JUPITER PRIME

Consulting • Training • Advisory

جوبيتر برايم للاستشارات والتدريب

COURSE BROCHURE

Dissolution Testing Training Course for Lab Supervisors and Quality Leads

1 – 5 November 2027
Geneva

Dissolution Testing Training Course for Lab Supervisors and Quality Leads

Ref: 2196_81124 **Date:** 1 – 5 November 2027 **Location:** Geneva **Fees:** 6500 GBP

Dissolution Testing Training Course for Lab Supervisors and Quality Leads is a 1-week training course for laboratory supervisors and quality leads who oversee tablet and capsule testing, and it ends with a Dissolution Lab Control Pack. Drug release data now decides batch disposition, so weak methods carry real cost. Jupiter Prime Training presents Dissolution Testing as a supervisory discipline as well as a bench technique.

Why Dissolution Testing Matters Now

Three forces shape dissolution work today: more complex formulations such as modified-release and poorly soluble actives, tighter data integrity expectations from inspectors, and the pressure on laboratories to release product faster with leaner teams. A laboratory that runs robust, discriminating methods catches formulation drift early and defends its results calmly during audits. One that does not faces rejected batches and long investigations. The course rests on the pharmacopoeial apparatus and procedure requirements, Quality Risk Management QRM principles and the Analytical Procedure Lifecycle APL approach, all described in practical terms.

Who Gains Most from Dissolution Testing

- Supervisors who schedule dissolution runs and sign off analyst results
- Quality leads who approve batch release and stability data
- Method owners who develop, transfer or revise dissolution procedures
- Equipment custodians who maintain baths, autosamplers and qualification records
- Investigation leads who handle failing and atypical drug release results

Quality control laboratories in generic manufacturing and contract testing gain most when a supervisor, a quality lead and a method owner attend together.

Dissolution Testing Capabilities

Participants move from running a dissolution procedure to steering how a laboratory designs, qualifies and defends it.

- Design a discriminating dissolution method for an immediate or modified-release product — formulation and method owners
- Specify qualification and mechanical calibration checks for paddle and basket apparatus — equipment custodians
- Assess sources of variability such as deaeration, coning and sinker choice — analysts and supervisors
- Apply profile comparison with the similarity factor f2 — product change decisions
- Build a phased out-of-specification investigation with clear root cause logic — quality leads
-

Communicate dissolution trends and risks to production and regulatory affairs — site leadership

Key Dissolution Testing Terms

- Discriminating method — a dissolution procedure able to detect meaningful changes in formulation or process that could affect drug release.
- Sink conditions — a medium volume at least several times that needed to dissolve the full dose, so solubility does not limit release.
- Similarity factor f2 — a calculation comparing two dissolution profiles; values from 50 to 100 indicate similar release.
- Mechanical calibration — measured checks of shaft wobble, vessel centring, height and speed that confirm the apparatus performs as specified.
- Coning — a mound of undissolved excipient beneath the paddle that slows release and produces artificially low results.
- Out-of-specification result — a test result falling outside the acceptance criteria that triggers a formal laboratory investigation.

Dissolution Testing Day by Day

Day 1: Drug Release Science and Laboratory Context

- Solubility, Permeability and Release Mechanisms — Why Formulations Behave Differently
- Immediate, Delayed and Extended Release Profiles — Choosing Test Expectations
- Role of Dissolution in Release and Stability — Batch Disposition Decisions
- Pharmacopoeial Apparatus Types One to Four — Matching Apparatus to Dosage Form
- Supervisory Accountabilities in the Dissolution Laboratory — Defining Sign-Off Points

Day 2: Method Design and Development

- Medium Selection, pH and Surfactant Use — Balancing Biorelevance and Robustness
- Agitation Speed and Sinker Choice — Avoiding Coning and Floating Units
- Deaeration and Medium Preparation Controls — Reducing Hidden Variability
- Sampling Times, Filters and Analytical Finish — Securing Accurate Profiles
- Robustness Studies and Method Lifecycle Records — Approving Method Transfer

Day 3: Apparatus Qualification and Data Integrity

- Installation, Operational and Performance Qualification — Release of New Baths
- Mechanical Calibration Checks and Tolerances — Scheduling Equipment Verification
- Performance Verification Tablets — Interpreting Apparatus Suitability Results
- Autosampler and Vessel Hygiene Controls — Preventing Carry-Over and Contamination
- Audit Trails and Raw Data Review — Defending Results During Inspections

Day 4: Interpreting Results and Investigating Failures

- Staged Acceptance Criteria and Unit Testing — Deciding When to Proceed
- Profile Comparison Using f2 — Supporting Product and Site Changes
- Phase One Laboratory Investigation — Separating Analyst Error From Product Issues
- Root Cause Tools for Atypical Release — Fishbone and Five Whys
- Corrective and Preventive Action Records — Closing Investigations With Confidence

Day 5: Practising the Dissolution Lab Control Pack

- Method Review Case From Two Product Types — Applying Development Criteria
- Qualification Gap Assessment of a Laboratory — Applying Apparatus Checks
- Mock Failing Result Investigation — Applying Phased Investigation Steps
- Analyst Competence Matrix and Coaching Plan — Leading the Testing Team
- Dissolution Lab Control Pack — Presenting Controls to Quality Leadership

Applying Dissolution Testing After the Course

- Lead a robustness review of one marketed product's dissolution method, recording medium, agitation and sinker risks.
- Run a mechanical calibration and qualification gap check across the laboratory's baths and present a revised verification schedule.

Dissolution Testing Questions FAQ

What is dissolution testing and why does it matter now?

Dissolution testing measures how quickly and completely a drug is released from a tablet or capsule. It matters now because complex formulations, inspection scrutiny and faster release targets make method quality and sound investigations essential for reliable supply.

Which roles gain most from dissolution testing training for supervisors?

Laboratory supervisors, quality leads, method owners and equipment custodians gain most. You need to judge method robustness, apparatus suitability and failing results with confidence.

How does this dissolution testing course differ from a general analytical method validation course?

It focuses on one test and its specific risks. A general validation course covers accuracy and precision across many techniques, while this dissolution testing course covers medium choice, coning, apparatus calibration, f2 comparison and release failure investigation in depth.

What do you bring back from dissolution testing training?

You bring back a control pack for your laboratory. It holds method review criteria, a qualification checklist, an investigation flow and an analyst competence plan.

Dissolution Testing: The Way Forward

The Dissolution Lab Control Pack gives supervisors one place to hold method criteria, apparatus checks and investigation steps. Its first use is often deciding whether a recurring low result points to the method, the bath or the product. Quality leads and method owners share it, and it is worth revisiting after the first real investigation to refine its root cause questions.