

Agilent LC Dissolution Software

# STREAMLINE LC DISSOLUTION ANALYSIS

The Measure of Confidence



**Agilent Technologies**

## STREAMLINE LC DISSOLUTION ANALYSIS AND IMPROVE YOUR LABORATORY WORKFLOW

A small link in the chain is often all that is required to make a significant improvement in the productivity of the laboratory workflow. The new Agilent LC Dissolution Software is such a link—simplifying the quantification and reporting of dissolution samples analyzed by HPLC.

The Agilent LC Dissolution Software is an add-on module for the ChemStation Edition of Agilent OpenLAB Chromatography Data System (CDS). This easy-to-install and easy-to-use software module automates the setup of the LC instrument, incorporates the dissolution methodology, performs the sample analysis, and generates the final reports. Further, tools are available to help your lab comply with 21 CFR Part 11 regulations such as access control, data security, data integrity and electronic signatures.

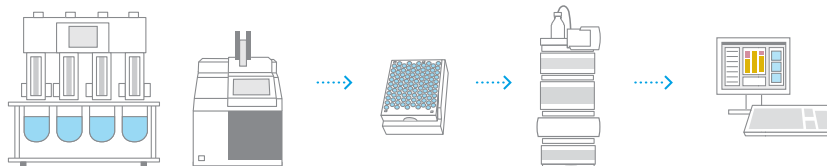
### Maximize Utilization of Your Dissolution Apparatus

With the LC Dissolution Software in full control of your LC instrumentation, there's no need for your dissolution apparatus to remain idle. While the LC instrument is analyzing a batch of samples, you can run the next batch of dissolution experiments. You can even have multiple apparatus running in parallel, collecting samples for later analysis.

### Maximize Utilization of Your LC Instrumentation

With multiple dissolution apparatus feeding a constant stream of samples, the LC Dissolution Software can reduce

Perform Dissolution Run, Sample, Filter, Collect    Sample Transfer    Analyze Samples    Review Data, Report Preparat



your LC instrument's idle time to near zero. During periods of lower sample loading, you can use the LC instrument for other applications. Plus, with the Agilent 1200 Infinity Series LCs you get the added benefits of UHPLC speed and performance for highest productivity.

### Maximize Your Investment in Software

Through automation of your dissolution analysis and reporting, the Agilent LC Dissolution Software makes it easy for you to leverage your investment in the ChemStation Edition of Agilent OpenLAB CDS, OpenLAB Data Store for centralized storage of OpenLAB CDS data, and OpenLAB Enterprise Content Manager (ECM).

While OpenLAB provides for secure, worldwide access to the generated data as well as integrated document approval and longterm archiving, the new OpenLAB ECM Intelligent Reporter includes a suite

of templates for reporting your experimental settings and dissolution results. The easy-to-use Report Template Editor allows you to create custom reports using simple drag-and-drop operations.

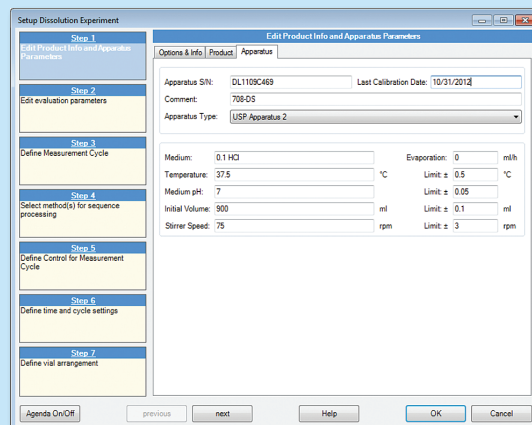
As an affordable alternative to content management, OpenLAB Data Store provides a simple solution for centralized storage of OpenLAB CDS data. Designed to accommodate existing laboratory workflows, OpenLAB Data Store is streamlined to focus on essential capabilities that make it easy to deploy and use on a daily basis.

Deploying Agilent's LC Dissolution Software also means you standardize on a single software platform, which gives you the added benefits of reduced training and validation effort.

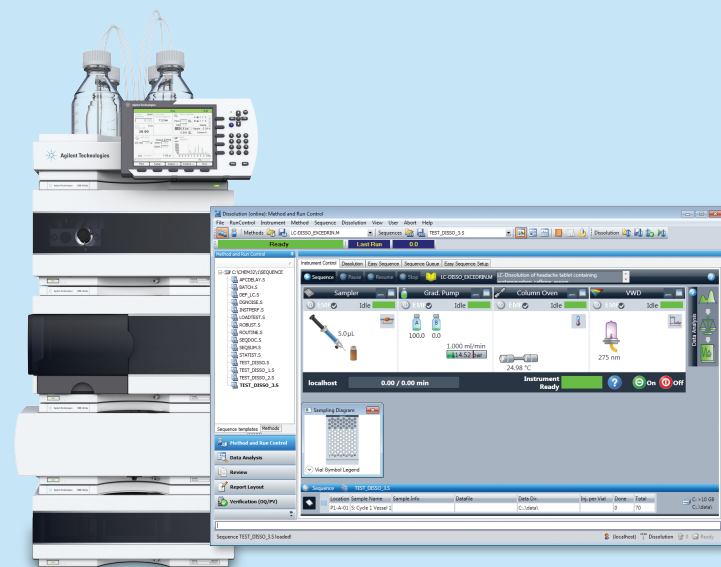
# Dissolution Experiment Workflow with LC Analysis



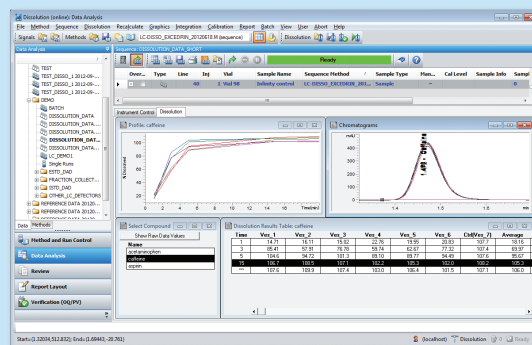
**1** Run your dissolution experiments and collect and filter your samples in septa-capped vials with the Agilent 850-DS Dissolution Sampling Station (or with your current equipment).



**2** Load or setup your LC analysis sequence in the LC Dissolution Software based on your dissolution experiment settings.



**3** Load the sample tray of your LC instrument and run the analyses.



**4** View or print your dissolution results through the LC dissolution software.

# CAPITALIZE ON YOUR EXISTING INVESTMENTS

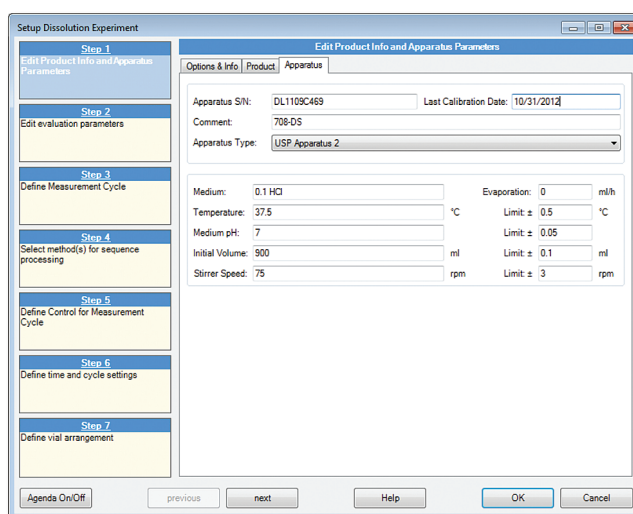
Integrating the Agilent LC Dissolution Software in your laboratory workflow helps you to capitalize on the investments you have made in dissolution apparatus and LC instrumentation and software. With separated dissolution and analysis functions, deploying the LC Dissolution Software ensures both sets of equipment can be fully utilized without having to wait for one of the two operations to finish.

## Straightforward Setup of LC Analysis Methods

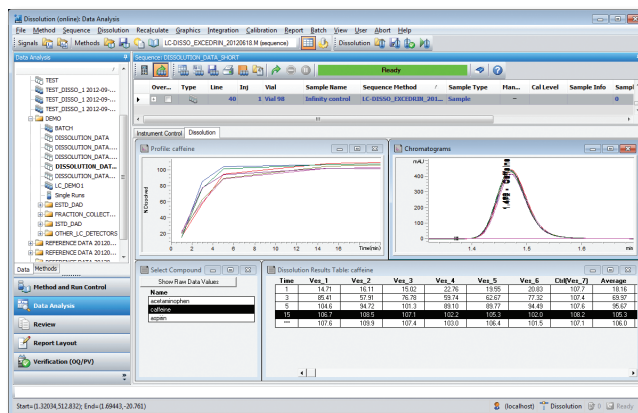
- Automatic generation of analysis sequence based on your dissolution experiment settings
- Sequence generation independent of hardware
- Seamless integration of existing LC methods for data acquisition and quantitative data analysis
- Full utilization of all LC ChemStation software capabilities

## At-a-Glance Overviews of Analysis and Results

- See your dissolution analysis progress by live updated views on dissolution tables and dissolution profiles for all active ingredients
- Get a quick overview based on a graphical view as dissolution profiles including quality limits



Setting up the apparatus condition for your dissolution test.



Dissolution results view with focus on caffeine and the chromatograms at the 15 minutes time point.



## Agilent's Solutions Maximize Efficiency and Save Costs

### No New Hardware Investment Required!

The new Agilent LC Dissolution Software allows you to use all the dissolution equipment and Agilent LC instrumentation that is in your lab today. Further, all of your Agilent LC systems can be integrated in your workflow and deployed for dissolution analysis.

The LC Dissolution Software is available as workstations or as networked workstations, whereby each workstation performing dissolution analysis requires an individual license.

The LC Dissolution Software operates in any environment you choose: regulated or non-GMP, single workstation or distributed network system.

### Agilent—Your Source for Practical Solutions

Agilent provides you complete workflow solutions to your dissolution needs. By purchasing from Agilent, you protect your investment. Our solutions are designed to facilitate easy integration into future hardware and software developments.

Further, our capabilities go well beyond just products. Our services include training and seminars to ensure your staff are properly trained and your methods optimized.

### Learn More

[www.agilent.com/lifesciences/lcdissolution](http://www.agilent.com/lifesciences/lcdissolution)

### Wide Selection of Testing Parameters

- Correction algorithm for the volume withdrawn at each timepoint
- Correct for medium loss due to evaporation
- Evaluate the USP acceptance criteria for immediate, delayed and extended releases of your dissolution experiment
- Define your own quality limits such as minimum and/or maximum values at one or more given dissolution timepoints

The screenshot shows the 'Edit evaluation parameters' window. Under 'Calculate Result as', 'QC Limits' is selected. The 'Calculate Result as' dropdown is set to '% Dissolved'. The 'Factor' is set to 1. There are checkboxes for 'Volume Changes per Measurement', 'Volume Correction' (checked), 'Zero Vessel Correction', and 'Normalize to Concentration (divide amount by injection volume)' (checked). The 'Equation' section displays the formula: 
$$\% \text{ Dissolved} = \left( \frac{\text{Concentration} \cdot \text{Volume}}{\text{Ingredient Weight}} \right) \cdot 100 \cdot \text{Factor}$$
 Below this is a 'Compound Table' with columns for Compound Name, Ingredient Weight [mg], and Description. The table contains three rows: Acetaminophen (250 mg), Caffeine (65 mg), and Aspirin (250 mg).

Setting up the dissolution calculation parameter and options.

### Extensive Reporting Options

- Calculate dissolution results based on existing sequence sample data
- Report dissolution results as % dissolved, weight or weight per weight of tablet data
- Integrate dissolution run and system configuration data in reports

The screenshot shows the 'Dissolution Results Report' window. It includes sections for 'Product Information', 'Apparatus', and 'Apparatus Parameters'. The 'Product Information' section shows: Product Name: Headache Relief, Product Type: Tablet, Type of Release: Immediate, Comment: Label Weight 680 mg, Compound Table: Weight of 100% released (mg). The 'Apparatus' section shows: Apparatus Information: DL1109C489, Apparatus SN: 7862012, Last Calibration Date: 7/8/2012, Apparatus Type: USP Apparatus 2. The 'Apparatus Parameters' section shows: Water, Medium Evaporation: 0 ml/h, Temperature: 37 ± 0.5 °C, Medium pH: 7 ± 0.05, Initial Volume: 900 ± 0.1 ml, Stirrer Speed: 75 ± 3 rpm. A table at the top lists compounds: Aspirin (250 mg), Acetaminophen (250 mg), and Caffeine (65 mg).

Dissolution results report.

# COMPLIANT AND ROBUST DATA FOR MORE CONFIDENCE IN YOUR DISSOLUTION RESULTS

The Agilent LC Dissolution Software integrates seamlessly within the Agilent OpenLAB Laboratory Software Suite, ensuring the integrity and security of your dissolution analysis data, as well as compatibility with 21 CFR Part 11 requirements in your laboratory and across your enterprise.

## Increase Efficiency and Realize Cost Savings with Agilent's OpenLAB Solutions

The Agilent OpenLAB Laboratory Software Suite is a rich, integrated suite of products—OpenLAB Chromatography Data Systems (CDS), OpenLAB Electronic Lab Notebook (ELN), OpenLAB Data Store for affordable, centralized storage of CDS data, and OpenLAB Enterprise Content Manager (ECM), a Scientific Data Management System (SDMS). OpenLAB addresses the complete life cycle of scientific data—from experimental design to data acquisition through knowledge management and analysis.

Agilent OpenLAB provides all the tools you need to make your data and procedures fully compliant with regulatory guidelines such as 21 CFR Part 11.

## Quality Assurance and Regulatory Compliance Are Essential to the Success of Your Business

Agilent Enterprise Edition harmonizes qualification protocols, streamlines compliance management and increases confidence that your laboratory is audit-ready. The single-protocol Enterprise Edition approach ensures consistent and accurate verification of system performance to simplify qualification and minimize risk. Our all-electronic, paperless compliance delivery solution is compatible with 21 CFR Part 11 requirements for electronic signatures. Enterprise Edition is built on Agilent's Compliance Engine (ACE) that provides reliable instrument qualification that's fully compliant with GMP predicate rules. ACE ensures adherence to protocol—so we deliver what you approve—and is flexible to integrate fully into your company's SOPs.

## Agilent's Services and Support

- Our service organization provides you with all services required for regulatory compliance.
- In addition application support for your LC Dissolution Software is provided. Our dissolution experts will help you solving all of your dissolution tasks.

## Quality and Value Beyond the System

Agilent offers much more than just innovative dissolution products. Agilent provides a complete solution including qualification services, training, SOP guidance and support options, as well as educational seminars, hotline and technical support for equipment, regulatory and method questions, and sponsorship for the vendor-neutral online Dissolution Discussion Group (DDG) forum.

## Hardware and Software Support Services

Agilent Support Services offer a flexible menu of comprehensive services to help you maximize your uptime and enhance your productivity. Our dedicated, worldwide network of specialists can assist with installation, training and ongoing support, while simultaneously providing the balance between your current needs and future requirements.

Use Agilent Analytical Instrument Qualification (AIQ) Services to ensure your instruments are properly maintained. Our documentation and qualification support includes: Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Mechanical Qualification (MQ).

The screenshot shows the DDG forum interface. At the top, there is a navigation bar with 'Home', 'Bulletin Board', and 'News'. Below this is a search bar and a list of forum threads. The threads are displayed in a table with columns for Title / Thread Starter, Replies / Views, and Last Post By. The threads include topics like 'Sticky: DDG Online Meeting Recordings / Replays', 'Sticky: DDG Registration and Posting Guidelines (Manufacturer/Product Discussion Prohibited)', 'General/How to prepare this media?', 'Discussate sodium as a dissolution method surfactant/solubility enhancer', 'Transfer of Material one code to other', 'General Question about USP Aspirin standard', 'Method Development Lumefantrine and Artemether combination tablets', 'Regulatory Discussion F2 values in Mixed Media', and 'Estradiol Dissolution'.

The Dissolution Discussion Group (DDG) is an independent forum which gives you the opportunity to anonymously discuss issues which challenge the industry and affect the day-to-day task of developing, performing, and validating dissolution tests and related chemical analyses—completely free of regulatory burdens.



Keep up with advances in the science of dissolution.  
Visit the DDG at: [www.dissolution.com](http://www.dissolution.com)

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USA and Canada

**1-800-227-9770**

**[agilent\\_inquiries@agilent.com](mailto:agilent_inquiries@agilent.com)**

Europe

**[info\\_agilent@agilent.com](mailto:info_agilent@agilent.com)**

Asia Pacific

**[inquiry\\_lsca@agilent.com](mailto:inquiry_lsca@agilent.com)**

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