## Slides for the August 8, 2012 Meeting of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology

Persons with disabilities having problems accessing the PDF file(s) below may call (301) 796-3634 for assistance

**FDA**

FDA Presentations for the August 8, 2012 Meeting of the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology

Topic 1: Uses and Limitations of In Vitro Dissolution Testing (PDF - 3.35MB)[1]

Topic 2: Biosimilars – An Update (PDF - 5.49MB)[2]

Page Last Updated: 08/16/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | • • • • | Ti•ng Vi•t | • • • | Tagalog | • • • • • • • | •••-•• | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | • • • | •••▪ | English



FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA



**Links on this page:**

1. /7993/20170404154915/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeforPharmaceutica
2. /7993/20170404154915/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeforPharmaceutica

SHIRE EX. 2038
KVK v. SHIRE
IPR2018-00290

# Use and Limitations of *In Vitro* Dissolution Testing: Topic Introduction and Overview

Lawrence X. Yu, Ph. D.
*Deputy Director for Science and Chemistry*
*Office of Generic Drugs*
*Food and Drug Administration*

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology
August 8, 2012

# *In Vitro* Dissolution Testing: Objectives

- Assure batch to batch quality
- Guide development of new formulations
- Provide “process control” and quality assurance
- Ascertain the need for bioequivalence studies
  - Different strengths
  - Post-approval changes
  - Multi-source products

# Dissolution Testing: Issues

- Dissolution testing can be “non-discriminating”.
- Dissolution testing can be “over discriminating”.
- Products that dissolve about 70% in 45 minutes often have no medically relevant bioequivalence problems.
- Dissolution testing (especially only a single point criterion) is often not sufficient to assure product quality/ bioavailability.
- Demonstration of *in vitro-in vivo* correlation (IVIVC) is necessary.
- IVIVC’s are “Product Specific”.

# Desired Future State of *In Vitro* Dissolution Testing

- Sensitive enough to detect relevant product changes so as to ensure the quality and consistent performance of products
- Predictive of *in vivo* performance of drug products and thus reduce unnecessary human studies, accelerate drug development, and hasten evaluation of post-approval changes

DOCKET ALARM

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

**LAW FIRMS**
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

**FINANCIAL INSTITUTIONS**
Litigation and bankruptcy checks for companies and debtors.

**E-DISCOVERY AND LEGAL VENDORS**
Sync your system to PACER to automate legal marketing.