studies 415; 23. Bioavailability of controlled-release dosage forms 425; 24. In vivo release and bioavailability of topical preparations 437; 25. Methods for enhancement of bioavailability 455; 26. Bioequivalence: general definitions 477; 27. Bioequivalence: case histories 481; 28. Correlation of in vitro rate of dissolution with in vivo bioavailability 491; 29. Determination of

bioequivalence and its regulatory aspects 517; 30. The official bioequivalence protocols and therapeutic equivalence 533.

USP, NF.

This guide to United States toxicology, ecotoxicology, environmental, analytical and support service laboratories is designed to help companies locate those laboratories which can test new and existing chemicals in order to determine potential hazards and risks associated with their manufacture, distribution and use. The health and safety and environmental effects of chemicals are described. The volume gives information on the following: toxicology laboratories (mammalian and related studies); ecotoxicology (aquatic and related studies); environmental effects/fate-analytical services (methods development and analysis); and specialized services eg radio label compound synthesis. It is intended for the use of companies seeking suitable laboratories to conduct reliable studies for either company-sponsored programmes or who are under a requirement to comply with government agency regulations.

Directory Of Toxicological And Related Testing Laboratories

Issues in Biochemistry and Biomaterials / 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Biochemistry and Biomaterials. The editors have built Issues in Biochemistry and Biomaterials: 2011 Edition

on the vast information databases of ScholarlyNews.™ You can expect the information about Biochemistry and Biomaterials in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in Biochemistry and Biomaterials / 2011 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at <http://www.ScholarlyEditions.com/>.

In Vitro-In Vivo Correlations

Issues in Biochemistry and Biomaterials: 2011 Edition

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns. Generic Drug Product Development: Solid Oral

USP35 NF30, 2012

Long acting injections and implants improve therapy, enhance patient compliance, improve dosing convenience, and are the most appropriate formulation choice for drugs that undergo extensive first pass metabolism or that exhibit poor oral bioavailability. An intriguing variety of technologies have been developed to provide long acting injections and implants. Many considerations need to go into the design of these systems in order to translate a concept from the lab bench to actual therapy for a patient. This book surveys and summarizes the field. Topics covered in Long Acting Injections and Implants include the historical development of the field, drugs, diseases and clinical applications for long acting injections and implants, anatomy and physiology for these systems, specific injectable technologies (including lipophilic solutions, aqueous suspensions, microspheres, liposomes, in situ forming depots and self-assembling lipid formulations), specific implantable technologies (including osmotic implants, drug eluting stents and microfabricated systems), peptide, protein and vaccine delivery, sterilization, drug release testing and regulatory aspects of long acting injections and implants. This volume provides essential information for experienced development professionals but was also written to be useful for scientists just beginning work in the field and for others who need an understanding of long acting injections and implants. This book will also be ideal as a graduate textbook.

Biopharmaceutics Applications in Drug Development

Handbook of Stability Testing in Pharmaceutical Development

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an

Statistical Design and Analysis of Stability Studies

Handbook of Pharmaceutical Wet Granulation: Theory and Practice in a Quality by Design Paradigm offers a single and comprehensive reference dedicated to all aspects of pharmaceutical wet granulation, taking a holistic approach by combining introductory principles with practical solutions. Chapters are written by international experts across industry, academic and regulatory settings, and cover a wide spectrum of relevant and contemporary wet granulation topics, techniques and processes. The books' focus on process analytical technology, quality by design principles, granulation equipment, modeling, scale-up, control and real time release makes it a timely and valuable resource for all those involved in pharmaceutical wet granulation. Discusses fundamentals of theory and current industrial practice in the field of wet granulation, including product and process design and role of material properties in wet

granulation Examines the modern evolution of wet granulation through current topics such as established and novel process analytical technologies (PATs), and product development and scale-up paradigms Written for scientists working within the pharmaceutical industry, as well as academics, regulatory officials and equipment vendors who provide PAT tools and granulation equipment

Food, Drug, Cosmetic Law Reporter

Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that

provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

The International Pharmacopoeia. -- 1981-

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Pharmaceutical Capsules

Oral Drug Absorption

Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about National, Regional, and Environmental Health and

Medicine. The editors have built Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about National, Regional, and Environmental Health and Medicine in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at <http://www.ScholarlyEditions.com/>.

Dissolution Shelf Life of Hydroxypropyl Methyl Cellulose Coated Aspirin Tablets at I.C.H. Temperatures and Various Relative Humidities

This adaptation of Bentley's Textbook of Pharmaceutics follows the same goals as those of the previous edition, albeit in a new look. The content of the old edition has been updated and expanded and several new chapters, viz. Complexations, Stability Testing as per ICH Guidelines, Parenteral Formulations, New Drug Delivery Systems and Pilot Plant Manufacturing, have been included, with an

intention to make the book more informative for the modern pharmacists. The book has six sections: Section I deals with the physicochemical principles. Two new chapters: Complexations and ICH Guidelines for Stability Testing, have been added to make it more informative. Section II conveys the information regarding pharmaceutical unit operations and processes. Section III describes the area of pharmaceutical practice. Extensive recent updates have been included in many chapters of this section. Two new chapters: Parenteral Formulations and New Drug Delivery Systems, have been added. Section IV contains radioactivity principles and applications. Section V deals with microbiology and animal products. Section VI contains the formulation and packaging aspects of pharmaceuticals. Pilot Plant Manufacturing concepts are added as a new chapter, which may be beneficial to readers to understand the art of designing of a plant from the pilot plant model.

Cutaneous Biometrics

Generic Drug Product Development

Poorly Soluble Drugs

Emphasizing the role of good statistical practices (GSP) in drug research and formulation, this book outlines important statistics applications for each stage of pharmaceutical development to ensure the valid design, analysis, and assessment of drug

products under investigation and establish the safety and efficacy of pharmaceutical compounds. Coverage include statistical techniques for assay validation and evaluation of drug performance characteristics, testing population/individual bioequivalence and in vitro bioequivalence according to the most recent FDA guidelines, basic considerations for the design and analysis of therapeutic equivalence and noninferiority trials.

Pharmaceutical Process Scale-Up

Pharmaceutical Dissolution Testing

Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage

Forms covers the in vitro release testing of: lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms Describes current regulatory conditions for in vitro drug release testing Features contributions from well respected global experts in dissolution testing In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmaceuticals, and regulatory affairs.

Nonclinical Statistics for Pharmaceutical and Biotechnology Industries

Introduction, Historical Highlights, and the Need for Dissolution Testing Theories of Dissolution Dissolution Testing Devices Automation in Dissolution Testing, by William A. Hanson and Albertha M. Paul Factors That Influence Dissolution Testing Interpretation of Dissolution Rate Data Techniques and of In Vivo Dissolution, by Umesh V. Banakar, Chetan D. Lathia, and John H. Wood Dissolution of Dosage Forms Dissolution of Modified-Release Dosage Forms Dissolution and Bioavailability Dissolution Testing and the Assessment of Bioavailability/Bioequivalence, by Santosh J. Vetticaden Dissolution Rediscovered, by John H. Wood Appendix: USP/NF Dissolution Test.

Issues in National, Regional, and Environmental Health and Medicine: 2011 Edition

Focusing on scientific and practical aspects of process scale-up, this resource details the theory and practice of transferring pharmaceutical processes from laboratory scale to the pilot plant and production scale. It covers parenteral and nonparenteral liquids and semi-solids, products derived from biotechnology, dry blending and powder handling, granulation and drying, fluid bed applications, compaction and tableting, and film coating and regulatory requirements for scale-up and postapproval changes. Drawing on the experience of twenty contributing researchers, the book employs dimensional analysis as a unified scientific approach to quantify similar processes on different scales.

Drug Intelligence & Clinical Pharmacy

Biometrics in dermatology is an essential tool where data evaluation results in valid interpretations. This book will be the first in this area. One part of the book will describe principal aspects of dermatological research focussing on practical advice. A special part will cover applied biometrics to provide the clinician and researcher with state-of-the-art guidelines to assess the severity of common skin diseases. An additional aspect that will be of interest to pharmacologists addresses pharmacologic assays.

Geigy Scientific Tables

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