Agilent Online UV Dissolution Systems

REALIZE THE ADVANTAGES OF INTEGRATION

The Measure of Confidence

Agilent Technologies

TWO SOLUTIONS FROM A SINGLE PROVIDER

For powerful, versatile UV dissolution analysis, look no further than Agilent's portfolio of automated diode array and scanning solutions. Our UV dissolution systems feature both the Cary 8454 and the Cary 60 UV-Vis Spectrophotometers, providing options for online or offline use as well as multicell-based analysis or in situ measurement via fiber optics.

Cary 8454 UV Dissolution System

- Agilent's diode array Cary 8454 UV-Vis Spectrophotometer is ideal for use with single and select multicomponent products.
- Utilizing Agilent's UV-ChemStation software platform, automated sampling, data evaluation and reporting can all be achieved with an easy-to-use pictorial interface.
- Online systems may be configured in various scalable solutions for multicell- or valve-based analysis.

Agilent's diode array online UV dissolution system: 708-DS Dissolution Apparatus with Cary 8454 UV-Vis Spectrophotometer.

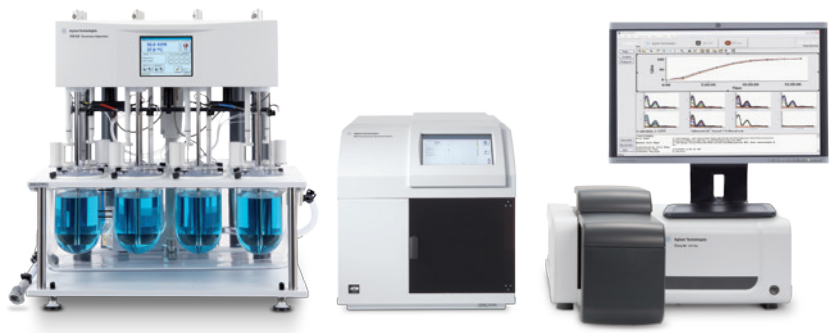
Cary 60 UV Dissolution System

Multicell UV Dissolution

- Multicell changer allows integration of two dissolution apparatus, with each vessel having a dedicated flow cell.
- Takes samples simultaneously and reads each one sequentially.
- Move samples with either a peristaltic pump or the syringe pump integrated into the 850-DS Dissolution Sampling Station, which also provides advanced filtration options, sample archival, or offline sample collection for HPLC analysis.

Fiber Optic UV Dissolution

- Uses a fiber optic multiplexer and may be integrated with either one or two dissolution apparatus.
- Analyzes samples in situ through fiber optic probes mounted on a moveable manifold that ensures precise sampling position.



Agilent's scanning online UV dissolution system featuring the 708-DS Dissolution Apparatus, 850-DS Dissolution Sampling Station and Cary 60 UV-Vis Spectrophotometer.

UV Dissolution Selection Chart

Cary 8454 and Cary 60 UV-Vis Spectrophotometers

General Information	Cary 8454	Cary 60
Software Package	ChemStation	Cary WinUV
Number of Apparatus	1 to 4 (Valve System)	1 or 2
Multicomponent Analysis	Yes	No
Fiber Optic System Availability	No	Yes

Spectrophotometer Details	Cary 8454	Cary 60
Wavelength Range	190-1100 nm	190-1100 nm
Slit Width	1 nm	1.5 nm
Lamp Type	Tungsten and Deuterium	Xenon Flash
Instrument Design	Diode Array	Scanning
Wavelength Accuracy	< ± 0.5 nm	< ± 0.5 nm
Wavelength Reproducibility	< ± 0.02 nm	± 0.1 nm
Photometric Accuracy	< ± 0.005 Abs (NIST 930E)	± 0.005 Abs (NIST 930D)
Photometric Noise	< 0.0002 Abs	± 0.0001 Abs
Baseline Flatness	< 0.001 Abs	< 0.001 Abs
Stray Light	< 1.0% (198 nm) < 0.05% (220 nm) < 0.03% (340 nm)	< 1.0% (198 nm) < 0.05% (220 nm) < 0.05% (370 nm)

Online Sampling System Details	Cary 8454	Cary 60
Closed Loop Sampling	Yes (Multicell)	Yes (Multicell)
Path Lengths (mm)	1, 2, 5, 10 (Multicell)	0.2, 0.5, 1, 2, 5, 10 (Multicell) 1, 2, 5, 10, 20 (Fiber Optic)
Automated Dosage Delivery and Sampling	Yes	Yes
Temperature Monitoring	Yes	Yes
Simultaneous Sampling	Yes (Multicell)	Yes (Multicell)
Sequential Sampling	Yes (Valve)	Yes (Fiber Optic)
Sample Filtration (min. pore size)	5 µm	0.2 or 0.45 µm (with 850-DS and optional filtration module)
Sample Archival	No	Yes (Multicell with 850-DS Dissolution Sampling Station)

SCALABLE SOLUTIONS USING THE CARY 8454

Easily pair a 708-DS or 709-DS Dissolution Apparatus with the Cary 8454 UV-Vis Spectrophotometer for a single-source UV dissolution testing solution. Multicell- or valve-based systems are available, each providing specific benefits depending on the end user environment.

Selecting the right Cary 8454 UV Dissolution System

For offline dissolution sample analysis, use standard cells and a sipper for greater convenience. An XY autosampler can be used to increase productivity and enable unattended operation; both the sipper and autosampler allow for user-defined sampling for blank, sample, and control.

Two types of sampling systems are available for online dissolution testing: parallel sampling using a multicell transport or sequential sampling using a valve.

Select the multicell-based system if:

- A closed-loop system is preferred
- Frequent or closely-spaced sample timepoints are required
- Carryover or cross-contamination is a concern
- Only a single dissolution apparatus will be configured

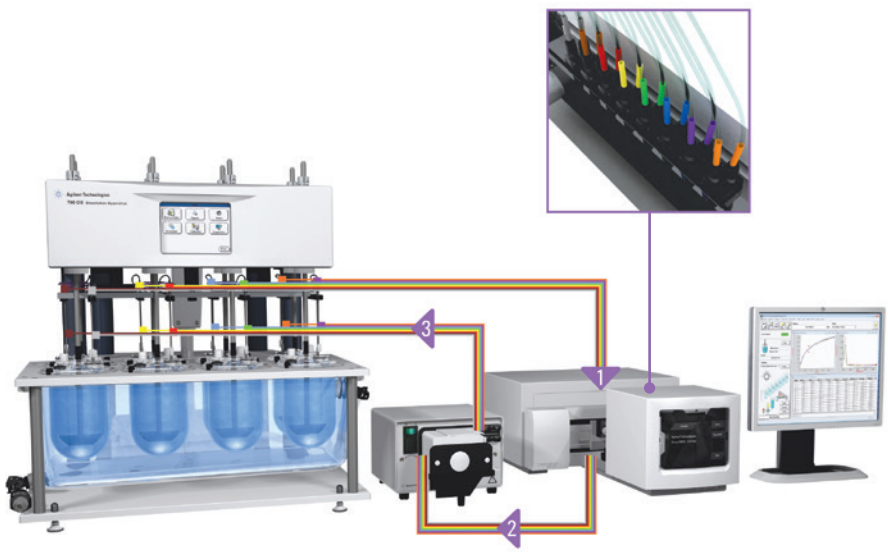
Select the valve-based system if:

- Upgrade to a multi-apparatus system is expected
- Sequential reading via one flow cell is acceptable
- Staggered dosage drop can be accomplished (manually or via dosage delivery module)
- Budgets are limited

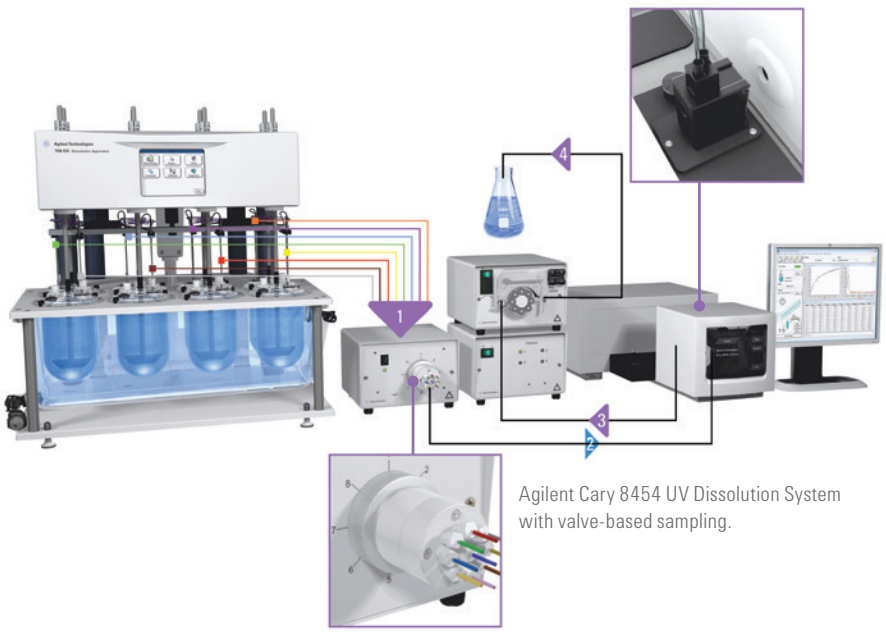
The Cary 8454 multicell transport houses up to eight (8) flow cells for Agilent's online UV dissolution systems.

Single Apparatus with Multicell Transport: Ideal for QA Testing and Formulation Development

Most common for single apparatus testing, this system uses a multicell transport with eight positions—one for the blank, up to six for the individual vessels and one for a control—and a multi-channel pump to sample all vessels simultaneously. A minimum cycle time of two minutes is possible and dissolution medium is returned to the vessel so that there is no change in medium volume during the test.



Single-apparatus online Cary 8454 UV Dissolution System with the 708-DS and multicell transport.



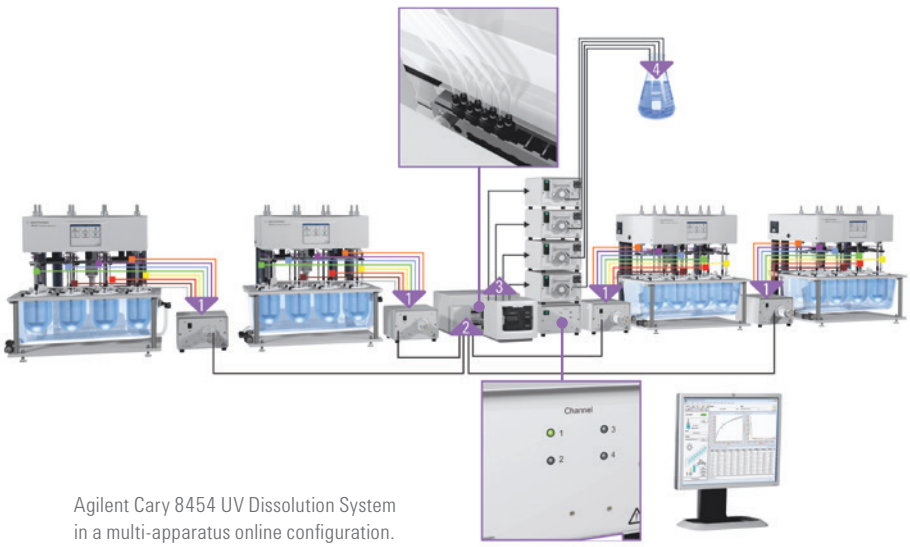
Agilent Cary 8454 UV Dissolution System with valve-based sampling.

Cost-effective Single-apparatus Valve-based Sampling System

The Cary 8454 valve-based system uses an eight-port valve to switch between blank, control, and the six dissolution vessels, and has a single channel to transfer the sample. Because the sampling is sequential, the minimum cycle time between samples is five minutes. At each sampling cycle, a small volume (~4 mL) of dissolution medium is delivered to waste; the software corrects for this loss.

Multi-apparatus Sampling for Increased Productivity

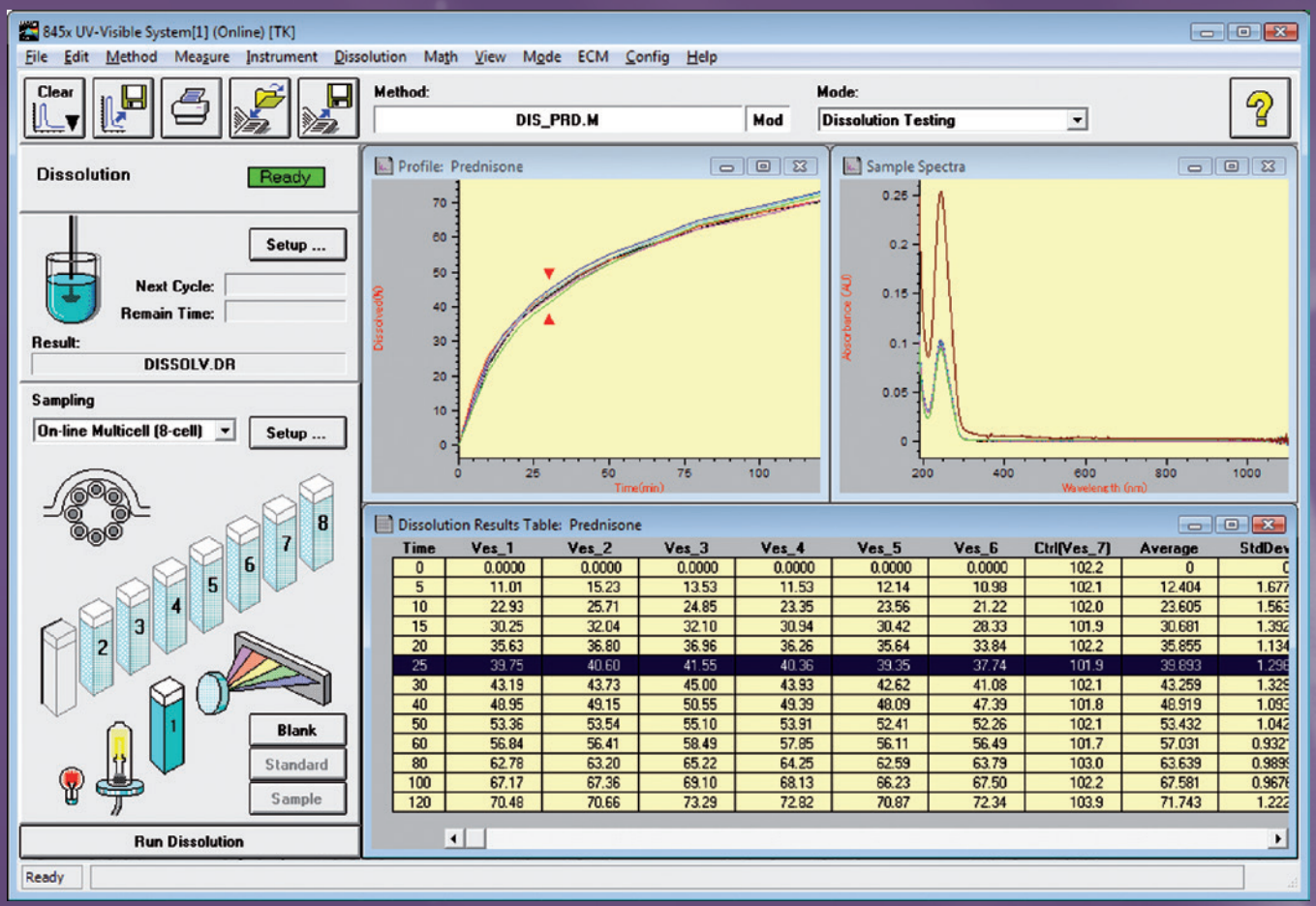
When throughput is critical and you have a large number of samples to analyze, the Cary 8454 system combined with the valve-based multi-apparatus sampling system offers the highest level of productivity. The system can measure a blank, six vessels, and a control in up to four apparatus, all within five minutes, and an individual method can be used on each apparatus. The available methods and features are identical to the single-apparatus valve-based system.



Agilent Cary 8454 UV Dissolution System in a multi-apparatus online configuration.

CARY 8454 WITH UV-CHEMSTATION SOFTWARE

Directly link Agilent, Varian, and VanKel dissolution apparatus to the diode array Cary 8454 UV-Vis Spectrophotometer for unattended, online test progress monitoring and analysis.



By seamlessly integrating the dissolution apparatus with the Cary 8454, UV-ChemStation software supports test preparation and post-run activities, as well as advanced capabilities for method development and validation, and a security pack for 21 CFR Part 11 compliance.

Online Sampling Systems

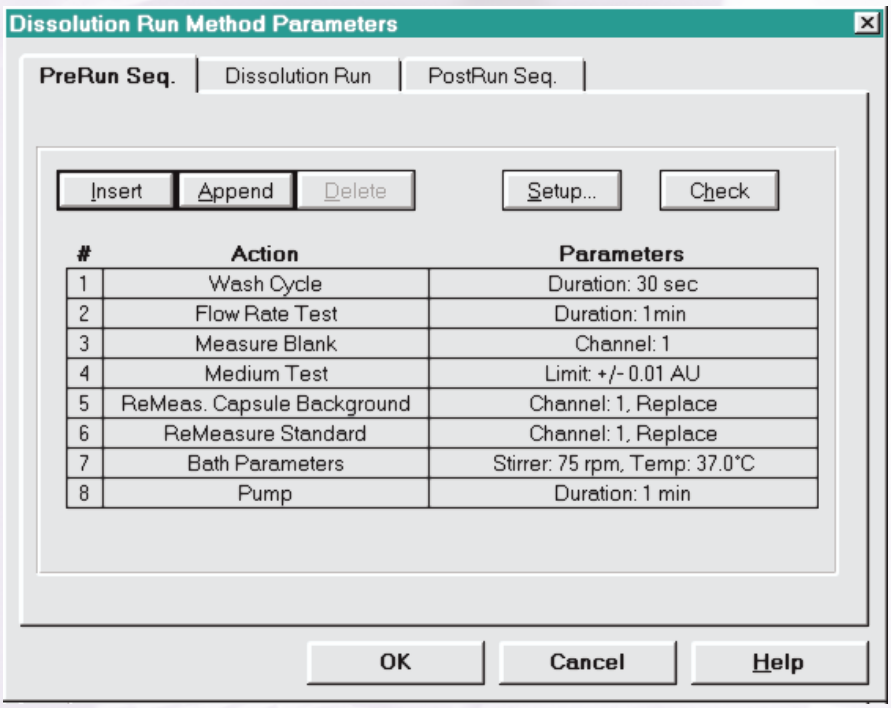
UV-ChemStation software automatically controls the sampling and pumping, and also allows for manual system operation. With convenient cassette-mounted tubing, the pumps offer variable speeds for adjustable flow rates, and are reversible.

Driver Software for Dissolution Apparatus Control

- Supports Agilent, Varian, and VanKel dissolution apparatus
- Constant RPM, water bath, and vessel temperature monitoring throughout testing
- Automated simultaneous or sequential dosage delivery
- Automated lowering/raising of sample cannulas (to a programmable location) minimizes hydrodynamic disturbance

Complete Control with UV-ChemStation Software

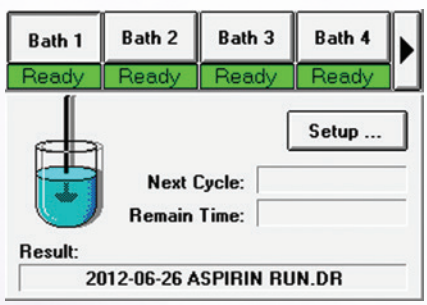
- The online sampling systems support eight measurement channels, depending on the hardware configuration.
- The measurement cycle at each sample timepoint is configurable with up to eight measurements consisting of a blank, standard and sample.
- Disposable cannula filters prevent the transfer of non-dissolved particles into the flow cells.
- Reversal of the pump direction at the end of a transfer cycle flushes particles from the filters, avoiding clogging.
- Flow tests before and after completion of a run can be applied to ensure the equipment has performed reliably throughout the run.
- A large variety of flow cells with different path lengths, from 1 to 10 mm, in combination with the variable pump times, enable ideal alignment of your target UV-visible analysis.
- Qualification services are available to verify proper performance of the entire system.



UV-ChemStation software provides real-time display of method progress and results and offers a versatile platform for method creation (shown above).

Solutions for Every Workflow

UV-ChemStation software allows for offline walkup analysis or configuration with a dissolution sampling system. These solutions are quite cost effective and can analyze samples from numerous dissolution apparatus. For an online system, you have the ability to sample from up to four apparatus in-line with a single Cary 8454 UV-Vis Spectrophotometer.



UV-ChemStation software can control up to four (4) dissolution apparatus for maximum sample throughput.

CARY 60 ONLINE UV DISSOLUTION

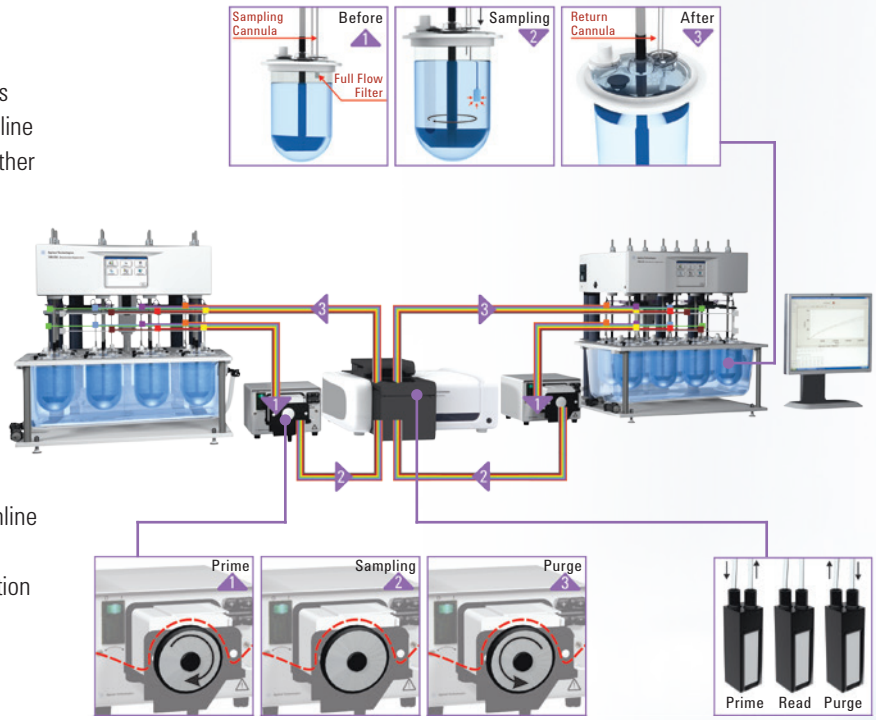
The Cary 60 UV-Vis Spectrophotometer integrates dissolution testing with online UV analysis to provide a single-source, automated performance testing solution.

With a proven optical design that exceeds pharmacopeia performance specifications, Agilent's Cary 60 UV Dissolution System is well suited for online analysis. The spectrophotometer accommodates either a multicell changer or rotary multiplexer for single- or dual-apparatus online UV dissolution testing.

Cary 60 Online Multicell UV Dissolution System

Precise and accurate determination of dissolution concentrations is achieved with the Cary 60 and online UV-visible methods. These methods remain among the most common analytical techniques for dissolution sample analysis.

- Available in either single- or dual-apparatus configurations, the system supports individual flow cells for a range of path lengths, from 0.2 to 10 mm.
- The multicell changer accommodates eight flow cells per dissolution apparatus, allowing for a blank, a standard, and six samples.
- The system can take both blank and standard readings during each time point, or offline values may be used.
- Each vessel contains its own flow cell and tubing, eliminating cross-contamination.
- Can support a peristaltic pump or 850-DS Dissolution Sampling Station for added filtration or sample archival, as well as online analysis.



One Cary 60 UV-Vis Spectrophotometer can support two dissolution apparatus running independent methods.

Using the Agilent 850-DS with the Cary 60 online multicell system provides for online UV dissolution analysis as well as offline HPLC sample collection.

Probes use silica fibers for optimal performance. Interchangeable tips with pathlengths from 1 to 20 mm can be replaced as needed without investing in new probes.

Cary 60 Online Fiber Optic UV Dissolution System

The fiber optic system offers versatility and flexibility while delivering the highest level of automation and data integration for your online UV dissolution needs. The Cary 60 UV-Vis Spectrophotometer provides excellent optical transmission and reproducibility capabilities, and the extended linear photometric range is ideally suited for fiber optic analysis. The fiber optic multiplexer ensures precise and rapid position-to-position movement to decrease time the needed between sample time points.

- Ideal for rapid time point requirements with the ability to take readings as often as every 45 seconds.
- Samples are read directly in the dissolution vessel.
- Corrects for samples with excipient and background interferences.
- Cleaning is simple, requiring only rinsing and wiping of the fiber optic probes and tips.
- Fewer moving parts and consumables reduce cost of ownership.

Agilent's Fiber Optic UV Dissolution System is available in single or dual-apparatus configurations.

Learn more: www.agilent.com/lifesciences/dissolution

AN IDEAL PLATFORM FOR ONLINE ANALYSIS

The Cary 60 UV-Vis Spectrophotometer provides accurate, reliable, and cost-effective results for both multicell and fiber optic online UV dissolution systems.

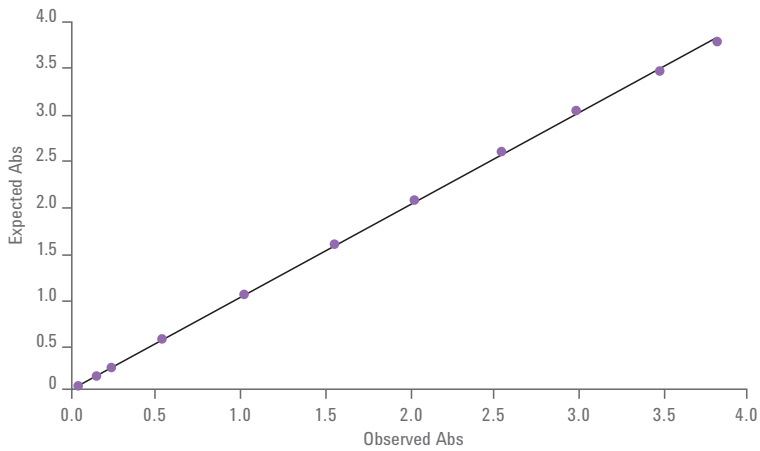
The Cary 60 uses Xenon flash lamp technology to provide a linear absorbance range of greater than 3.5 Abs, supporting a variety of pharmaceutical samples or turbid solutions. The remarkably long lamp life coupled with exceptionally fast data collection — able to scan the entire wavelength range (190–1100 nm) in under 3 seconds — make this spectrophotometer an indispensable part of your laboratory.

Cary 60 UV-Vis Spectrophotometer

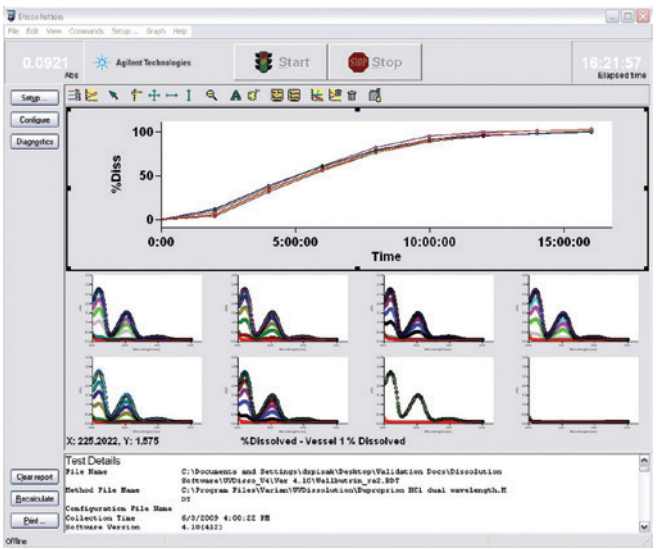
The Power of Xenon

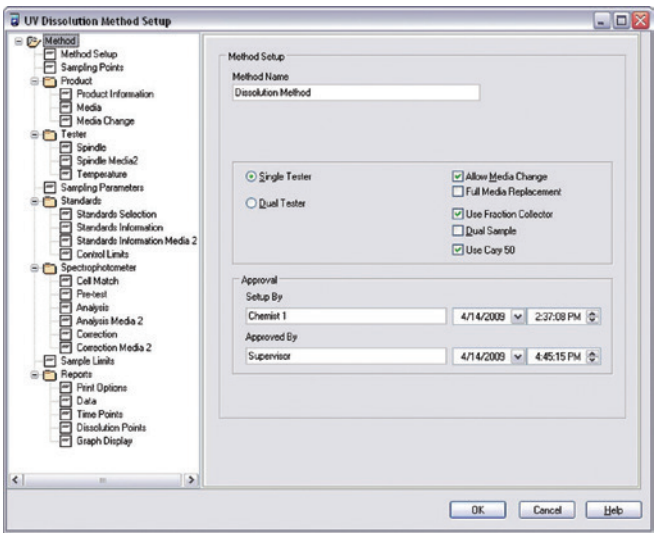
Based on the proven performance of its pioneering UV-Vis technology, the Cary 60 is:

- **Room-light immune** — the unique optical design enables measurements to be made with the sample compartment open, allowing large or odd-shaped samples to be measured. The highly focused beam also provides superior coupling to fiber optics, making the Cary 60 the best choice for UV-Vis fiber optic measurements.
- **Robust** — the combination of the xenon lamp and superior mechanical design ensures the inherent reliability of the Cary 60, significantly reducing cost of ownership — most Cary 50 instruments purchased over a decade ago are still using the initial lamp!
- **Efficient** — the lamp only flashes when a reading is taken, resulting in zero warm-up time and very low electrical energy use and maintenance requirements. Photodegradation is also eliminated, as precious or light-sensitive samples are not excessively exposed to UV light or heat.



Superior accuracy and photometric linear range
Using certified standards (Starna, S/N 14727, set type RM-9ND) and measuring the absorbance at 525 nm using a 1 second signal averaging time, the above demonstrates that the photometric range of the Agilent Cary 60 extends above 3.5 absorbance units with a correlation co-efficient of 0.999.





The Cary WinUV Dissolution Software provides a flexible platform created especially for dissolution analysis.

Cary WinUV Dissolution Software

Using a common platform for both the multicell and fiber optic systems, the Cary WinUV Dissolution Software generates accurate and robust data and accommodates a broad range of dissolution samples and methods. Analysts can easily customize final reports with a complete summary of the data acquisition using comparison and statistical evaluation tools, data tables, and dissolution profiles.

The software supports the 708-DS and 709-DS Dissolution Apparatus and easily pairs with a peristaltic pump or the 850-DS Dissolution Sampling Station for accurate preparation of samples and optional archiving.

- Controls apparatus features such as dosage delivery, automated sampling, and vessel temperature monitoring.
- Provides data processing and reports for samples taken offline using the UV dissolution manual program.
- Supports media change methods, capsule blank correction, and check standards.
- Offline standards can be used in a variety of ways to prevent standard preparation for each test.
- Test reports can be customized to include relevant data in your desired format.
- 21 CFR Part 11 compliance package is available for electronic records and secure data storage.

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