

In Vitro Dissolution Testing for Solid Oral Dosage Forms

Introduction

Dissolution testing is a requirement for all solid oral dosage forms and is used in all phases of development for product release and stability testing¹. It is a key analytical test used for detecting physical changes in an active pharmaceutical ingredient (API) and in the formulated product.

At early stages of development, *in vitro* dissolution testing guides the optimization of drug release from formulations. Over the past 50 years, dissolution testing has also been employed as a quality control (QC) procedure, in R&D to detect the influence of critical manufacturing variables and in comparative studies for *in vitro-in vivo* correlation (IVIVC).²

The FDA guidance on dissolution testing for immediate release solid oral dosage forms¹ includes the use of the Biopharmaceutics Classification System (BCS) guidelines for biorelevant dissolution tests, which is based upon API solubility and permeability.³ According to the BCS guidelines, *in vitro* dissolution testing may be a useful tool to forecast the *in vivo* performance of drug products and potentially reduce the number of bioavailability/bioequivalence studies required. The FDA guidance on scale-up and post-approval changes (SUPAC) for immediate release oral dosage forms recommends the use of *in vitro* dissolution to justify post-approval changes.⁴

Despite being readily-entrained in pharmaceutical and biotechnology industry, the basics of the dissolution test are often misunderstood. The test must be rugged and reproducible and highlight or discriminate significant changes in product performance.

The specific dissolution technique employed is determined by the dosage form characteristics and the intended route of administration. For solid dosage forms, industry standard dissolution testing methodologies are the United States Pharmacopoeia (USP) Ap-

paratus 1 (basket) and the USP Apparatus 2 (paddle) (see Figure 1). Immediate-release, modified-release and extended release tablets are usually tested in classical dissolution baths with USP 2 paddles. Floating capsules and tablets generally use USP 1 baskets. Other dissolution techniques and equipment include USP 3 (reciprocating cylinders), USP 4 (flow-through-cell), USP 5 (paddle-over-disk), USP 6 (cylinder) and USP 7 (reciprocating holders).⁵

The development of a dissolution procedure involves selecting the dissolution media, apparatus type and hydrodynamics (agitation rate) appropriate for the product. This overview article will focus on the most commonplace (USP 1 and 2) dissolution apparatus and present an overview of typical method parameters that should be considered during dissolution development.

Dissolution

For most dosage forms to be efficacious, the API(s) must be absorbed into the systemic circulation so that it can be transported to its site of activity. This process contributes to the bioavailability of

the drug substance and involves two steps: dissolution and absorption (or permeability). Understanding the multi-step dissolution process is essential to proper *in vitro* method development. Dissolution is the process of extracting the API out of the dosage form solid-state matrix into solution within the gastrointestinal tract. Absorption is the process of transporting the drug substance from the gastrointestinal lumen into the systemic circulation.

Dissolution testing is an *in vitro* method that characterizes how an API is extracted out of a solid dosage form. It can indicate the efficiency of *in vitro* dissolution but does not provide any information on drug substance absorption. Pharmacokinetic data supplements and provides additional information regarding API absorption rate.

Selection of the appropriate *in vitro* conditions (media and hydrodynamics) that simulate the *in vivo* conditions can lead to the generation of successful IVIVC or at the very least, *in vitro-in vivo* relations (IVIVR).² Conditions that are optimal for QC purposes may not be applicable for establishing IVIVC so it may be necessary to use two dissolution tests to meet different objectives such as development needs or regulatory demands.

Dissolution Method Parameters

A logical, systematic approach taking into consideration both scientific and regulatory principles, should be followed when developing a dissolution method. Table 1 lists common parameters and conditions that are evaluated during method development.⁶

A robust dissolution method must be free of artifacts, yield low-to-moderate variability, have good profile shape and must be challenged to pick up critical quality attributes. Once the medium and apparatus are selected, the method should be further optimized for parameters such as agitation rate, ionic strength, and surfactant concentration, if applicable. The

final method should discriminate between formulations yet possess sufficient reproducibility and robustness. In terms of statistics, a relative standard deviation of <20% at early time points and <10% at later time points is common.

Typically, the percent dissolved API (up to 100%) vs. time is plotted. Dissolution profiles of dosage forms with known formulation, manufacturing or bioavailability differences can aid in identifying a discriminatory set of media/hydrodynamic conditions. Figure 2 illustrates a dissolution plot at 50 rpm (tablet with increased release variability due to a method artifact known as coning), 75 rpm (tablet showing proper release), and a mis-manufactured tablet at 75 rpm (showing slower and improper/incomplete release).

API

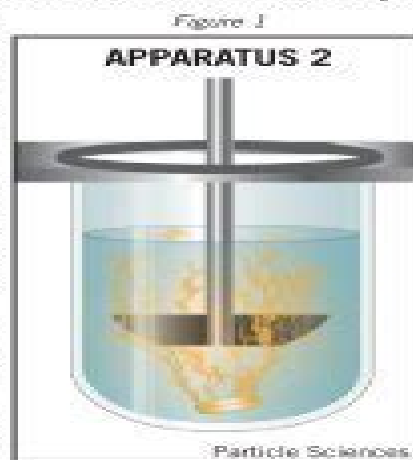
Review of API properties (BCS-classification, pK_a, stability, solubility as a function of pH/surfactant concentration, particle size, and polymorphism) that are likely to affect the *in vitro* dissolution behavior should be evaluated as part of method development.

Dosage Form

The key properties of the dosage unit, including dosage form type (tablet, capsule), expected number of potencies and desired release mechanism plus specific formulation information such as excipients, lubricants, disintegrants, moisture content, surface coating and known stability issues (cross-linking, friability) are all important factors to consider. Manufacturing variables such as lubrication blend time, compression force, excipient/API addition order, drying parameters and coating parameters are also critical to understanding API release differences between formulations.

Media

The first step is to screen formulations with aqueous-based media in the range of pH 1.2 to 6.8 at



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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 *Guidance for Industry*, 1995 **Handbook of Pharmaceutical**

Manufacturing Formulations, Third Edition Sarfaraz K. Niazi, 2019-12-06 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Four Semisolid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this fourth volume of a six volume set compiles data from FDA and EMA new drug applications patents and patent applications and other sources of generic and proprietary formulations including author s own experience to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent Features Largest source of authoritative and practical formulations cGMP compliance guidance and self audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing bioequivalence testing and full compliance with drug product safety elements Written by a well recognized authority on drug and dosage form development including biological drugs and alternative medicines [Percutaneous Absorption](#) Robert L. Bronaugh, Howard I. Maibach, 1999-05-28 Since publication of the Second Edition in 1989 numerous innovations have

occurred that affect the way scientists look at issues in the field of percutaneous absorption Focusing on recent advances as well as updating and expanding the scope of topics covered in the previous edition Percutaneous Absorption Third Edition provides thorough coverage of the skin's role as an important portal of entry for chemicals into the body Assembles the work of nearly 80 experts 30 more than the Second Edition into a unified comprehensive volume that contains the latest ideas and research Complete with nearly 600 drawings photographs equations and tables and more than 1600 bibliographic citations of pertinent literature Percutaneous Absorption Third Edition details the applied biology of percutaneous penetration factors that affect skin permeation such as age vehicles metabolism hydration of skin and chemical structure in vivo and in vitro techniques for measuring absorption examining factors influencing methodology such as animal models volatility of test compound multiple dosage and artificial membranes procedures for use in transdermal delivery exploring topics such as effects of penetration enhancers on absorption optimizing absorption and the topical delivery of drugs to muscle tissue And presents new chapters on mathematical models cutaneous metabolism prediction of percutaneous absorption in vitro absorption methodology dermal decontamination concentration of chemicals in skin transdermal drug delivery mechanisms of absorption safety evaluation of cosmetics absorption of drugs and cosmetic ingredients nail penetration Emphasizes human applications particularly useful for pharmacists pharmacologists dermatologists cosmetic scientists biochemists toxicologists public health officials manufacturers of cosmetic and toiletry products and graduate students in these disciplines An invaluable reference source for readers who need to keep up with the latest developments in the field

Percutaneous Absorption Third Edition is also an excellent experimental guide for laboratory personnel **Handbook of Pharmaceutical Manufacturing Formulations** Sarfaraz K. Niazi, 2016-04-19 The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments creams gels suppositories and special topical dosage forms Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter **Controlled Release Veterinary Drug Delivery**

Michael J. Rathbone, R. Gurny, 2000-07-20 Many controlled release veterinary drug delivery systems CRVDDS are presently in use and recently there has been a host of new CRVDDS within veterinary medicine The challenges of this area of drug delivery arise from the unique anatomy and physiology of the target animal the cost constraints associated with the value of the animal being treated and the extended periods of time that delivery must be sustained for often measured in months The purpose of this book is to introduce the reader to the unique opportunities and challenges of the field of CRVDDS and to explain and discuss the basic controlled release principles underlying the development of CRVDDS Its aim is to provide an overview of many of the areas where CRVDDS have application and to highlight the opportunities and prospects for controlled release technology in the veterinary field Controlled Release Veterinary Drug Delivery comprises chapters that provide workers in the field and those interested in this area with information on the design development and assessment of

a variety of CRVDDS The book contains chapters that describe the relevant animal physiological and anatomical considerations alongside descriptions of current and emerging controlled release delivery systems for a variety of routes for drug delivery and present overviews on the physical and chemical assessment of veterinary controlled release delivery systems The veterinary area is abound with opportunities for the development of controlled release drug delivery technologies It is an area of medicine that is open to the acceptance of novel drug delivery devices and which readily encompasses the use of novel routes of administration It is an area of many unmet needs most of which offer opportunities and unique challenges for the innovative formulation scientist to provide solutions This book will provide an insight into the biological clinical and pharmaceutical challenges that face the formulation scientist in this interesting and diverse area of research

Applications of Pharmacokinetic Principles in Drug Development Rajesh Krishna,2012-12-06 This volume is an important advancement in the application of pharmacokinetic PK and pharmacodynamic PO principles to drug development The series of topics presented deal with the application of these tools to everyday decisions that a pharmaceutical scientist encounters The ability to integrate these topics using PK and PO methods has optimized drug development pathways in the clinic New technologies in the areas of in vitro assays that are more predictive of human absorption and metabolism and advancement in bioanalytical assays are leading the way to minimize drug failures in later more expensive clinical development programs of Pharmacokinetics and pharmacodynamics have become an important component understanding the drug action on the body and is becoming increasingly important in drug labeling due to its potential for predicting drug behavior in populations that may be difficult to study in adequate numbers during drug development The ability to correlate drug exposure to effect and model it during the drug development value chain provides valuable insight into optimizing the next steps to derive maximum information from each study These principles and modeling techniques have resulted in an expanded and integrated view of PK and PO and have led to the expectations that we may be able to optimally design clinical trials and eventually lead us to identifying the optimal therapy for the patient while minimizing cost and speeding up drug development There is wide utility for the book both as a text and as a reference

Federal Register ,1995-11 **Pharmaceutical Product Development** Vandana B. Patravale,John I. Disouza,Maharukh Rustomjee,2016-05-25 Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality efficacy and safety of resulting products Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up to date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms

The book presents pharmaceutical product development information in an easy to read mode with simplified theories case studies and guidelines for students academicians and professionals in the pharmaceutical industry It is an invaluable resource and hands on guide covering managerial regulatory and practical aspects of pharmaceutical product lifecycle management

Dissolution Shelf Life of Hydroxypropyl Methyl Cellulose Coated Aspirin Tablets at I.C.H. Temperatures and Various Relative Humidities Shannon Patrick Adams,1998 *Nitroglycerin Sustained Release Tablet. Formulation Design and Evaluation* Subrata Bhadra,2013-08-07 Master s Thesis from the year 2010 in the subject Medicine Pharmacology Pharmacy University of Dhaka M Pharm in Pharmaceutical Technology language English abstract The aim of the present studies was to develop and characterize 2.6 mg sustained release matrix tablets of Nitroglycerin Tablets were prepared by direct compression method Methocel K15M CR and Methocel K100LV CR polymers were used as rate retarding agents in nine formulations F 1 to F 9 The granules were evaluated for angle of repose loose bulk density tapped bulk density Carr s index Hausner ratio moisture content total porosity and assay The tablets were subjected to diameter thickness assay uniformity of content assay after 1Month at 40 C 75%RH hardness friability and in vitro dissolution studies The granules showed satisfactory flow properties compressibility and drug content All the tablet formulations showed acceptable pharmacotechnical properties and complied with pharmacopoeial specifications for tested parameters The in vitro dissolution study was carried out for 8 hour using USP 2009 Apparatus I Rotating basket method in distilled water as the dissolution medium The release mechanisms were explored and explained by Zero order First order Higuchi Korsmeyer Peppas and Hixson Crowell equations Nine formulations were prepared by using three variable ratio of two polymers Methocel K15M CR 25% 20% and 15% and Methocel K100LV CR 15% 10% and 5% where all the formulations F 1 to F 9 contained 0.5% colloidal silicon dioxide and 1% magnesium stearate Among these nine formulations six formulations F 2 Methocel K15M CR Methocel K100LV CR 25% 10% F 3 Methocel K15M CR Methocel K100LV CR 25% 5% F 4 Methocel K15M CR Methocel K100LV CR 20% 15% F 5 Methocel K15M CR Methocel K100LV CR 20% 10% F 6 Methocel K15M CR Methocel K100LV CR 20% 5% and F 7 Methocel K15M CR Methocel K100LV CR 15% 15% met the official specification of release profile It was also found that the type and the amount of polymers significantly affect the time required for 50% T50% or MDT of drug release release rate constant and diffusion exponent Higher the MDT value indicates a higher drug retaining capacity of the polymers and vice versa Kinetic modeling of in vitro dissolution profiles revealed the drug release mechanism of all proposed formulations followed anomalous type or non Fickian transport $n = 0.43$ and $n = 0.43$

The United States pharmacopeia ,2012 **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 *Guidance for Industry Immediate Release Solid Oral Dosage Forms*, 1995 Technical Report Series, 2006 **The Bioavailability of Drug Products, 1978** APhA Bioavailability Project, 1978 *The Bioavailability of Drug Products* 1975 American Pharmaceutical Association, 1975 Journal of the American Pharmaceutical Association (1961), 1973 WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2006 This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms The report is complemented by a number of annexes These include a list of available international chemical reference substances and international infrared spectra supplementary guidelines on good manufacturing practices for heating ventilation and air conditioning systems for non sterile pharmaceutical dosage forms updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines supplementary guidelines on good manufacturing practices for validation good distribution practices for pharmaceutical products a model quality assurance system for procurement agencies recommendations for quality assurance systems focusing on prequalification of products and manufacturers purchasing storage and distribution of pharmaceutical products multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release solid oral dosage forms and additional guidance for organizations performing in vivo bioequivalence studies This is an excellent book with a misleading title a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients API and finished pharmaceutical products Annex 5 on Good distribution practices GDP for pharmaceutical products is an excellent Annex that splits the task of GDP into 20 small easy to digest sections that guide the reader through the process of understanding the complexity of controlling distribution of pharmaceutical products It contains a comprehensive glossary of terms used in GDP a useful reference book for anyone involved in Quality Assurance Manufacturing of marketed products Clinical Manufacturing and Development Industrial Pharmacy **Pharmaceutical and Biomedical Materials and Technology II** Jirapornchai Suksaeree, 2020-08-18 Selected peer reviewed full text papers from the 3rd International Conference and Exhibition on Pharmaceutical Sciences and Technology PST 2020 Selected peer reviewed papers from the 3rd International conference and exhibition on Pharmaceutical Sciences and Technology PST 2020 May 19 20 2020 Bangkok Thailand

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