



# Pharmaceutical Dissolution Testing

**Umesh V. Banakar**



## **Pharmaceutical Dissolution Testing:**

**Pharmaceutical Dissolution Testing** Umesh V. Banakar,1991-09-25 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

Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence Umesh V. Banakar,2022-01-19 Explore the cutting edge of dissolution testing in an authoritative one stop resource In Pharmaceutical Dissolution Testing Bioavailability and Bioequivalence Science Applications and Beyond distinguished pharmaceutical advisor and consultant Dr Umesh Banakar delivers a comprehensive and up to date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development After discussing the fundamentals of the subject the included resources go on to explore common testing practices and methods along with their associated challenges and issues in the drug development life cycle Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution apart from mere quality control Readers will discover a wide range of topics including automation generic and biosimilar drug development patents and clinical safety This volume offers a one stop resource for information otherwise scattered amongst several different regulatory regimes It also includes A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility dissolution permeability and classification systems in drug development In depth examinations of the mechanics of dissolution including mathematical models and simulations An elaborate assessment of biophysiological relevant dissolution testing and IVIVCs and their unique applications A complete understanding of the methods requirements and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists quality control and assurance professionals and regulators *Pharmaceutical Dissolution Testing Bioavailability and Bioequivalence* is also the perfect resource for intellectual property assessors

*Handbook of Dissolution Testing* William A. Hanson,1982 *Pharmaceutical Dissolution Testing* Jennifer J. Dressman,Johannes Kramer,2005-07-08 An expertly written source on the devices systems and technologies used in the dissolution testing of oral pharmaceutical dosage forms this reference provides reader friendly chapters on currently utilized equipment equipment qualification consideration of the gastrointestinal physiology in test design the analysis and interpretation of data *In Vitro Drug Release Testing of Special Dosage Forms* Nikoletta Fotaki,Sandra Klein,2019-10-11 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 *Developing Solid Oral Dosage Forms* Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William Porter, 2009-03-10 *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 *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems* Loyd V. Allen, Nicholas G. Popovich, Howard C. Ansel, 2011 Thanks to its comprehensive coverage clear explanations and logical organization Ansel s *Pharmaceutical Dosage Forms and Drug*

Delivery Systems has been a core pharmaceuticals text in the pharmacy curriculum for more than 40 years. As you progress through this thoroughly updated Ninth Edition you will master all the principles, practices, and technologies essential for the preparation of pharmaceutical dosage forms and drug delivery systems. The text's integrated approach will help you understand the interrelationships among pharmaceutical and biopharmaceutical principles, product design, formulation, manufacturing, compounding, and the clinical application of dosage forms for effective patient care.

**Book Jacket** *Poorly Soluble Drugs* Gregory K. Webster, Robert G. Bell, J. Derek Jackson, 2017-01-06. 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 of 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.

*Automation of Pharmaceutical Operations* David J. Fraade, 1983. Explores computer applications in the pharmaceutical research laboratory, production plant.

*Current Concepts in the Pharmaceutical Sciences: Biopharmaceutics* James Swarbrick, 1970.

**Handbook of Dissolution Testing** Royal Hanson, Vivian Gray, 2004.

**Principles and Perspectives in Drug Bioavailability** James Blanchard, Ronald J. Sawchuk, Bernard B. Brodie, 1979.

*Solid-state Chemistry of Drugs* Stephen R. Byrn, 1999.

**Pharmaceutical Technology--drug Stability** Michael Henry Rubinstein, 1989.

**Remington's Pharmaceutical Sciences** Joseph Price Remington, Alfonso R. Gennaro, 1990.

*Chromatographic Analysis of Pharmaceuticals* John A. Adamovics, 1990.

**Improvements to biorelevant dissolution testing: lyophilized media, buffer alternatives and miniaturized apparatus** Julia Elisabeth Boni, 2009-08-13. Dissolution in different steps of pharmaceutical drug development was considered in this work. Dissolution is used as an informative tool throughout the entire development process. After identification of a possible drug candidate, intrinsic dissolution in different buffer media is tested.

for physicochemical characterization In galenics dissolution is used to develop and optimize formulations by comparative release studies During scale up dissolution testing is used to observe influence of process or parameter changes For regulatory affairs all of these dissolution studies are of interest and many have to be presented to the authorities Most of the dissolution testing designs in pharmaceutical development are following pharmacopoeial monographs or general chapters and official guidelines In addition these official dissolution testing setups a progression of more innovative dissolution methods closer to physiological conditions are used Devices simulating movement and flow of the GIT combined with media simulating the gastrointestinal fluids are often used Disadvantages of these methods are that they are time consuming and expensive both of which limit throughput The aims of this thesis were to a reduce time consumption regarding preparation of biorelevant dissolution b increase biorelevance of the media FaSSIF and FeSSIF by substituting the non physiological buffer systems for bicarbonate and c to increase throughput by miniaturization of dissolution devices To meet the first goal a novel preparation method for the biorelevant media FaSSIF and FeSSIF was established The conventional method uses chlorinated organic solvent is time consuming in preparation approx 2 hours and needs to be done daily The investigated method uses freeze drying for the preparation of instant biorelevant media The instant media only consist of bile salt and lecithin in mixed micelles In situ preparation is done by simply adding blank buffer to the rapidly dissolving lyophilisate Freeze dried product gave comparable results to freshly prepared media and improved reproducibility Comparison to commercial available instant media indicated superiority of the freeze drying method Next a buffer system based on the more physiological bicarbonate buffer was investigated A method to maintain a stable buffer system throughout the dissolution testing The buffer therefore was created by sparging carbon dioxide into alkali saline solution to forming carbonate and bicarbonate as buffer system At equilibrium the media was transferred to the vessels and supply of carbon dioxide continued by sparging the gas above the solution Therewith bubble formation could be minimized although not excluded Only a small range of buffer strength and pH combinations was possible The lowest pH still providing effective buffer capacity 5 mmol l pH was 5.5 Physiologically relevant buffer capacities of 10 and 30 mmol l pH were tested at pH 6.5 The buffer turned out to be very sensitive against pH modifying agents by loosening its buffer capacity and strength Standard deviations were generally higher No superiority over conventional buffer systems like phosphate or acetate buffer regarding IVIVC was given Therefore it is concluded that bicarbonate buffer is not a suitable medium for in vitro dissolution testing Subsequently methods for small scale dissolution testing were established Improvement of throughput in dissolution testing was achieved The investigated BI miniDiss method can be used to test release profiles of small particulate formulations or intermediates High throughput excipient screening for early formulation is possible by using the well plate method In the first series of tests downscaling by factor 10 was conducted by miniaturizing and automating standard dissolution apparatus Small vessels of 20 ml volume and paddles of about 8 mm diameter were used Automating was done by sampling through paddle hollow shafts and online UV VIS

measurement Since no filtration was possible due to the small sample volume the true % dissolved was calculated using mathematical scatter correction of spectra from turbid solutions In this way release profiles comparable to standard dissolution testing were obtained Cleaning and restart is accelerated and therewith throughput increased The 10fold reduced consumption of drug formulation reduces API consumption so that a larger variety of formulations can be prepared and tested with the same amount of API The BI miniDiss is limited to multiparticulates like pellets extrudates minitables granules or intermediates Downscaling of matrix or IR tablets will likely result in different results due to changed surface to volume ratio The well plate method offers a miniaturization of factor 100 Dissolution of multiparticulates showed significant differences compared to standard methods However ranking of formulations was possible in several cases The well plate method is not suitable for conducting comparative release profiles However it can be used for selection of excipients by supersaturation testing It is an informative tool in early formulation screening helping to optimize formulation of poorly soluble compounds As last part of the work the BI miniDiss was used to screen various buffers to finding the best media for IVIVC retrospectively The BI miniDiss proved to be useful as a fast and cost and effective screening method In summary several improvements in dissolution for pharmaceutical development purposes have been developed regarding consumption of API costs and efficiency An easy and rapid preparation of biorelevant media was established making their use in pharmaceutical development and routine quality control more feasible The miniaturized dissolution methods and the improved high throughput fulfil demands from pharmaceutical industries to facilitate API saving methods in development

**Applied Biopharmaceutics & Pharmacokinetics, Fifth Edition** Leon Shargel,Susanna Wu-Pong,Andrew Yu,2004-08-19 The most comprehensive text on the practical applications of biopharmaceutics and pharmacokinetics 4 STAR DOODY S REVIEW The updated edition provides the reader with a solid foundation in the basic principles of pharmacokinetics and biopharmaceutics Students will be able to apply the information to their clinical practice and researchers will find this to be a valuable reference This modestly priced book should be the gold standard for student use Doody s Review Service The primary emphasis of this book is on the application and understanding of concepts Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided along with illustrative examples and practice problems and solutions to help the student gain skill in practical problem solving Pharmaceutical Process Validation, Second Edition Ira R. Berry,Robert A. Nash,1993-01-29 The second edition of this text has been updated and enlarged to reflect current good manufacturing practice CGMP regulations and the increased interest in and applicability of process validation Pharmaceutical Process Validation offers up to the minute coverage of regulations and validation sterile process validation organization in validation processes solid dosage forms validation raw material validation analytical methods validation and prospective and retrospective validation Providing the contributions of leading experts in the field the text also supplies examinations of current concepts in validation and new topics such as validation of cleaning

systems and computer systems equipment and water systems validation and lyophilized and aerosol product validation  
Applied Spectroscopy ,1993

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