

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

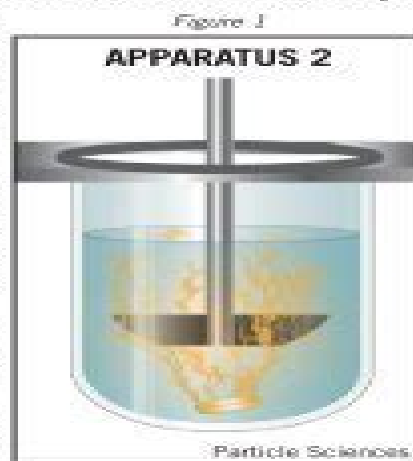
Review of API properties (BCS-classification, pK_a, stability, solubility as a function of pH/surfactant concentration, particle size, and polymorphism) that are likely to affect the *in vitro* dissolution behavior should be evaluated as part of method development.

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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web one unknown in each sample is an organic acid e g carboxylic acid phenol or sulfonic acid the other unknown in each sample is a neutral organic compound e g ketone ester amide etc the unknowns will be separated by extraction monitored by thin layer chromatography

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web 1 you have an unknown that is either an alcohol or a phenol using the following 1h nmr data is the unknown an alcohol or a phenol briefly explain your answer observed resonances doublet at 1.3 ppm septet at 2.8 ppm doublet at 3.7 ppm and a singlet at 4.1 ppm 2 you have an unknown organic compound that is either a ketone or an

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web the chromatography for gc and gc ms is identical in theory however the column used in the gc ms experiment is a capillary column as opposed to the packed column used in the gc experiment done in chemistry 105 a capillary column is simply a long tube made of glass with a small internal diameter for this experiment a 30 cm column with an

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web introduction along with synthesis and the examination of the reaction mechanisms an equally important part of organic chemistry has to do with the characterization and identification of compounds which may be encountered in sources ranging from a laboratory reaction to exotic tropical plants

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web nov 7 2021 lab report on identification of unknown organic compounds course chemistry institution bicol university the purpose of this laboratory activity was to identify the functional groups present in the given unknown and eventually identify what organic compound the unknown is preview 2 out of 5 pages report copyright violation other

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web the title of the abstract is the same as the title of the longer report that it summarizes the authors name and the place where the work was done are included using melting point to determine the identity of an unknown organic acid martha a hass albany college of pharmacy organic chemistry lab tuesday morning section june 15 2002 the

example unknowns lab report organic chemistry lab final - Oct 29 2022

web identification of unknowns marks a point of mastery within an organic chemistry lab because it involves the unification of a series of systematic tests observations and analysis that only when considered all together can provide the complete picture of

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web pre lab report 5 identification of unknown organic compounds pre lab grading rubric name rachel studocu points are assigned 5 pts total score 10 pts the liquid to its original bottle do not put other compounds or contaminated unknowns back into 2

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web apr 12 2020 all prelabs and lab reports are graded on a 100 point scale with the following distribution individual prelab

100 pts due at the beginning of each experiment

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web identification of unknown o attach ir and nmr with relevant peaks labeled things listed above it was determined that the unknown molecule was piperonylamine and when looking up the molecule the molecule also had a melting point of 138 139 c and has a ama of 151

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web chem 3306 lab report n1 lab report 5 lab related documents experiment 1 exp1 3106 313 exp 4 lab report quiz 12 quiz 7 quiz 3 quiz 2 preview text identification of unknown organic compound purpose the purpose of this lab is to collect qualitative data on an unknown compound in order to discover the identity of the unknown via

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web qualitative analysis of an organic unknown is an important proficiency for any student completing the organic chemistry laboratory course this experiment culminates the laboratory techniques that you have learned this semester and requires you to put the various pieces of information together to identify an unknown organic molecule

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web unknown reports you should submit an unknown preliminary report as soon as you have completed the experiments described below for the solid unknown you will take an accurate mp an ir spectrum using the kbr procedure solubility tests and based upon an analysis of this information do specific functionality tests as described in the manual

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web ms the spectrum for the unknown shows the molecular ion at 135 99 m z the base peak is at 56 98 m z which is the peak identified to be a butane chain of carbons the m 2 peak is at 138 99 m z and is roughly the same size as the m peak indicating the presence of bromine in this compound

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In Vitro Dissolution Testing For Solid Oral Dosage Forms

web in this paper several methods for identification characterization tests of organic compounds determination of molecular weight solubility of unknown compounds tlc technique each of you will receive two vials one containing a liquid unknown and one a solid unknown

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web 13 organic chemistry post lab 6 nutmeg and preparation of myristic acid organic chemistry laboratory i chm2210l assignments 100 17 organic chemisry lab report 12 organic chemistry laboratory i chm2210l assignments 100 17 experiment 6 isolation of trinyristin from nutmeg and preparation of myristic acid from

orgo 2 lab 6 lab report lab 6 an unknown binary mixture studocu - Feb 01 2023

web this lab report is based upon unknown binary mixture e containing unknowns 6s and 15l as it contains a solid liquid mixture vacuum filtration was conducted 6s is insoluble in 15l procedure 1 take the unknown binary mixture and make observations about the mixture by stating its state odor color and solubility characteristics