Dissolution Testing: Apparatus Qualification, Method Development and f2 Profile Comparison

15 – 19 November 2027
Barcelona - Eixample district four-star



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Introduction:

Dissolution testing links a solid oral dosage form's release behaviour to batch quality and, through biopharmaceutics, to how the medicine performs in patients. Yet many laboratories run methods with poorly justified media, apparatus that drift out of mechanical calibration and profile comparisons that fail scientific review. This Core Concept course trains QC analysts, formulation scientists and analytical development staff to qualify dissolution apparatus, control sources of variability, develop and validate discriminating methods, apply stage testing and compare profiles with the f2 similarity factor. Participants build a Dissolution Method Development and Justification Report for a case tablet.

Course Objectives:

- Explain the role of dissolution testing in batch release, formulation development and biopharmaceutics, including the Biopharmaceutics Classification System at overview
- Select and set up pharmacopoeial Apparatus 1 to 4 for immediate-release, modified-release and special dosage forms
- Qualify dissolution equipment through mechanical calibration and performance verification and control deaeration, vibration, coning and sampling variability
- Develop a discriminating dissolution method by justifying medium, pH, surfactant, sink conditions, agitation rate and analytical finish
- Validate dissolution procedures and apply acceptance criteria, stage testing and f2 profile comparison to real results
- Investigate out-of-specification and out-of-trend dissolution results with defensible, data-integrity compliant records

Target Audience:

- QC analysts who run routine dissolution tests and report release and stability results
- Formulation scientists who design tablets and capsules and need dissolution data to guide formulation choices
- Analytical development scientists who develop, validate and transfer dissolution methods
- Laboratory reviewers who check dissolution raw data, calculations and audit trails before result approval
- Laboratory equipment coordinators who schedule calibration and maintenance of dissolution baths and samplers

Course Outline:

Day 1: Dissolution Purpose, Biopharmaceutics and Laboratory Baseline

- Dissolution Test Purpose: Batch Release, Formulation Screening and Change Control
- Noyes-Whitney Equation and Drug Release Mechanisms From Solid Dosage Forms
- Biopharmaceutics Classification System Overview: Solubility, Permeability and Biowaiver Logic
- In Vitro-In Vivo Correlation Levels at Overview
- Dissolution Laboratory Baseline Checklist: Methods, Equipment and Result Trends

Day 2: Pharmacopoeial Apparatus, Qualification and Variability Control

- Apparatus 1 Basket and Apparatus 2 Paddle: Geometry, Set-Up and Typical Uses
- Apparatus 3 Reciprocating Cylinder and Apparatus 4 Flow-Through Cell for Poorly Soluble and Modified-Release Products
- Mechanical Calibration Parameters: Shaft Wobble, Centring, Vessel Verticality and Height
- Performance Verification Test With Reference Tablets and Trend Records
- Variability Sources: Medium Deaeration, Bath Vibration, Coning and Sinker Selection

Day 3: Dissolution Method Development and Analytical Finish

- Media Selection: pH Range, Buffer Capacity and Biorelevant Media at Overview
- Surfactant Choice and Sink Condition Calculation for Poorly Soluble Drugs
- Agitation Rate, Sampling Time Points and Discriminating Power Experiments
- Analytical Finish Options: UV Spectrophotometry, Fibre-Optic Probes and HPLC Quantitation
- Manual Versus Automated Sampling: Filter Validation, Volume Replacement and Carry-Over

Day 4: Validation, Acceptance Criteria, Profile Comparison and Investigations

- Dissolution Method Validation: Specificity, Linearity, Accuracy, Precision and Robustness
- Q Value Acceptance Criteria and Stage 1, Stage 2 and Stage 3 Testing Logic
- Profile Comparison Using the f2 Similarity Factor and Its Applicability Conditions
- Modified-Release, Chewable, Orally Disintegrating and Capsule Products at Overview
- Out-of-Specification and Out-of-Trend Dissolution Investigation With Audit Trail Review

Day 5: Case Tablet Method Development and Justification Report

- Case Tablet Dossier Review: Drug Solubility Data, Formulation and Target Release
- Case Work: Media and Apparatus Selection With Sink Condition Evidence
- Case Work: f2 Calculation Workbook for a Formulation Change Comparison
- Case Work: Failed Stage 2 Result Root Cause and Corrective Action Record
- Dissolution Method Development and Justification Report Presentation and Peer Critique

Skills You Will Gain:

- Dissolution Apparatus Qualification
- Dissolution Variability Control
- Dissolution Medium Design
- Sink Condition Assessment
- Dissolution Method Validation
- Stage Testing Evaluation
- f2 Profile Similarity Analysis
- Dissolution Result Investigation

Why Attend This Course:

- Leave with a Dissolution Method Development and Justification Report for a case tablet that mirrors your own product challenges
- Cut repeat tests caused by coning, air bubbles and poor sampling by knowing what to check before each run
- Defend medium, agitation and f2 choices confidently when reviewers question a method or a formulation change
- Compare dissolution practice with peers from innovator, generic and contract testing laboratories

Conclusion:

A dissolution result is only meaningful when the apparatus is qualified, variability is controlled and the method is proven to discriminate. The week moves from the purpose of dissolution and biopharmaceutics, through pharmacopoeial apparatus, mechanical calibration and variability sources, to media, sink conditions, agitation and analytical finish. It then covers validation, stage testing, f2 comparison, special dosage forms and investigations, and closes with case work and a Dissolution Method Development and Justification Report for each participant.