

Development and Validation of Dissolution Procedures

Course Overview

This course has been entirely revised in order to reflect the content of the complete overhaul of *USP* General Chapter <1092> published in *USP 38–NF 33 First Supplement* with the official date of August 1, 2015. Building on your basic understanding of USP's approach to dissolution, this course provides a foundation for developing and validating dissolution methods used for batch release and stability testing. These tests are in vitro performance tests for most dosage forms, such as tablets, capsules, suspensions, transdermal patches, and suppositories. They are important components of the specifications that establish the strength, quality, purity, and bioavailability of a drug product.

Learning Objectives

This course will cover

- Development of dissolution and drug release testing methods based on physicochemical characterization of drug substance
- Physiological considerations when setting up tests
- Selection of dissolution testing conditions, such as instruments and media, etc.
- Automation
- Interpretation of dissolution test results
- Validation
- Performance verification tests

Who Should Participate

- Scientists
- Chemists who perform dissolution testing
- Lab managers
- Product/formulation development staff
- Regulatory professionals

USP Approved Instructors

Erika Stippler, Ph.D.
Principal Scientist, USP



Why Choose USP Education?

USP Education provides year-round courses and programs on how to effectively interpret and apply USP's internationally recognized quality standards. The standards help ensure the quality and safety of medicines, dietary supplements and foods.

USP courses are created by the scientists and experts who help develop the USP standards that are used worldwide. Courses are presented by approved instructors with practical, first-hand knowledge of the subject area and related standards. The insights they share will not only make your daily work easier, but will also connect you to an independent, nonprofit scientific body with the goal of creating a strong foundation for a healthier world.

Duration: Two Days

Location: Bucharest, Romania

Format: Classroom

Course ID: CM-1092-01

Date: October 3-4, 2018