

Dissolution: Theory and Best Practices

The United States Pharmacopeia (USP)—the federally recognized standards-setting organization for drugs, dietary supplements, and other healthcare products—has developed standards-based professional education programs for pharmaceutical and allied health professionals worldwide.

USP's educational programming is unique in that all coursework is developed and delivered by the USP experts who are responsible for creating the standards trusted in more than 130 countries.

You can now benefit from the curriculum created by USP experts.

Course Overview

This **newly revised** two-day course provides focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing as described in *USP* General Chapter <711>. Gain an overview of the theory, practice, and history of dissolution. Learn the practical aspects of conducting dissolution tests, best practices, and performance verification testing. The newly revised course covers recent changes to the PVT test and the acceptance criteria and General Chapter <711>.

Duration: 2 days (lecture and lab)

Course Topics

- **Dissolution history**
- **Dissolution theory**
- **Performance verification testing**
- **Best practices in dissolution testing**

Who Should Participate

Scientists, chemists and laboratory technicians who perform dissolution testing in the laboratory, and QC and product development professionals who review dissolution data.

Schedule Information:

Date: **May 15, 2012 – Lecture**
May 16, 2012 – Lab

Location: SOTAX Corporation
Hopkinton, MA

Time: 8:30 am – 5:00 pm

Fee: \$950.00

Save \$100 by registering on or before April 24 OR register 3 or more from the same organization and save \$100! (contact pharmed@usp.org for code). Call Jennifer Barry at 301-816-8371 if you have questions.

To Register

For more information or to register, visit <http://www.usp.org/education/pe/courses/moreInfo.html?courseID=13> or contact USP Pharmacopeial Education at 301-230-6304. Payment can be made via credit card or check.

PE249F09

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Detailed Course Outline

1. Historical Perspective

- Historical highlights of dissolution
- PVT: Current approach, ISO framework, and proposal
- USP's responsibility and obligation
- Theory
 - Definition
 - Dissolution rate
 - Noyes-Whitney equation
 - Sink conditions equation
 - Intrinsic dissolution rate constant
 - Dissolution pathways
- Dissolution in practice
 - Dosage form factors
 - Dissolution test factors
- Significance of dissolution testing

2. Performance Verification Testing

- ISO standards
- Analytical instrument qualification: Installation (IQ), operational (OQ), and performance (PQ)
- USP performance verification test
 - Visual inspection
 - Routine maintenance
 - Drive mechanism
 - Water bath
 - Paddles and baskets, including shafts
 - Vessels
 - Vibration
- Reference Standards; *USP <711>*
- Sources of error and retests after failure
- When to perform PVT

3. Best Practices

- Performance verification testing
 - PVT best practices in general
 - USP Reference Standard tablets
 - Testing prednisone
- General dissolution testing
 - Some variables
 - Analyst training
 - Laboratory environment, moving equipment, water bath, media, sampling, and filtering
 - Acceptance criteria

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