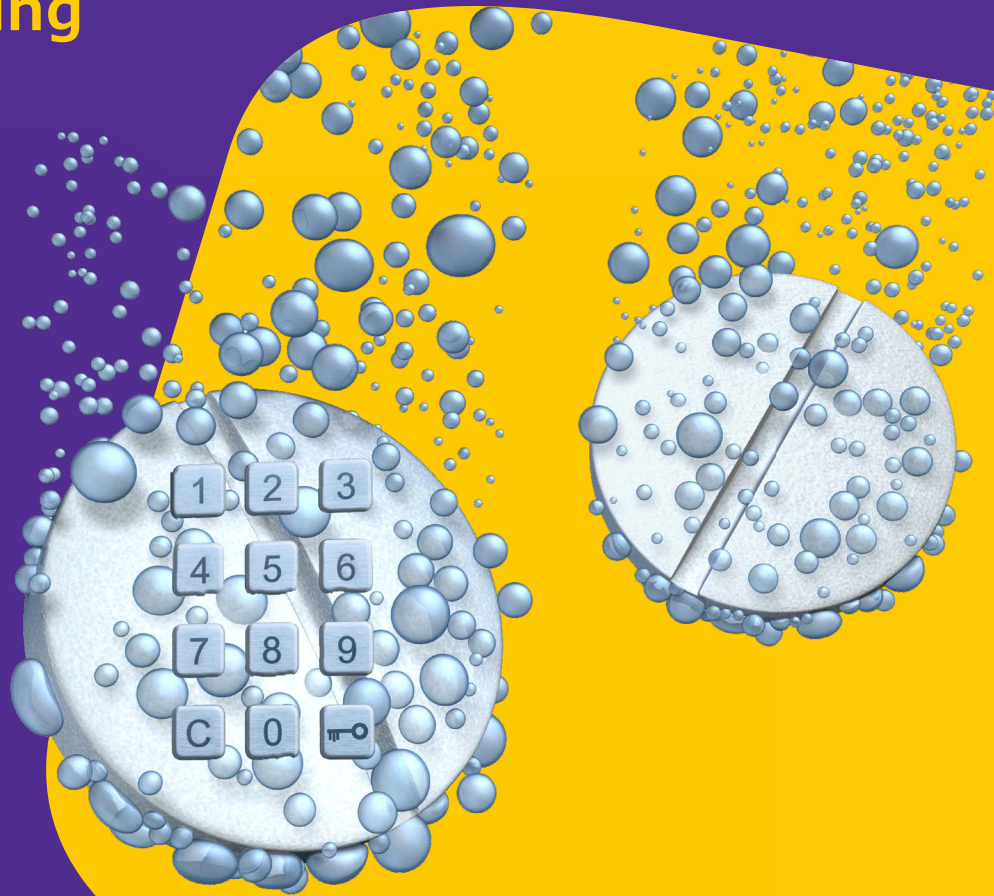


# SECURE YOUR PHARMA ANALYSIS & QC

A quick guide to  
dissolution testing



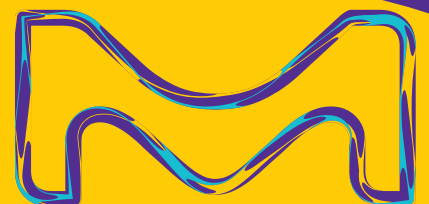
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Analytical Products

**Millipore**<sup>®</sup>  
Preparation, Separation,  
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**Milli-Q**<sup>®</sup>  
Lab Water Solutions

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The Supelco® portfolio of analytical solutions of Merck 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.

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The Millipore® portfolio of Merck 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.

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The Milli-Q® portfolio of lab water solutions of Merck 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.

## Sigma-Aldrich®

Lab & Production Materials

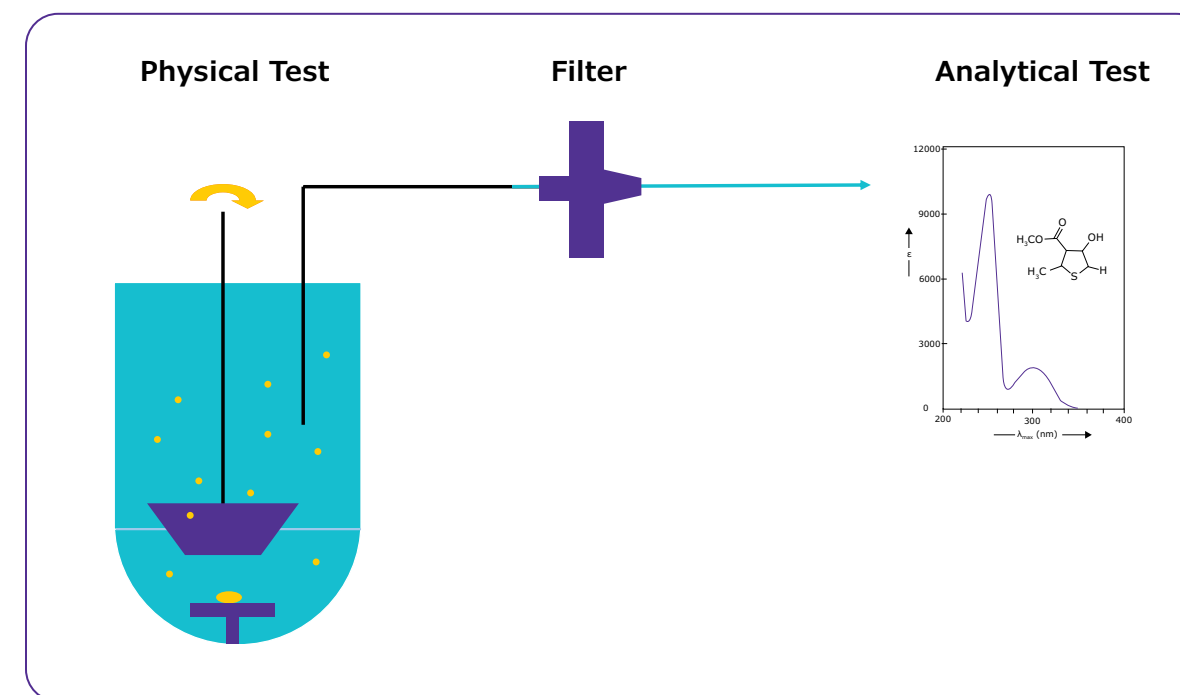
The Sigma-Aldrich® portfolio of Merck offers a strong and ever-expanding offering of lab and production materials. Through our technical support and scientific partnerships, we help connect our customers with a whole world of progress.

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

# SOLID DOSAGE DISSOLUTION WORKFLOW



## Discovery

- No Dissolution Test



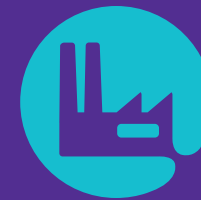
## Development

- 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

### 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

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

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