Tablet Dissolution Tester

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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 **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 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 *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

Effect of Tablet Compression on the Dissolution of Aspirin Tablets Using a Novel Off-center Paddle Impeller (opi) Dissolution Testing System Chuan Sun,2013 In the pharmaceutical industry dissolution testing is routinely carried out to determine the dissolution rate of oral solid dosage forms Among several testing devices the USP Dissolution Apparatus 2 is the device most commonly used However despite its widespread use this apparatus has been shown to produce test failures and to be very sensitive to a number of small geometry changes The objective of this study was to determine whether a novel dissolution system termed OPI for off center paddle impeller was sensitive enough to determine differences in tablet dissolution profiles caused by different compression pressure during the tablet manufacturing process The OPI Dissolution System simply consists of a modified Apparatus 2 in which the impeller is placed 8mm off center in the vessel In this work aspirin tablets were manufactured from powder with a manual tablet press using three different compression pressures The dissolution profiles of these tablets were then obtained in both the OPI system and the standard USP Apparatus 2 system Tests were conducted by dropping the tablets in the vessels at the beginning of an experiment and in separate experiments by initially immobilizing the tablets on the vessel bottom at nine different locations This approach has been used in the past by our group to determine the sensitivity of the dissolution apparatus to minor changes in the geometry of the dissolution system All dissolution profiles were found to be affected by the compression pressure Faster dissolution profiles were obtained at lower compression pressures When tablets were dropped in the vessel a comparison of the dissolution profiles obtained in the standard Apparatus 2 system and in the OPI system showed that similarly manufactured tablets produced statistically similar dissolution profiles in both systems i e that the OPI system was just as sensitive as the standard system to

variations in the tablet manufacturing process However when the tablets were immobilized during the dissolution process the standard system generated very different dissolution profiles even for tablets manufactured at the same compression pressure By contrast the dissolution profiles in the OPI system for tablets manufactured at different pressure but located at different positions were very similar It can be concluded that the OPI system is sensitive enough to detect differences in intrinsic tablet dissolution rates such as those caused as in this case by changes in the manufacturing process while being unaffected by small changes in the system geometry that instead caused the standard system to fail Therefore the OPI system appears to be a more reliable dissolution testing apparatus than the current apparatus *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

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 **Effects of Operating and Geometric Variables on Hydrodynamics and Tablet Dissolution in Standard and Modified Dissolution Testing Apparatuses 2** Yimin Wang,2011 Dissolution testing is routinely conducted in the pharmaceutical industry to provide critical in vitro drug release information for quality control

purposes and especially to assess batch to batch consistency of solid oral dosage forms such as tablets Among the different types of apparatuses listed in the United States Pharmacopoeia USP the most commonly used dissolution system for solid dosage forms is the USP Dissolution Testing Apparatus 2 consisting of an unbaffled hemispherical bottomed vessel equipped with a 2 blade radial impeller Despite its extensive use in industry and a large body of work some key aspects of the hydrodynamics of Apparatus 2 have received very little attention such as the determination of its power dissipation requirements which controls solid liquid mass transfer processes and the velocity distribution under the different agitation conditions at which this system is routinely operated In addition the tablet dissolution performance of Apparatus 2 has been shown to be highly sensitive to a number of small geometric factors such as the exact locations of the impeller and the dissolving tablet Therefore in this study computation and experimental work was conducted to a quantify the roles of some key hydrodynamic variables of importance for the standard Apparatus 2 system and determine their impact on the dissolution profiles of solid dosage forms and b design and test a modified Apparatus 2 that can overcome the major limitations of the standard system and especially those related to the sensitivity of the current apparatus to tablet location Accordingly the hydrodynamics in the standard USP Apparatus 2 vessel was experimentally quantified using Laser Doppler Velocimetry LDV and Particle Image Velocimetry PIV Complete experimental mapping of the velocity distribution inside the standard Apparatus 2 was obtained at three agitation intensities i e 50 rpm NRe 4939 75 rpm NRe 7409 and 100 rpm NRe 9878 The velocity distributions from both LDV and PIV were typically found to be very similar It was found that the overall flow pattern throughout the whole vessel was dominated by the tangential component of the velocity at all agitation speeds whereas the magnitudes of the axial and radial velocity components were typically much smaller In the bottom zone of the vessel two regions were observed i e a central low velocity inner core region and an outer recirculation loop below the impeller rotating around the central inner core region This core region typically persisted irrespective of the impeller agitation speed Computation Fluid Dynamics CFD was additionally used to predict velocity profiles Typically the CFD predictions matched well the experimental results The power dissipated by the impeller in Apparatus 2 was experimentally measured using a frictionless system coupled with torque measurement CFD was additionally used to predict the power consumption using two different approaches one based on the integration of the local value of the energy dissipation rate and the other based on the prediction of the pressure distribution on the impeller blade from which the torque and the power required to rotate the impeller were predicted The agreement between the experimental data and both types of numerical predictions was found to be quite satisfactory in most cases The results were expressed in terms of the non dimensional Power number Po which was typically found to be on the order of 0 3 The power number was observed to decrease very gradually with increasing agitation speeds The results of this work and of previous work with the standard USP Apparatus 2 confirm that this apparatus is very sensitive to the location of the tablet which is typically not controlled in a typical test since the tablet is

dropped into the vessel at the beginning of the test and it may rest at random locations on the vessel bottom Therefore in this work a modified USP Dissolution Testing Apparatus 2 in which the impeller was placed 8 mm off center in the vessel was designed and tested This design eliminates the poorly mixed inner core region below the impeller observed in the standard Apparatus 2 vessel Dissolution tests were conducted with the Modified Apparatus for different tablet locations using both disintegrating calibrator tablets Prednisone and non disintegrating calibrator tablets Salicylic Acid The experimental data clearly showed that all dissolution profiles in the Modified Apparatus were not affected by the tablet location at the bottom of the vessel This design can effectively eliminate artifacts generated by having the tablet settle randomly at different locations on the vessel bottom after dropping it at the beginning of a dissolution testing experiment The hydrodynamic and mixing characteristics of the modified Apparatus 2 were studied in some detail by experimentally measuring and computationally predicting the velocity distribution power dissipation and mixing time in the modified system The velocity profiles near the bottom of the vessel were found to be significantly more uniform than in the standard Apparatus 2 because of the elimination of the poorly mixed zone below the impeller The power dissipation in the modified Apparatus 2 was typically higher than in the standard system as expected for an non symmetrical system and the corresponding Power number Po was less dependent on Reynolds number than Po in the standard system Finally the mixing time in the modified system as experimentally measured by using a decolorization method and computationally predicted through CFD simulation was found to be shorter in the modified Apparatus 2 by 7 7 % 12 9 % as compared to Apparatus 2 It can be concluded that the modified Apparatus 2 is a more robust testing apparatus which is capable of producing dissolution profiles that are less sensitive to small geometric factors that play a major role in the standard USP Apparatus 2 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 Kinetics of Calibrator and Matrix Tablets in the U.S.P. Dissolution Apparatus Kenneth R. Freebern,1993 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 **Experimental Determination of the Agitation Requirements for Solids Suspension in Dissolution Systems Using a Mini Paddle Apparatus** Yang Song,2015 Dissolution testing is a critical step in quality control of manufactured final products in the pharmaceutical industry The United State Pharmacopeia USP Dissolution Testing Apparatus 2 paddle is the most widely used dissolution test devices in the pharmaceutical industry to formulate solid drug dosage forms and to develop quality control specifications for its manufacturing process Mini vessels and mini paddle dissolution testing systems are smaller versions of the USP 2 Apparatus The concept of the mini paddle apparatus is similar to that of the USP 2 setup but it is scaled down about to 1 5 of the volume

and 40% with respect to vessel and impeller sizes Mini vessel systems requiring a small volume 200 mL and a mini paddle impeller are becoming increasing common in the pharmaceutical industry to overcome the limitations associated with the USP 2 dissolution testing method especially for dissolution testing involving very small tablets Mini apparatuses can be useful tools in characterizing drug release profiles since smaller sample sizes and smaller volumes of media are needed thus offering several advantages in terms of substance analytical and material cost savings when evaluating release properties of drug candidates Despite their increasing importance in dissolution testing little information is currently available on mini vessels and especially on the agitation speed needed to prevent coning effects Typically during dissolution testing a disintegrating tablet becomes rapidly fragmented and the resulting solid particles may or may not become suspended depending on the agitation speed of the paddle and other geometric and operating parameters Coning the accumulation of particle fragments from a disintegrating tablet often appears in dissolution testing but can be eliminated by increasing the agitation speed N Therefore it is important to be able to predict the minimum rotation speed at which coning phenomena disappears in a dissolution testing system and especially in mini vessels systems The focus of this work was the determination of the minimum agitation speed Njs at which the just suspended state by dispersed particles is achieved in a mini paddle system thus removing coning effects In the past Njs has been experimentally obtained in mixing systems by determining the agitation speed at which no particles are visually observed to be at rest on the vessel bottom for more than one to two seconds Therefore the first objective of this work was to develop an observer independent method to measure experimentally Njs This was achieved by extending to mini vessel a method that was recently developed in our laboratory and that is based on the determination of the fraction of unsuspended solids in the vessel at different agitation speed Njs Ds method The results of this method agree well the visually observable values of Njs Njs visual Once new method was validated in mini vessels Njs was experimentally measured using well characterized solid particles under a number of operating conditions such as liquid level to vessel diameter ratio H T particle size dp and paddle clearance to vessel diameter ratio Cb T The results could be interpreted using the Zwietering Equation originally developed for solids suspension in baffled stirred tanks The Zwietering S parameter was obtained for the mini vessel system thus enabling the use of this equation to predict when coning effects can be eliminated in mini vessel systems during tablet dissolution testing **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 Dissolution of Different Commercial Aspirin Tablets Using a Novel Off-center Paddle Impeller (OPI) Dissolution Testing System Yang Qu,2013 Dissolution testing is routinely conducted in the pharmaceutical industry to provide in vitro drug release information for quality control purposes The most common dissolution testing system for solid dosage forms is the United States Pharmacopeia USP Dissolution Testing Apparatus 2 In this work a modified Apparatus 2 termed OPI System for off center paddle impeller in which the impeller is placed 8 mm off center in the vessel is tested to determine its sensitivity to differentiate between the dissolution profiles of differently formulated and manufactured tablets Dissolution tests are conducted with both the OPI System and the Standard System using three different brands of aspirin at nine different tablet positions The OPI system produces dissolution profiles that are highly dependent on the different brands of aspirin used similarly to those generates in the Standard System However the dissolution profiles obtained with the OPI apparatus are found to be largely independent of the tablet location at the vessel bottom whereas those obtained in the Standard System generates statistically different profiles depending on tablet location It can be concluded that the newly proposed OPI system can effectively eliminate artifacts generated by random settling of the tablet at the vessel bottom thus making the test more robust while at the same time being just as sensitive as the Standard System to actual differences in differently manufactured tablets having intrinsically different dissolution profiles *Evaluation of Magnetic Basket Dissolution Apparatus* Thomas E. Needham,L. A. Luzzi,Richard Earl Shepherd,1973 *Evaluation of the Dissolution Testing for Ibuprofen Tablets* Alain Joseph Romero,1988 **Analysis of Pharmaceuticals by Capillary Electrophoresis** Kevin D. Altria,2013-04-17 Dieser erste Titel einer ganzen Serie von anwendungsbezogenen Handb chern zur Kapillarelektrophorese besch ftigt sich mit der Analytik von pharmazeutischen Substanzen Dabei werden verschiedene Techniken praxisnah erl utert Jeder der im Labor ob wissenschaftlich oder praxisnah mit der Analyse von oft chiralen Pharmazeutika konfrontiert ist wird viele Hinweise und Tips f r seine Arbeit finden USP Einzige Monographie zur Analyse von Pharmazeutika mit CE This book describes the current state of the art for the analysis of pharmaceuticals by capillary electrophoresis and contains several hundred references to specific applications and methods The main purpose of the book is to present the application possibilities of CE an therefore tabulated application data are provided Chapters of the book are devoted to providing details of individual application areas such as chiral analysis determination of drug related impurities determination of drug counter ions drug residue monitoring and main component assay An introductory chapter provides theoretical background to CE an related techniques A chapter is dedicated to capillary electrochromatography which highlights the importance this technique currently possesses Successful regulatory acceptance of CE methods is also described A comprehensive chapter covers method validation aspects Other

chapters include discrete areas such as the use of non aqueous solvents forensic applications of CE the application of experimental designs determination of drugs in biofluids and the analysis of vitamins by CE *In Vitro-In Vivo Correlations* David B. Young,John G. Devane,Jackie Butler,2013-03-08 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 Sep tember 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 com pany 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 Not tingham in the UK The principal collaborators are Dr Jackie Butler Elan Corporation Prof Owen Corrigan Trinity College Dublin Dr lain 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 devel opment of in vitro in vivo relationships for ER products The original idea went back ap proximately 15 months prior to the workshop itself For some time the principal collaborators had been working together on various aspects of dosage form development

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