

DISSOLUTION SEMINAR SERIES

In Vitro Dissolution of Ointments, Creams and Transdermals



SEMINAR SERIES

About the course

The *In Vitro* Dissolution of Ointments, Creams and Transdermals seminar is a comprehensive, two-day course designed for academic researchers and industry scientists with interests in evaluating drug release from topical preparations. The goal of the course is for the participant to learn the application of current dissolution testing techniques and equipment in the evaluation of drug release from semi-solids and transdermal drug delivery systems (both immediate and controlled release). Discussion includes the use of this technology in product development and quality control.

Topics covered

- Compendial testing - Apparatus 5, 6 and 7
- Non-compendial testing
- Proposed calibration methodology
- Use of the Enhancer and Franz cells
- World community regulatory requirements
- Method validation
- Aspects of membrane selection
- SUPAC guidance
- Method development

This course is designed for individuals involved in the development, manufacturing or quality control of topical products.

Upon successful completion of this course, the attendee should be able to:

- Describe basics of compendial dissolution testing with USP Apparatus 5, 6 and 7
- Outline uses and restrictions non-compendial testing and apparatus
- Explain uses of the Enhancer and Franz cells
- Describe ointment, cream and transdermal method development and validation techniques
- Describe SUPAC guidelines for topicals
- Explain regulatory requirements with perspective on the world community

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Day One Syllabus

8:30 – 10:30 Overview

- Fundamentals of dissolution testing
 - Definition
 - Need for dissolution testing
- Locally applied / locally acting products
 - Definition
 - Peculiarities
 - Testing methods of the pharmacopoeias
- General requirements for *in vitro* dissolution of semi-solid dosage forms
 - SUPAC guidelines
 - Other regulatory requirements

10:30 – 10:45 Break

10:45 – 12:30 USP Compendial Drug Release Testing

- Transdermal delivery systems
- Apparatus 5
- Apparatus 6
- Apparatus 7

12:30 – 1:15 Lunch

1:15 – 2:30 Procedures Featuring Enhancer and Franz Cells

- Calibration of apparatus
- Validation of the analytical method
- Method development
- Documentation and presentation of results
- Acceptance criteria

2:30 – 2:45 Break

2:45 – 4:30 Workshop / Demonstration on Enhancer and Franz Cells

Day Two Syllabus

8:30 – 10:30 Non-compendial Drug Release Testing

- Purpose, formulation, QC, QA
- Apparatus
- Calibration proposal, Enhancer Cell
- System variables

10:30 – 10:45 Break

10:45 – 12:30 Examples

- Examples using Franz Cells
- Examples using Enhancer Cells
- Comparison of results
- Other methods used in product development

12:30 – 1:15 Lunch

1:15 – 2:15 Demonstration – Apparatus Setup

2:15 – 2:30 Break

2:30 – 4:15 Workshop on Apparatus 5, 6 and 7 and the Enhancer Cell

4:15 – 4:30 Closing Remarks and Evaluations

Refund Policy

- 100% refund for cancellations received 10+ business days prior to course date.
- 50% refund for cancellations received six to nine business days prior to course date.
- No refund for cancellations received five or fewer business days prior to course date.
- No refund for no-shows.

