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Dissolution Testing

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Dissolution Testing

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 **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 and procedure automation laying the foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract

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

Handbook of Dissolution Testing William A. Hanson,1982 *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 pharmaceutics and regulatory affairs

Analytics of dissolution testing of products containing nanosized drugs with a view to predicting plasma profiles Daniel Jünemann,2012-01-31 The oral bioavailability of a drug substance is strongly related to its aqueous solubility Only complete dissolution during the GI passage can maintain an optimal bioavailability Poor aqueous drug solubility results according to the Nernst Brunner equation into a slow dissolution rate sometimes too slow for complete dissolution in the GI tract The dissolution rate increases with decreasing particle size and therefore increasing surface area of the drug particles In consequence micronization of the drug is applied to increase oral bioavailability but often meets with modest success Recently developed techniques were applied to decrease the particle size into the nanometer range For some substances pharmacokinetic parameters could be influenced decisively e g the obviation of a food effect for the drugs aprepitant and fenofibrate The assessment of a dosage form is investigated by dissolution testing For a reasonable assessment of such tests a separation of solid and liquids has to be ensured within an appropriate time frame For particle sizes of about 150 nm it appears questionable whether such separation can be succeeded by classical techniques e g the use of syringe filters with a pore size of 0 45 m The aims of this thesis were to investigate the suitability of various analytical techniques in analysis of dissolution tests containing nanosized drug substance Furthermore a suitable analytical tool is applied to establish an in vitro in vivo correlation of the nanosized drug fenofibrate At first several techniques were investigated in theory to assess their

ability to ensure a rapid and complete separation of solids and liquids The classical dialysis turbidity measurement and UV measurement via fiber optics were excluded from further investigation due to various reasons e g the speed of separation for dyialisis The asymmetrical flow field flow fractionation appeared to be a promising tool but lack of equipment precluded further investigation The ultrasonic resonance technology ResoScan the microdialysis and the use of centrifugal filter devices have shown to be inappropriate for the analytics of nanosized drugs in dissolution test The use of syringe filters with various pore sizes and the ionselective electrode ISE was promising so these techniques were examined more intensively The syringe filters with various filter pore sizes were investigated for their ability to hold back colloidal drug Fenofibrate was chosen as model drug since this is commercially available both as micronized and nanosized formulation Lipidil TerR and Lipidil 145 ONER enabling direct comparison The experiments with micronized fenofibrate which contains little or no colloidal fenofibrate yielded similar dissolution profiles irrespective of filter pore size f2 was always greater than 65 indicating less than 5% difference between the dissolution profiles in any medium Using a pore size of 0 1 m or less the maximum concentration of drug achieved in solution from the nanosized formulation was commensurate with the saturation solubility of fenofibrate in all tested media Filtration with a pore size of 0 2 m or 0 45 m generated concentrations exceeding the saturation solubility These results in combination with higher standard deviations of the analytical results indicate that the apparent supersaturation is caused by colloidal fenofibrate which is too fine to be held back by these filters The f2 value of less than 50 when comparing the profiles obtained from 0 1 m and 0 2 m filter pore size indicates that the choice of filter pore size is crucial to the interpretation of the dissolution profiles To separate nanosized drug from molecularly dissolved fenofibrate in Lipidil 145 ONER a filter pore size of 0 1 m or less appears to be appropriate It was observed that the experimental increase of dissolution rate is not congruent with common hypothesis regarding the boundary layer h for decreasing particle sizes and subsequent application of the Nernst Brunner equation The initial dissolution rates of both formulations were investigated by using a filter pore size of 0 1 m The results were utilized in an in silico model STELLAc to correlate the in vitro results with in vivo data Model A In the preprandial state a good in correlation was established for the micronized fenofibrate while for the nanosized fenofibrate the plasma levels were overpredicted The model was expanded to investigate the impact of an absorption step at the intestinal membrane on the in vitro in vivo correlation It was found that even a minor deceleration of absorption results in varied plasma profiles caused by a lagged appearance of drug in the blood For both formulations the rate determining step was identified When changing from the micronized to the nanosized formulation the rate determining step for absorption may change from completely dissolution controlled to at least partly permeationcontrolled in the fasted state In the fed state gastric emptying appears to be rate determining for absorption of fenofibrate from both the micronized and the nanosized formulation Another technique appears to be suitable for analysis of nanosized drugs in dissolution testing The Ion selective electrode ISE is a recently developed analytical system measuring

the changes of the electrochemical potential in solutions A transformation via the Nikolski Eisenmann equation results into the concentration of the respective drug in solution Since only dissolved drug is detected obviating the need for separation of dissolved from undissolved drug this system appears to be very promising in the analytics of nanocrystalline drugs Diphenhydramine_HCl was chosen as model substance for the ISE studies It was the goal of investigation to test compatibility of the ISE with complex media e g all biorelevant dissolution media This is done in advance of application of the ISE in these media for nanocrystalline drug substance The results were compared to manual sampling filtration and subsequent HPLC UV analysis The results demonstrate that the ion selective electrode is suitable for measurements of diphenhydramine HCl in fasted state biorelevant media FaSSGF FaSSIF FaSSIF V2 as both a stand alone system Method A and in conjunction with a single point conventional assay Method B The results acquired are similar to those obtained by manual sampling and subsequent HPLC UV analysis The ISE also delivers satisfactory results in a milk based medium FeSSGF in which it has distinct advantages over manual sampling with HPLC UV analysis by obviating the need for sample preparation The application of the ISE in FeSSIF type media will need further study Finally as an on line technology ISE offers more efficient generation of dissolution profiles than conventional sample based methods *Handbook of Dissolution Testing* Royal Hanson,Vivian Gray,2004 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 minitablets 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

Dissolution of Disintegrating Solid Dosage Forms in a Modified Dissolution Testing Apparatus 2 Shrutiben Rameshbhai Parekh,2011 Dissolution tests are routinely carried out in the pharmaceutical industry to determine the dissolution rate of solid dosage forms Dissolution testing serves as a surrogate for drug bioavailability through in vitro in vivo correlation IVIVR and it additionally helps in guiding the development of new formulations and in assessing lot to lot consistency thus ensuring product quality The United States Pharmacopoeia USP Dissolution Testing Apparatus 2 is the device most commonly used for this purpose Despite its widespread use dissolution testing using this apparatus remains susceptible to significant error and test failures There is documented evidence that this apparatus is sensitive to several geometric variables that can affect the release profile of oral dosage forms including tablet location during the dissolution process In this work the dissolution profiles of disintegrating calibrator tablets containing Prednisone were experimentally determined using two systems i e a Standard USP Dissolution Testing Apparatus 2 Standard System and a Modified Standard USP Dissolution Testing Apparatus 2 Modified System in which the impeller was located 8 mm off the vessel centerline The dissolving tablets were located at different off center positions on the vessel bottom to test the effect of tablet location in these two systems Tablet dissolution in the Standard System was found to be strongly dependent on tablet location as previously reported by this and other research groups This apparatus appears to generate variable results that may not be associated with the tablets undergoing testing but with the hydrodynamic characteristics of the apparatus itself and the location of the tablet on the vessel bottom However when the same experiments were conducted in the Modified System the dissolution profiles for the same tablets were found to be nearly completely insensitive to tablet location The dissolution process in the Modified System was faster than that in the Standard System because of the improved mixing performance of the Modified System resulting from the non symmetrical placement of the impeller However when the Modified System was operated at 35 rpm the dissolution profiles for centrally located tablets were found to be very similar to those for the Standard System operating at 50 rpm Unlike the Standard System however the dissolution profiles obtained at 35 rpm in the Modified System were found to be insensitive to tablet location It can be concluded that the newly proposed Modified System for dissolution testing is a simple and yet robust and valid alternative to the current dissolution testing practice using the Standard USP Dissolution Testing Apparatus

Dissolution Testing of Solid Dosage Forms Amjad Khan,2022-09-07 Dissolution testing has been a key tool during drug development stages and for commercial preparation of the dosage forms At the drug development stage dissolution testing is used to help in formulation development evaluation of stability monitoring of product consistency and assessment of the effect of variables changes in formulation and process parameters affecting the characteristics of the final product In

case of the commercial products dissolution testing applied for confirmation of manufacturing and product consistency and evaluation of process variables With the accumulation of both in vivo and in vitro experience during a product s development cycle the dissolution test method should be critically re evaluated and potentially simplified for final quality control testing This books covers dissolution testing of solid dosage forms both conventional and novel dosage forms Development and validation of dissolution testing method for different types of tablets have been described as separate chapters **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 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

Biorelevant Dissolution Test Methods for Modified Release Dosage Forms Sandra Klein,2005 *Guidelines for Dissolution Testing (kit).* United States,1980 **Hydrodynamic Effects of a Cannula in a USP Dissolution Testing Apparatus 2** Qianqian Liu,2013 Dissolution testing is routinely used in the pharmaceutical industry to provide in vitro drug release information for drug development and quality control purposes The USP Testing Apparatus 2 is the most common dissolution testing system for solid dosage forms Usually sampling cannulas are used to take samples manually from the dissolution medium However the inserted cannula can alter the normal fluid flow within the vessel and produce different dissolution testing results The hydrodynamic effects introduced by a permanently inserted cannula in a USP Dissolution Testing Apparatus 2 were evaluated by two approaches Firstly the dissolution tests were conducted with two dissolution systems the testing system with cannula and the standard system without cannula for nine different tablet positions using non disintegrating salicylic acid calibrator tablets The dissolution profiles at each tablet location in the two systems were

compared using statistical tools Secondly Particle Image Velocimetry PIV was used to obtain experimentally velocity vector maps and velocity profiles in the vessel for the two systems and to quantify changes in the velocities on selected horizontal so surfaces The results show that the system with the cannula produced higher dissolution profiles than that without the cannula and that the magnitude of the difference between dissolution profiles in the two systems depended on tablet location However in most dissolution tests the changes in dissolution profile due to the cannula were small enough to satisfy the FDA criteria for similarity between dissolution profiles f1 and f2 values PIV measurements showed slightly changes in the velocities of the fluid flow in the vessel where the cannula was inserted The most significant velocity changes were observed closest to the cannula However generally the hydrodynamic effect generated by the cannula did not appear to be particularly strong which was consistent to dissolution test results It can be concluded that the hydrodynamic effects generated by the inserted cannula are real and observable Such effects result in slightly mod fications of the fluid flow in the dissolution vessel and in detectable differences in the dissolution profiles which although limited can introduce variations in test results possibly leading to failure of routine dissolution tests **Dissolution Testing of Prednisone and Salicylic Acid Calibrator Tablets at Different Tablet Locations** Anandhavalavan Arulmozhi,2011 Dissolution testing is routinely carried out in the pharmaceutical industry to determine the rate of dissolution of solid dosage forms This test is one of the several tests that pharmaceutical companies typically conduct on oral dosage formulations e g tablets to determine compliance The USP Dissolution Testing Apparatus 2 is the most common of the apparatuses listed in the USP However it has been shown previously that the dissolution profile of a tablet undergoing dissolution in the USP Dissolution Apparatus 2 can be affected by the tablet location in the apparatus In this work the dissolution rates of both non disintegrating tablets salicylic acid and disintegrating tablets Prednisone were experimentally determined for many different tablet locations both centered on the vessel bottom and off center The location of the tablet was experimentally varied in very small increments in order to determine the exact location where a transition in the dissolution profile occurred It was found that in a small region 2 4 mm in radius centered around the vessel centerline just below the impeller the dissolution profiles were similar to those observed with a centered tablet However outside this region the dissolution profiles were found to be significantly different as indicated by the values of the Similarity Factor f1 and the Difference Factor f2 These finding are consistent with previous hydrodynamic investigations that showed the existence of a poorly mixed zone below the USP Apparatus 2 impeller The results of this work can guide the practitioner on when to accept dissolution testing results based on tablet location **Long Term Dissolution Testing of Mine Waste** Kim Lapakko,1995 Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS Niranjan Goud Kotla,Yashwant Y.,Ashwini Shivapooja,2014-02 Till date pursuit for cost effective and animal sparing colon specific bio relevant dissolution media has been a foremost challenge facing pharmaceutical scientists over many decades It is problematic to mimic the dynamic and ecologically diverse features of the colon in dissolution vessel With

the knowledge of enormous colonic microflora the predominant species Bacteroides Bifidobacterium Eubacterium Streptococcus and Lactobacillus species were cultured in 12% w v skimmed milk powder and 5%w v grade A honey Probiotic culture was added to the dissolution media in order to test the drug release of polysaccharide based formulations USP dissolution apparatus I II with gradient pH dissolution method were used to evaluate the drug release from formulations meant for colonic drug delivery Drug release from 5 fluorouracil granules and metronidazole tablets were assed under gastric small intestine conditions and also within a simulated colonic environment involving existing rat caecal human fecal media and compared with novel probiotic media The present method can be successfully applied for the drug release testing of any oral formulations meant for colonic delivery **A Novel Approach to in Vitro Dissolution Testing** Frank Anthony Volpe,1983 **Mechanistic Studies of Drug Dissolution Testing** Paula Lehto,2010 **Accelerating Dissolution Testing Time with Extended Release Drugs While Maintaining Dissolution Profiles** Andrew Phelps,2013

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