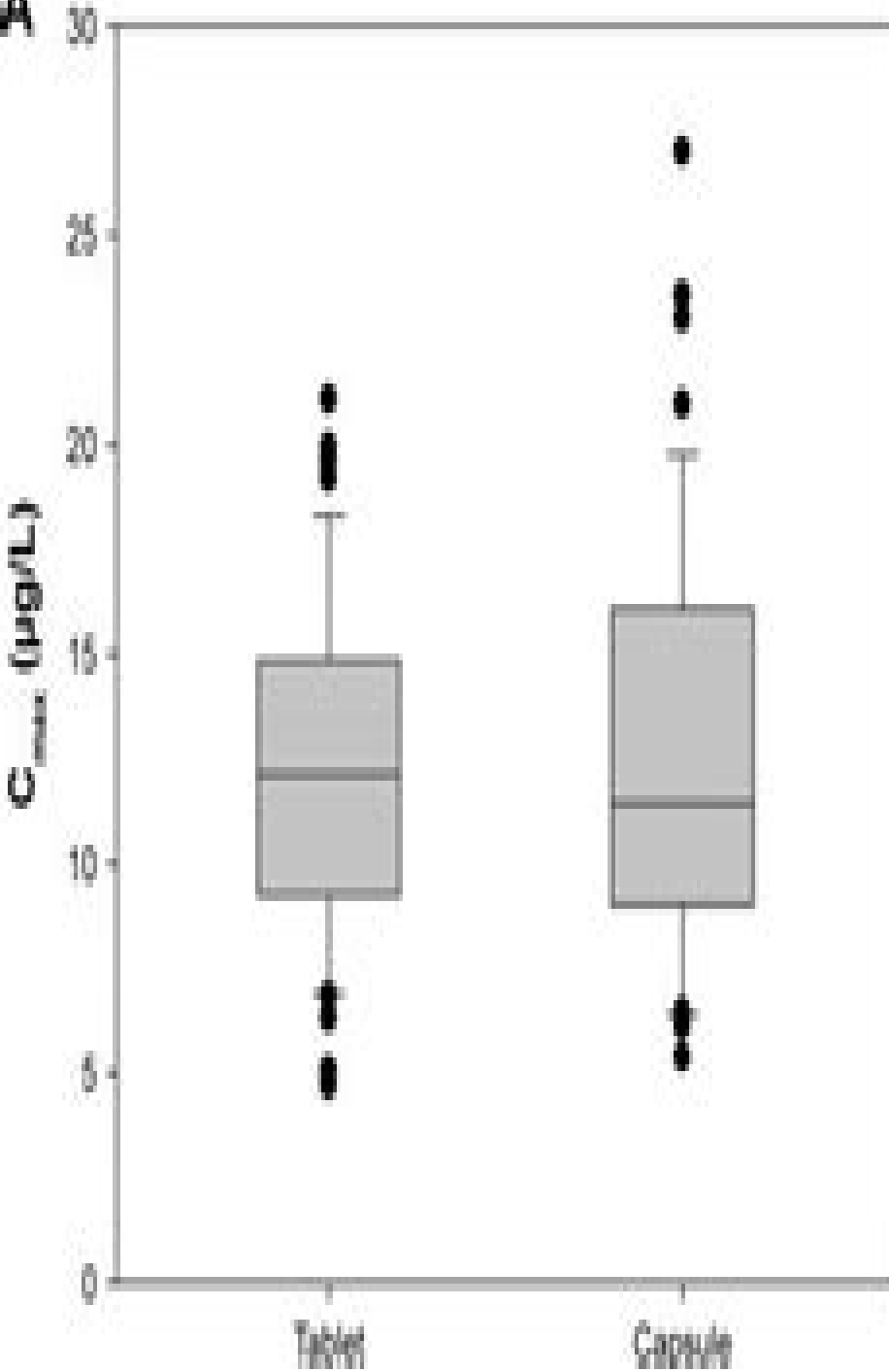
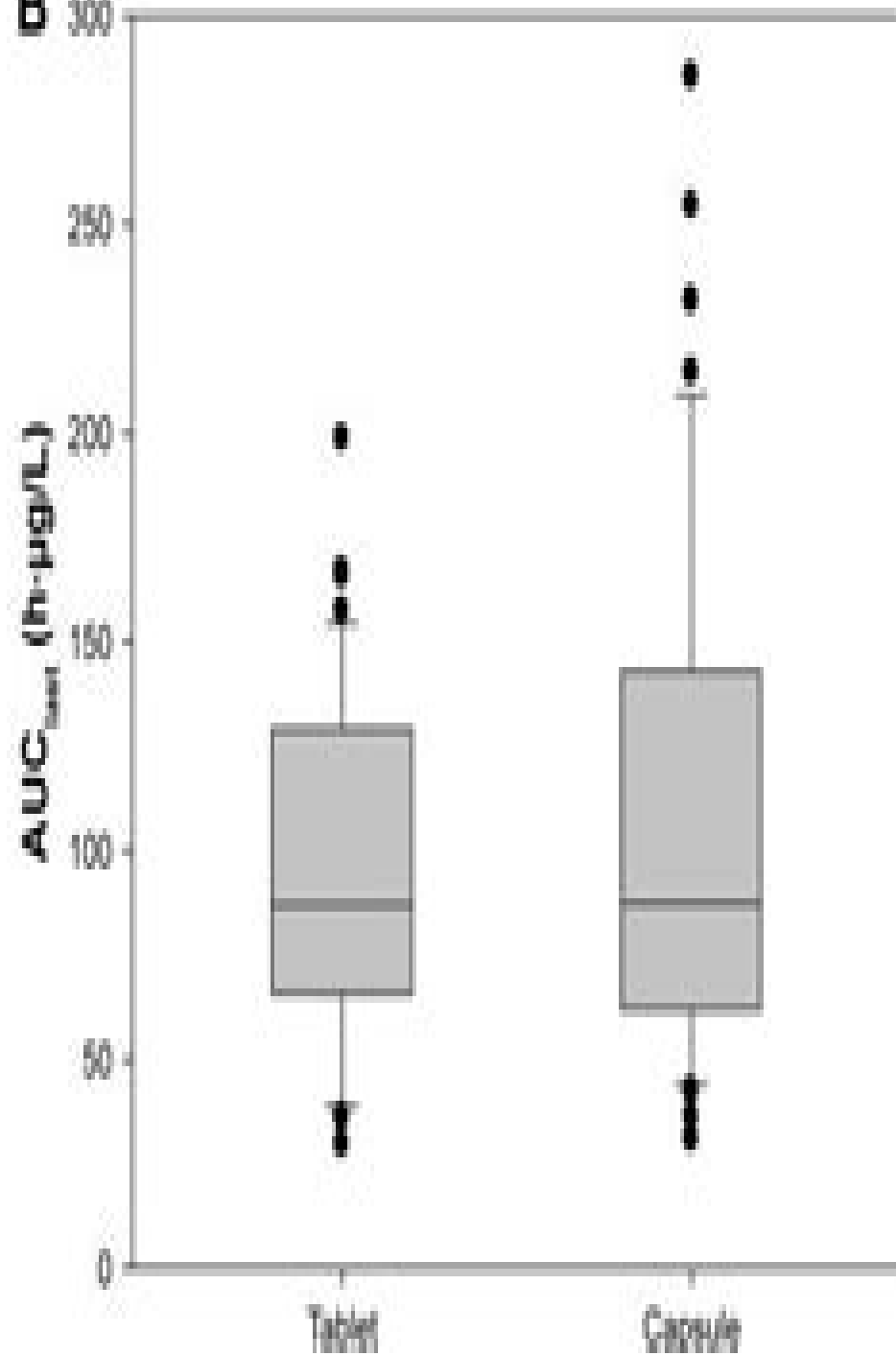


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Dissolution Test Of Tacrolimus Capsule Quality Effects Of

Qianqian Liu



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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

Remington David B. Troy, Paul Beringer, 2006 For over 100 years Remington has been the definitive textbook and reference on the science and practice of pharmacy This Twenty First Edition keeps pace with recent changes in the pharmacy curriculum and professional pharmacy practice More than 95 new contributors and 5 new section editors provide fresh perspectives on the field New chapters include pharmacogenomics application of ethical principles to practice dilemmas technology and automation professional communication medication errors re engineering pharmacy practice management of special risk medicines specialization in pharmacy practice disease state management emergency patient care and wound care Purchasers of this textbook are entitled to a new fully indexed Bonus CD ROM affording instant access to the full content of Remington in a convenient and portable format

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

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 pharmaceuticals and regulatory affairs

Handbook of Dissolution Testing Royal Hanson,Vivian Gray,2004 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

Handbook of Dissolution Testing William A. Hanson,1982 *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 N_{js} at which the just suspended state by dispersed particles is achieved in a

mini paddle system thus removing coning effects In the past N_{js} 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 N_{js} 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 N_{js} Ds method The results of this method agree well the visually observable values of N_{js} N_{js} visual Once new method was validated in mini vessels N_{js} 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 d_p and paddle clearance to vessel diameter ratio C_b/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

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 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 N_{Re} 4939 75 rpm N_{Re} 7409 and 100 rpm N_{Re} 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 a 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 % to 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

Development of in Vitro Dissolution Test for Dihydroartemisinin Capsules Unalom Chiablaem, Mahāwitthayālai

Mahidon, Mahāwitthayālai Mahidon. Faculty of Pharmacy, 2002

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

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