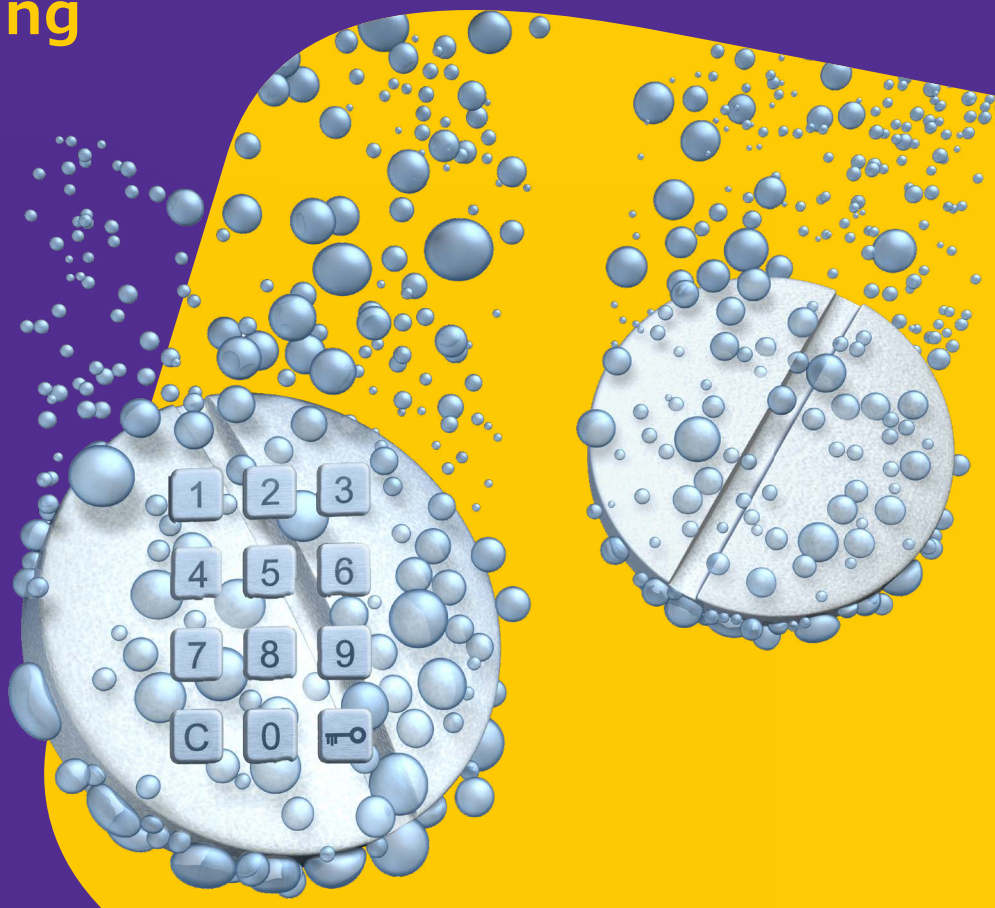
MilliporeSigma

SECURE YOUR PHARMA ANALYSIS & QC

A quick guide to dissolution testing



Supelco®
Analytical Products

Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Milli-Q®
Lab Water Solutions

Sigma-Aldrich®
Lab & Production Materials

MilliporeSigma has brought together the world's leading Life Science brands, so whatever your life science problem, you can benefit from our expert products and services.

Supelco®

Analytical Products

The Supelco® portfolio of analytical solutions of MilliporeSigma is developed by analytical chemists for analytical chemists to ensure your results are accurate, precise and reproducible. Every product is meticulously quality-controlled to maintain the integrity of your testing protocols and, with our dedicated scientists, the expertise you need is always on hand.

Milli-Q®

Lab Water Solutions

The Milli-Q® portfolio of lab water solutions of MilliporeSigma takes care of all your water quality and purity needs. Our solutions are backed by consistent quality and full compliance and work seamlessly together to let you focus on your vital work.

Millipore®

Preparation, Separation, Filtration & Monitoring Products

The Millipore® portfolio of MilliporeSigma offers an ecosystem of industry-leading products and services, spanning preparation, separation, filtration and monitoring – all of which are deeply rooted in quality, reliability and timetested processes. Our proven products, regulatory and application expertise are a strong foundation you can rely on to consistently perform at the highest level.

Sigma-Aldrich®

Lab & Production Materials

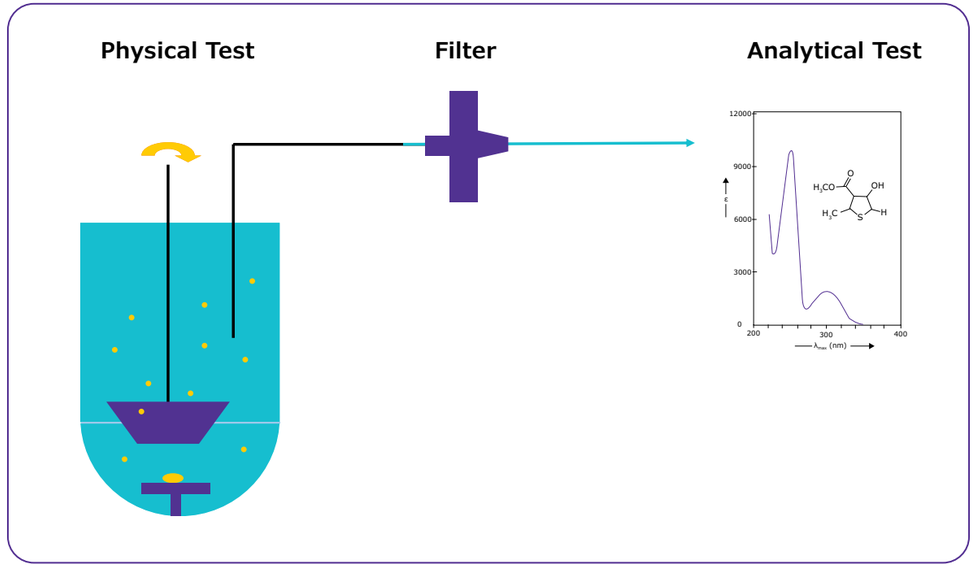
The Sigma-Aldrich® portfolio of MilliporeSigma offers a strong and ever-expanding offering of lab and production materials. Through our technical support and scientific partnerships, we help connect our customers with a whole world of progress.

Why analyte binding to syringe filters must be studied during filter validation for QC testing

Read the white paper

What is dissolution testing?

Dissolution testing is the measurement of how quickly an orally administered drug (e.g. tablet) dissolves and releases a drug. Analytical measurements by UV spectroscopy or HPLC analysis are made at specific time points to determine rates of release.



Why is it critical?

In vitro dissolution testing is a critical, multistep QC analysis used to characterize the efficacy of solid oral dosage dissolution workflow. Dissolution testing measures the rate and extent of drug dissolution under standardized conditions. In early drug development, dissolution testing aids in formulation design and optimization, while in commercial drug production, dissolution testing serves as a critical quality control process, ensuring batch-to-batch consistency.

Method validation – what to consider?

Since precise, reliable quantification of analytes is critical in dissolution testing, method validation should include considerations of lab water quality, reagent consistency and sample filter validation studies to evaluate sources of unwanted variation and sensitivity issues caused by analyte loss to the membrane. Proper validation combined with reliable high-quality product sourcing is important to maintain high QC standards and regulatory compliance.

Discover a range of reliable, consistent filters and reagents for your dissolution testing protocol backed by our extensive pharmaceutical analysis expertise.

Learn More

From Development to Drug Release

SOLID DOSAGE DISSOLUTION WORKFLOW

Discovery

- No Dissolution Test

Development

- Formulation optimization
- Formulation changes
- IVIVC

Approval

- NDA submission
- FDA requirement
- IVIVC

Production

- Manufacturing changes
- Process modifications
- QC release test
- IVIVC

Finished Product

- Bio-equivalence
- Manufacturing changes
- QC release test
- (Ph EUR/USP/JP/ChP…)
- IVIVC

Media Preparation

- High purity reagents
- Milli-Q® water purification systems
- Bottled high purity water
- pH calibrators
- Pipettes, pipettors, tips & labware
- Media filtration

Sampling

- Analytical standards

Sample Filtration

- Filtration tools

Millipore® products
Supelco® products
Sigma-Aldrich® products
Milli-Q® products

UV Spectroscopy

- Cuvettes
- Cuvette racks, washers, tools
- UV/Vis reagents
- UV/Vis solvents
- pH calibrators
- Photometers
- Milli-Q® water purification systems

HPLC Analysis

- Analytical standards
- Solvents, inorganics, safety & essentials
- Milli-Q® water purification systems
- High purity reagents
- High purity solvent
- Mobile phase filtration
- HPLC & UHPLC columns
- Pipettes, pipettors, tips & labware

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