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Research paper

## Evaluation of dissolution techniques for orally disintegrating mini-tablets

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## ARTICLE INFO

## Keywords:

Paediatric drug delivery  
Orally disintegrating mini-tablet  
Drug dissolution  
Paddle rotation speed  
Membrane filter

## ABSTRACT

Mini-tablets are suitable for paediatric as well as geriatric use since they may provide flexible and accurate dosing and administration. Due to the minute tablet size, there is a need for new standardized quality evaluation procedures and conventional techniques may have to be adopted. The main objective of the study was to evaluate different dissolution techniques for orally disintegrating mini-tablets. Dissolution tests using mini-paddle apparatus were compared with standard size paddle apparatus, and the effect of paddle rotation speed was evaluated. Also, the filter choice, and its impact on dissolution, was considered. Sodium salicylate was used as a model drug substance and was mixed with different size fractions of mannitol. The powder mixtures were compacted into 2 mm flat faced tablets. The mini-tablets were characterized regarding weight and content uniformity, tensile strength, friability, disintegration and dissolution. Similar dissolution profiles were obtained with both mini and standard equipment. The paddle rotation speed affected the dissolution profiles; a low paddle speed resulted in a slower dissolution. Furthermore, choosing a chemically inert filter will increase the likelihood of obtaining reliable and accurate results. An appropriately designed dissolution test using mini-paddle apparatus is required prior to further implementation in quality control procedures.

## 1. Introduction

There has been an increasing demand for research and development of age-appropriate dosage forms in order to improve drug treatment of children. Mini-tablets are suitable for paediatric as well as geriatric use since they provide flexible and accurate dosing and administration [1–3] [49]. Mini-tablets typically have a diameter of  $\leq 3$  mm and can be manufactured using a conventional tablet machine, fitted with single-tip or multiple-tip punches. Different types of mini-tablets can be produced, e.g. extended release formulations or orally disintegrating mini-tablets (ODMT). Mini-tablets can either be administered individually or filled in capsules or compacted into larger tablets. Previous studies have shown that mini-tablets are well accepted by children of different ages, and children as young as six months demonstrated high swallowability of mini-tablets [3–10]. In a cross-over study Spooner et al. [8], also showed that mini-tablets were highly accepted in children 6–12 months of age, and comparable with a sweet liquid formulation [3]. Scottenberg and Breckkreutz have shown that orally disintegrating mini-tablets could be a suitable dosage form for children [3]. Mini-tablets can thus be regarded as a suitable dosage form for young children and used as an alternative to liquid formulations.

An appropriate dosage form for paediatric use should ideally possess

convenient administration (including palatability and minimal manipulation pre-administration), flexibility in dosing and safety. Being a solid dosage form, mini-tablets have several advantages over liquid formulations, for example stability and taste masking. They also offer a high degree of dose flexibility, and may provide a more accurate dosing for paediatrics, compared to splitting of tablets initially intended for adults [11]. Mini-tablets also have some limitations and challenges; they can be difficult to handle due to the small size and it may be difficult to obtain an acceptable dose homogeneity in a single unit.

When manufacturing mini-tablets, a good powder flowability is essential to obtain a uniform die filling, and to fulfil weight and dose uniformity requirements. There is also a particle size limitation, since the die diameter is narrow, to avoid die blocking. The die diameter and length affect the powder flow rate, where a smaller opening lowers the flow rate [12]. Direct compression is the preferred manufacturing technique for mini-tablets, provided that the powder mixture has sufficient flow properties [13,14]. Multiple-tip tools are generally used since this increases the output. However, care must be taken regarding mechanical stability and precision of the tools, since a high die wall friction can lead to abrasion and tool damage [15].

Mini-tablets are especially suitable for administration of low doses of potent drugs, in order to make the number of mini-tablets in one dose as

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<https://doi.org/10.1016/j.jddst.2020.102191>

Received 27 August 2020; Received in revised form 29 September 2020; Accepted 29 October 2020

Available online 4 November 2020

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# Dissolution Techniques For Evaluation Of Novel Drug

**Michael Hoelscher**



## **Dissolution Techniques For Evaluation Of Novel Drug:**

**Developing Solid Oral Dosage Forms** Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lawrence Yu, Rao V.

Mantri, 2016-11-08 *Developing Solid Oral Dosage Forms Pharmaceutical Theory and Practice Second Edition* illustrates how to develop high quality safe and effective pharmaceutical products by discussing the latest techniques tools and scientific advances in preformulation investigation formulation process design characterization scale up and production operations This book covers the essential principles of physical pharmacy biopharmaceutics and industrial pharmacy and their application to the research and development process of oral dosage forms Chapters have been added combined deleted and completely revised as necessary to produce a comprehensive well organized valuable reference for industry professionals and academics engaged in all aspects of the development process New and important topics include spray drying amorphous solid dispersion using hot melt extrusion modeling and simulation bioequivalence of complex modified released dosage forms biowaivers and much more Written and edited by an international team of leading experts with experience and knowledge across industry academia and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon predictive biopharmaceutics and pharmacokinetics the development of formulations for drug discovery support and much more Presents new case studies throughout and a section completely devoted to regulatory aspects including global product regulation and international perspectives *Regulatory Affairs in the Pharmaceutical Industry* Javed Ali, Sanjula Baboota, 2021-11-14 *Regulatory Affairs in the Pharmaceutical Industry* is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs the content covers new drugs generic drugs and their development regulatory filings in different countries different phases of clinical trials and the submission of regulatory documents like IND Investigational New Drug NDA New Drug Application and ANDA Abbreviated New Drug Application Chapters cover documentation in the pharmaceutical industry generic drug development code of Federal Regulation CFR the ANDA regulatory approval process the process and documentation for US registration of foreign drugs the regulation of combination products and medical devices the CTD and ECTD formats and much more Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance **Drug Delivery Systems**, 2019-10-23 *Drug Delivery Systems* examines the current state of the field within pharmaceutical science and concisely explains the history of drug delivery systems including key developments The book translates the physicochemical properties of drugs into drug delivery systems administered via various routes such as oral parenteral transdermal and inhalational Regulatory and product development topics are also explored Written by experts in the field this volume in the *Advances in Pharmaceutical*

Product Development and Research series deepens our understanding of drug delivery systems within the pharmaceutical sciences industry and research as well as in chemical engineering Each chapter delves into a particular aspect of this fundamental field to cover the principles methodologies and technologies employed by pharmaceutical scientists This book provides a comprehensive examination that is suitable for researchers and advanced students working in pharmaceuticals cosmetics biotechnologies and related industries Provides up to date information on how to translate the physicochemical properties of drugs into drug delivery systems Explores how drugs are administered via various routes such as oral parenteral transdermal and inhalational Contains extensive references and further reading for course and self study **Oral**

**Bioavailability and Drug Delivery** Ming Hu,Xiaoling Li,2024-02-13 ORAL BIOAVAILABILITY AND DRUG DELIVERY Improve the performance and viability of newly developed and approved drugs with this crucial guide Bioavailability is the parameter which measures the rate and extent to which a drug reaches a user s circulatory system depending on the method of administration For example intravenous administration produces a bioavailability of 100% since the drugs are injected directly into the circulatory system in the case of oral administration however bioavailability can vary widely based on factors which if not properly understood can result in a failure in drug development adverse effects and other complications The mechanics of oral bioavailability are therefore critical aspects of drug development Oral Bioavailability and Drug Delivery provides a comprehensive coverage of this subject as well as its drug development applications Beginning with basic terminology and fundamental concepts it provides a thorough understanding of the challenges and barriers to oral bioavailability as well as the possibilities for improving this parameter The resulting book is an indispensable tool for drug development research Oral Bioavailability and Drug Delivery readers will also find Discussion questions in many chapters to facilitate comprehension Detailed discussion of topics including dissolution absorption metabolism and more Real world examples of methods in actions throughout Oral Bioavailability and Drug Delivery is ideal for pharmaceutical and biotechnology scientists working in drug discovery and development researchers in chemistry biology pharmacology immunology neuroscience and other related fields and graduate courses in drug development and delivery

9789815223026 Dilpreet Singh, Prashant Tiwari,2024-03-25 Software and Programming Tools in Pharmaceutical Research is a detailed primer on the use for computer programs in the design and development of new drugs Chapters offer information about different programs and computational techniques in pharmacology The book will help readers to harness computer technologies in pharmaceutical investigations Readers will also appreciate the pivotal role that software applications and programming tools play in revolutionizing the pharmaceutical industry The book includes nine structured chapters each addressing a critical aspect of pharmaceutical research and software utilization From an introduction to pharmaceutical informatics and computational chemistry to advanced topics like molecular modeling data mining and high throughput screening this book covers a wide range of topics Key Features Practical Insights Presents practical knowledge

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**New Scientist**, 2001 **Shargel and Yu's Applied Biopharmaceutics & Pharmacokinetics, 8th Edition** Murray P. Ducharme, Leon Shargel, Andrew B. C. Yu, 2022-01-24 The authoritative textbook on the principles and practical applications of biopharmaceutics and pharmacokinetics Shargel Yu s Applied Biopharmaceutics Pharmacokinetics has been the standard textbook in its field for over 40 years This eighth edition includes recent scientific developments in the field and embodies the collective contribution of experts with deep knowledge and experience in the selected subject areas Shargel Yu s Applied Biopharmaceutics Pharmacokinetics Eighth Edition provides the reader with a fundamental understanding of biopharmaceutics and pharmacokinetics principles that can be applied to patient drug therapy and rational drug product development Shargel Yu s Applied Biopharmaceutics Pharmacokinetics Eighth Edition has been expanded and revised to include advancements in biopharmaceutics and pharmacokinetics The chapter sequence has been reorganized into four main sections providing a more logical sequence for students The textbook starts with fundamental concepts followed by application of these principles to optimize drug therapy and to the rational development of drug products Each chapter includes theoretical concepts with practical examples and clinical applications Frequently asked questions provide a discussion of overall concepts Features Expanded and revised chapters to include scientific advances in biopharmaceutics and pharmacokinetics Four main sections providing a natural buildup of knowledge introduction to biopharmaceutics and pharmacokinetics fundamentals of biopharmaceutics pharmacokinetic calculations

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Frequently asked questions practice problems clinical examples and learning questions *The Development and Control of  
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Shargel, Susanna Wu-Pong, Andrew Yu, 2004-08-19 The most comprehensive text on the practical applications of  
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illustrative examples and practice problems and solutions to help the student gain skill in practical problem solving *Nano  
Hybrids and Composites Vol. 12* Sooraj Hussain Nandyala, 2016-11-01 Nanomaterials Advances in Biomedical and  
Environmental Applications Special topic volume with invited peer reviewed papers only **Applied Biopharmaceutics &  
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areas involving bioavailability population pharmacokinetics pharmacodynamics metabolism and drug delivery **New  
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