USP Pharmacopeial Education

Dissolution: Theory and Best Practices

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

This one or two day course provides focused, relevant instruction on the fundamentals of pharmaceutical dissolution testing as described in USP General Chapter <711>.

This course will enable scientists to

- gain an overview of the theory, practice, and history of dissolution testing
- learn the practical aspects of conducting dissolution tests, best practices, and performance verification testing

Duration: **1 day (lecture only)**
2 day (lecture and lab)

Format: **Day 1 – Classroom**
Day 2 – Laboratory Practical

Language: **English**

Courses subject to change

Course Topics

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

Who Should Participate

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

Why Choose USP?

USP Pharmacopeial Education courses are developed and presented by USP experts who have practical firsthand knowledge of specific subject areas, have been instrumental in setting the USP standards followed in over 130 countries, and have proven professional presentation skills suited for the pharmaceutical industry.

Registration

Space is limited.

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

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USP Pharmacopeial Education

Dissolution: Theory and Best Practices – Syllabus

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)**
- **Dissolution equipment qualification**
  - **Visual inspection**
  - **Routine maintenance**
  - **Mechanical calibration**
  - **The performance verification tests**
- **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 and salicylic acid**
- **General dissolution testing**
  - **Some important variables**
  - **Analyst training**
  - **Laboratory environment**
  - **Moving equipment**
  - **Sampling and filtering**
  - **Acceptance criteria**
  - **Solution stability**

4. Optional Laboratory Practical

- **Check-in and orientation**
- **Medium preparation and equipment set-up**
- **Mechanical calibration**
- **Testing with baskets**
- **Testing with paddles**
- **Review of results**
- **Discussion - questions and answers**

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Dissolution: Theory and Best Practices – Registration

Course Information

Duration: **1 or 2 Days**
Format: **Day 1 – Classroom**
Day 2 – Laboratory Practical
Dates: **December 10-11, 2008**
Location: **The Faculty of Pharmaceutical Sciences, University of Copenhagen, Denmark**

Fees: **€750 / DKK5600 + VAT 25% (Lecture Only)**
€1400 / DKK10500 + VAT 25% (Lecture & Lab)

Payment Information

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: USPDissolution@Bioneer-FARMA.dk

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

Questions

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

Contact Information

Last Name: _____

First Name: _____

Title: _____

Email: _____

Organization: _____

Address: _____

City: _____

Country: _____

Post Code: _____

Phone: _____ Fax: _____

Payment Options

Payments may be made in Euros or Danish Krone

☐ **1-day: €750 / DKK5600 +25% VAT**

☐ **2-days: €1400 / DKK10500 +25% VAT**

☐ **Payments by credit transfer to:**

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DK-1090 Copenhagen K

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