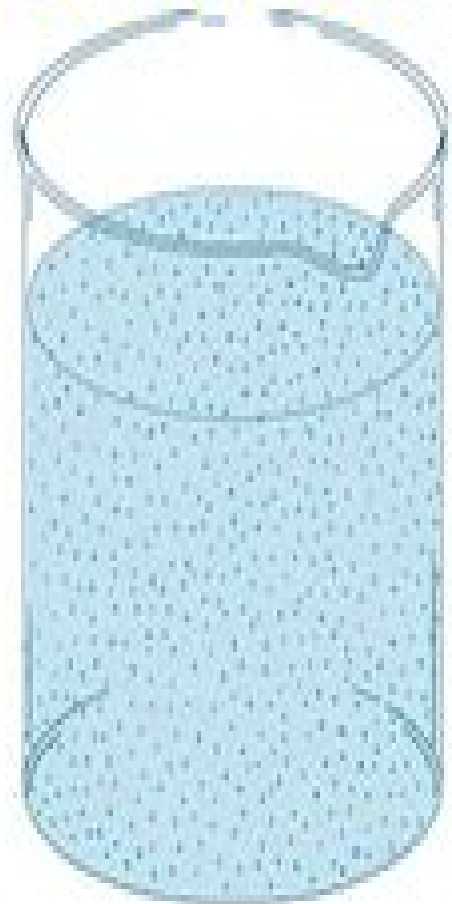


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Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence Umesh V. Banakar, 2022-01-19 Explore the cutting edge of dissolution testing in an authoritative one stop resource In *Pharmaceutical Dissolution Testing Bioavailability and Bioequivalence 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 biophysiologically 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

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 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 minitabets 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 find 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.

Handbook of Divorce and Relationship Dissolution Mark A. Fine, John H. Harvey, 2013-12-19 This Handbook presents up to date scholarship on the causes and predictors, processes and consequences of divorce and relationship dissolution. Featuring contributions from multiple disciplines, this Handbook reviews relationship termination including variations depending on legal status, race, ethnicity and sexual orientation. The Handbook focuses on the often neglected processes involved as the relationship unfolds, such as infidelity, hurt and remarriage. It also covers the legal and policy aspects, the demographics and the historical aspects of divorce. Intended for researchers, practitioners, counselors, clinicians and advanced students in psychology, sociology, family studies, communication and nursing, the book serves as a text in courses on divorce, marriage and the family and close relationships.

Mineral Dissolution Kinetics: New Perspectives Victor W. Truesdale, Jim E. Greenwood, Tim G. Southern, 2025-05-09 Mineral Dissolution Kinetics: New Perspectives is at its core a search for a universal rate equation for mineral dissolutions. It documents and details the journey undertaken by its authors, appealing not only to specialists and experts in related fields but also to novice readers seeking to learn more about this unique subject. The book reveals how the compounding of many otherwise subtle misunderstandings has resulted in the underdevelopment of fundamental concepts in mineral dissolution kinetics despite its long history of study. By examining a wide cross section of existing studies, it uncovers these misunderstandings and forges a new way forward. Although mineral dissolution kinetics has been immensely important in explaining continental weathering, landform development and the maintenance of water supplies for agricultural and human use, it remains a critically undervalued field of chemistry. It is also foundational to our understanding of the marine environment and serves as an essential tool in the long term storage of CO₂ and radionuclide waste. More recently, it has helped address the human induced rise in tropospheric CO₂, a key cause of global warming and ocean acidification. Complex subjects such as the hydrodynamics of dissolution, the thermodynamics of the aqueous carbonate system and central omissions at the very core of homogeneous kinetics are explained clearly and simply while still remaining at the cutting edge of the field.

Growth, Dissolution and Pattern Formation in Geosystems B. Jamtveit, P. Meakin, 2013-03-09 This book is the proceedings of the 11th Kongsberg seminar held at the

Norwegian Mining Museum in the city of Kongsberg about 70 km Southwest of Oslo The Kongs berg district is known for numerous Permian vein deposits rich in native silver Mining activity in the area lasted for more than 300 years finally ceasing in 1957 The first eight Kongsberg seminars organized by professor Arne BjØrlykke now director of the Norwegian Geological Survey were focused on ore forming processes These seminars have always been a meeting point for people with a variety of geological backgrounds Since 1995 the Kongsberg seminars have focussed on geological processes rather than on specific geological systems and the selection of invited speakers has been strongly influenced by their interest in the dynamics of geological systems In 1995 and 1996 various aspects of fluid flow and transport in rocks were emphasized The first Kongsberg proceedings of the 1995 seminar published by Chapman and Hall Jamtveit and Yardley 1997 contained 17 chapters dealing with a wide range of topics from field based studies of the effects of fluid flow in sedimentary and metamorphic rocks to computer simulations of flow in complex porous and fractured media In 1997 the focus was changed to growth and dissolution processes in geological systems

Effects of Acid Deposition on Dissolution of Carbonate Stone During Summer Storms in the Adirondack Mountains, New York, 1987-89 Paul F. Schuster, Michael M. Reddy, Susan Ingrid Sherwood, 1994

The History of Roche Abbey, from Its Foundation to Its Dissolution James Hobson Aveling, 1870

Implications of Parent-Child Boundary Dissolution for Developmental Psychopathology Patricia K. Kerig, 2014-06-03 Gain a better understanding of parent child boundaries and the mechanisms for their dissolution The breakdown of appropriate generational boundaries between parent and child can threaten the child s psychological development Implications of Parent Child Boundary Dissolution for Developmental Psychopathology Who Is the Parent and Who Is the Child explores this covert and oftentimes ignored form of emotional abuse discussing in detail the various ways it can manifest This revealing text comprehensively examines how the burden of meeting the emotional needs of the parent interferes with the child s healthy development The boundary dissolution patterns of role reversal enmeshment psychological control and triangulation are closely examined with an eye toward providing appropriate strategies for dealing with the problem Implications of Parent Child Boundary Dissolution for Developmental Psychopathology is separated into four sections to focus extensively on every aspect of the problem The first section discusses definitions concepts and methodological concerns of the phenomena including a consideration of the child s developmental responses to boundary dissolution The second section explores the empirical research concerning boundary dissolution within the family system and includes intriguing information on the actual mechanism that passes the pattern of role reversal on to the following generation The next section closely examines boundary violations within high risk families with a focus on those undergoing divorce The final section concentrates on cultural contexts of boundary dissolution and includes a look at the perception of familial responsibility and its effects on Bosnian youths This one of a kind resource is extensively referenced and provides a solid foundation to inspire a new generation of theory research and clinical work Implications of Parent Child Boundary

Dissolution for Developmental Psychopathology examines a multidimensional model of boundary dissolution with supporting research a comprehensive review of published literature in the areas of attachment theory developmental capacities of the infant child rearing practices and parental beliefs the theoretical background supporting the construct of boundary dissolution the boundary disturbance patterns of enmeshment and control the relationships between interparental conflict parental responses to children's emotions and representations of role reversal and vulnerability in children's family drawings the spill over effect of marital conflict role reversal in high risk families children's rejection of one parent over another in custody disputes post war adjustment of Bosnian adolescents psychological control in individualist and collectivist groups representations of parents and children in twentieth century American novels Implications of Parent Child Boundary

Dissolution for Developmental Psychopathology is crucial reading for researchers and clinicians who deal with families and psychopathology and is of particular interest to graduate students in clinical child psychology child and family studies social work and developmental psychology

Handbook of Dissolution Testing William A. Hanson, 1982 **Code Practice** Edwin Eustace Bryant, 1898 **Marriage and Marriage Dissolution in California** California. Department of Health, 1977

A Treatise on the Law of Injunctions James Lambert High, 1873 **The Dissolution of Granular Solids in Liquids** Kenneth Merle Watson, 1929 **Tax Aspects of Marital Dissolution** Harold G. Wren, 1987 *Appendix to the Journals of the House of Representatives of New Zealand* New Zealand. Parliament. House of Representatives, 1886 **Marriages, Divorces and Annulments with Dissolution Ratios for Counties in Illinois**, 1976 **The New York Supplement**, 1898 Cases argued and determined in the Court of Appeals Supreme and lower courts of record of New York State with key number annotations varies **Biennial Report** Wyoming. Secretary of State, 1898 *In re Dissolution of Hecla Co.; City of Detroit v. Hertz*, 184 MICH 512 (1915), 1915 111 **The Genesis and dissolution of the faculty of speech** Joseph Collins, 1898

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