

# Advanced Dissolution

The United States Pharmacopeia is pleased to announce a two-day course in collaboration with the Danish Dissolution Discussion Group and Bioneer:FARMA at The Faculty of Pharmaceutical Sciences, University of Copenhagen

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

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An in-depth overview of USP dissolution and drug release testing. These tests are *in vitro* performance tests for most pharmacopeial dosage forms, such as tablets, capsules, suspensions, transdermal patches, suppositories, etc. They are important components of the specifications that establish the quality, efficacy, and safety of a drug product.

This two-day course will enable scientists to

- acquire a working knowledge and understanding of advanced concepts related to dissolution and drug release testing
- learn to develop dissolution and drug release testing methods
- ensure data quality/instrument qualification
- understand how dissolution testing relates to drug product quality and performance

**Duration:** 2 days

**Format:** Classroom

**Language:** English

*Courses subject to change*

### Course Topics

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#### Theory and importance of dissolution testing

- Theory of dissolution
- Compendial dissolution testing
- IVIVC/IVIVR

#### Development of dissolution and drug release testing methods

- Drug substance characteristics
- Selection of instruments and media
- Interpretation of results

#### Data quality - analytical instrument qualification

- Qualification of instruments
- Sources of variability
- Performance verification test

#### Validation of dissolution and drug release methods

### Who Should Participate

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Scientists, chemists, and technicians who perform dissolution testing; lab managers; quality control staff; and product development professionals.

### Registration

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Space is limited.

To register, complete the form on page 3 and submit as soon as possible.

# Advanced Dissolution – Syllabus

1. **Introduction – overview of history and theory**
2. **Compendial dissolution testing – what's in the book**
  - Relevant USP chapters
  - Nomenclature of dosage forms
  - Reason for multiple dissolution tests in monographs
3. **Goals of dissolution/drug release testing**
  - Importance of reliable results
  - FDA product recall examples
  - Determination of release rate
  - Reasons for product stability testing
4. **IVIVC / IVIVR**
  - FDA and WHO biopharmaceutics definitions
  - Relevant USP chapters
  - Which parameters are correlated
  - IVIVC correlation levels A, B, C
  - Using the BCS to categorize drugs
  - Dissolution as part of quality control
  - SUPAC guidance
5. **Development of dissolution/drug release testing methods**
  - Characteristics of quality dissolution methods
  - Dissolution procedure requirements
  - Categorization of API according to the BCS
6. **Development – from API to dosage form**
  - Formulation type, excipients, release characteristics
  - Dissolution apparatus and medium, sampling, and analysis
  - Apparatus for conventional oral dosage forms
7. **Development – selecting instruments and media**
  - Testing special dosage forms
  - Examples of typical media
  - Sampling schedule
  - FDA guidance
8. **Development – interpreting results**
  - Data treatment in Chapter <1010>
  - Chapter <711> acceptance tables
  - Techniques for profile comparison
  - f1 and f2 factors
  - Practice exercises
9. **Development – setting specifications**
  - Specifications for NDAs, ANDAs, IR drug products, generic products, etc.
  - Alteration and widening of dissolution specifications
  - Response to out-of-specification test results
10. **Data Quality – analytical instrument qualification**
  - Sources of variability
  - Causes of artifacts
  - Qualification of dissolution apparatus and vessels according to Chapter <711>
  - FDA draft guidance
  - Dissolution Toolkit
11. **Validation – the dissolution test**
  - Validation of dissolution procedures
  - Validation of operational conditions
12. **Validation – API and dissolution media**
  - Validation of API-linked, excipient-linked, and media-related parameters
  - Deaeration techniques
  - Perturbation studies
13. **Validation – sampling, transfer, and processing**
  - Variability sources in the test procedure
  - Manual vs. automatic sampling
  - Appropriate sampling times
  - Processing: filtration and dilution
  - Sample transfer and storage
14. **Validation – chemical analysis**
  - ICH guidance
  - Placebo interference
  - HPLC specificity
  - System and method repeatability

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## Advanced Dissolution – Registration

### Course Information

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**Duration:** 2 Days  
**Format:** Classroom  
**Dates:** December 8-9, 2008  
**Location:** The Faculty of Pharmaceutical Sciences,  
University of Copenhagen, Denmark

**Fee:** €1250 DKK9400 + 25% VAT

### Payment Information

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Full payment must accompany the registration form before it can be processed.

One registration per form.

*Please copy the form for additional registrations.*

**Mail:** Bioneer A/S  
Kogle Allé 2  
DK-2970 Hørsholm  
Denmark

**Fax:** +45 45 16 04 55

**Email:** USPDisolution@Bioneer-FARMA.dk

Attendees should make their own hotel arrangements. Information on local hotels will be included with your registration confirmation.

### Questions

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Please contact Randi Brundstedt or Gitte Andersen on +45 45 16 04 44

### Contact Information

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Last Name: \_\_\_\_\_

First Name: \_\_\_\_\_

Title: \_\_\_\_\_

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Address: \_\_\_\_\_

City: \_\_\_\_\_

Country: \_\_\_\_\_

Post Code: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

### Payment Options

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**Payments may be made in Euros or Danish Krone**

**€1250 DKK9400 + 25% VAT**

**Payments by credit transfer to:**

Danske Bank, Holmens Kanal 2,  
DK-1090 Copenhagen K

SWIFT: DABADKKK

Euro account IBAN: DK7730004777 342983

DKK account IBAN: DK0230004777 342975

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