

Cary 60 UV Dissolution Systems

THE STANDARD FOR MULTICELL OR FIBER OPTIC DISSOLUTION TESTING

The Measure of Confidence



Agilent Technologies

FIVE REASONS WHY THE CARY 60 SHOULD BE YOUR CHOICE FOR UV DISSOLUTION TESTING

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

1. The standard for dissolution testing

- The Cary 60 is ideally suited for online dissolution analysis with a proven optical design that exceeds the performance specifications of the USP/EP.
- The spectrophotometer accommodates either a multicell changer or rotary multiplexer for single- or dual-apparatus online UV dissolution testing. In either configuration you get accurate and reproducible results.
- Agilent Support Services are never more than a phone call away, anywhere in the world. Find your contact at www.agilent.com/chem/contactus

2. Unique xenon light source

- The xenon flash lamp is efficient, only flashing as a measurement is being taken. This means photo-degradation of samples is minimized (or eliminated) as precious or light-sensitive samples are not exposed to excessive UV light or heat. Because the xenon light source is a flash lamp, and only flashes when taking a reading, the lamp life typically exceeds 10 years! The result is a significant savings - fewer replacement lamps, no instrument downtime and no revalidation.
- The absorbance range of up to 3.5 Abs is ideal when dealing with turbid samples.



Agilent Multicell UV Dissolution System with 810 Peristaltic Pump.

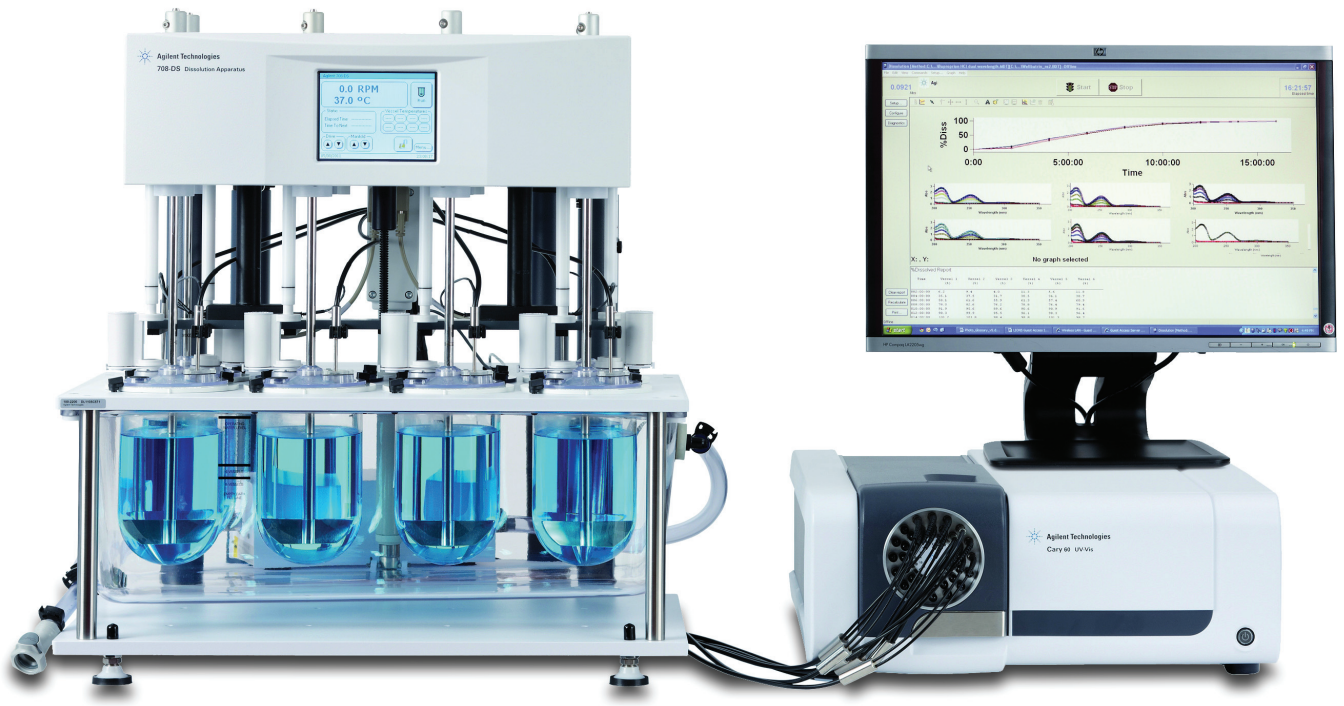


Agilent Multicell UV Dissolution System with 806 Syringe Pump, 808 Filter Changer and 8000 Dissolution Sampling Station for sample archiving.

3. Dual system capability in multicell or fiber optic mode

- When configured with two dissolution apparatus, two different methods can be run simultaneously from one Cary 60.
- Because the flow cells or fiber optic probes are dedicated to a single dissolution vessel, there is no sample cross-contamination.

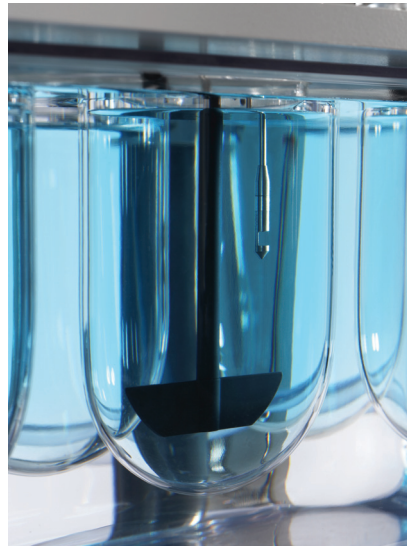
- The 8000 Dissolution Sampling Station can be incorporated into a multicell system. This allows the online UV analysis of samples as well as sample archival. Other options include integrating the 806 Syringe Pump and the 808 Filter Changer. This configuration allows filtration down to 0.45 micron. When the autosampler is incorporated inline with the spectrophotometer, it becomes very easy to perform online UV analysis for one method and then switch to collection only for a method requiring an LC finish. No re-plumbing of the system is required!



Agilent 708-DS Dissolution Apparatus with Cary 60 UV-visible spectrophotometer and multiplexer for real-time fiber optic sampling.

4. Online fiber optic dissolution testing

- The highly focused beam of the Cary 60 xenon light source along with the extended linear photometric range is ideal for fiber optic applications. Fiber optic measurement is possible even in turbid samples.
- In applications involving microspheres or nanoparticles, the in-situ measurements overcome problems associated with removing undissolved particles from filtration techniques.
- Samples can be read as fast as 45 seconds between timepoints.
- Unlike other fiber optic solutions that are based on custom spectrophotometer designs, this solution is based on the proven design of the standard Cary 60 spectrophotometer sold and serviced around the world.



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



Agilent provides all components of this dual apparatus, multicell system, including the 708-DS and 709-DS Dissolution Apparatus, pumps, Cary 60 UV-visible Spectrophotometer and WinUV software.

5. Cary WinUV Dissolution Software

- Supports both multicell and fiber optic online UV dissolution systems.
- Can integrate a peristaltic or syringe pump, filter changer and autosampler.
- Controls apparatus features such as dosage delivery, automated sampling and vessel temperature monitoring.
- 21 CFR Part 11 compliant.

Other software highlights:

- 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 available for electronic records and secure data storage.

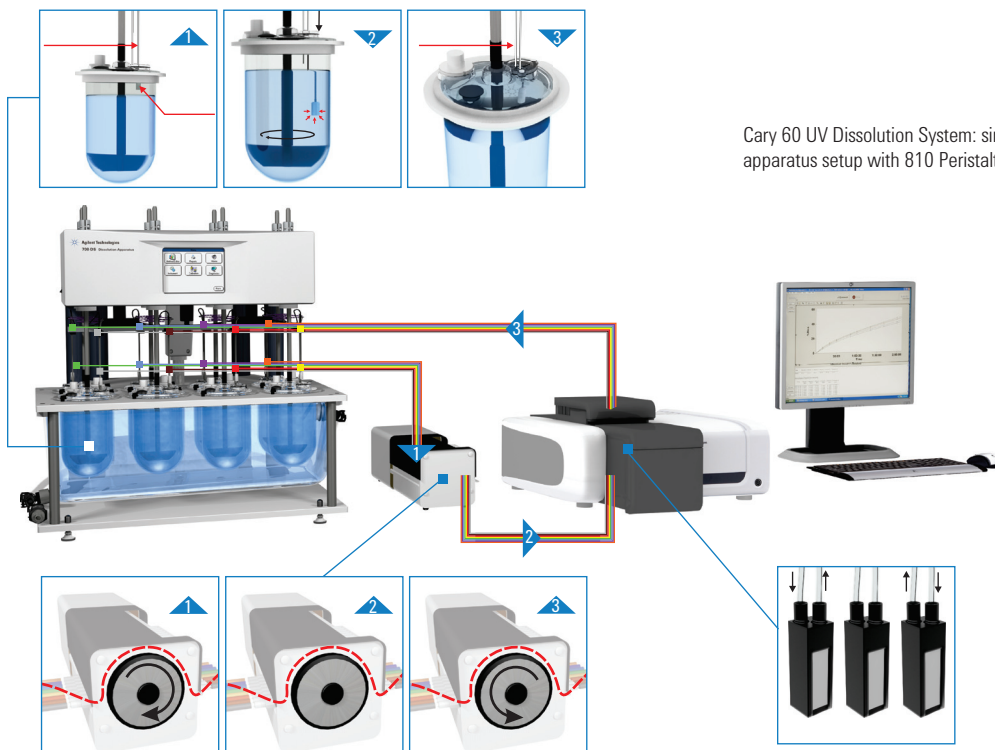
Following is a system-by-system guide to assist you in further evaluation of the specific Cary 60 UV Dissolution System that best meets your needs.

Cary 60 UV Dissolution System: single or dual apparatus with 810 Peristaltic Pump

The Cary 60 can be configured with a peristaltic pump to transfer the sample to the flow cell. Cells are analyzed and the sample is returned to the vessel maintaining vessel volume and eliminating the need for media replacement. Should you wish to retain a sample, the 8000 Dissolution Sampling System can be used in conjunction with the spectrophotometer. The sample will be read and a portion retained for failure investigation if needed.

Flow Configuration (as shown below)

1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the peristaltic pump simultaneously.
2. The pump then moves the sample into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
3. After the samples are measured, the pump reverses flow and returns all sample volume to the dissolution vessels. No volume is lost in this closed-loop system. The sample lines remain empty until the next timepoint.



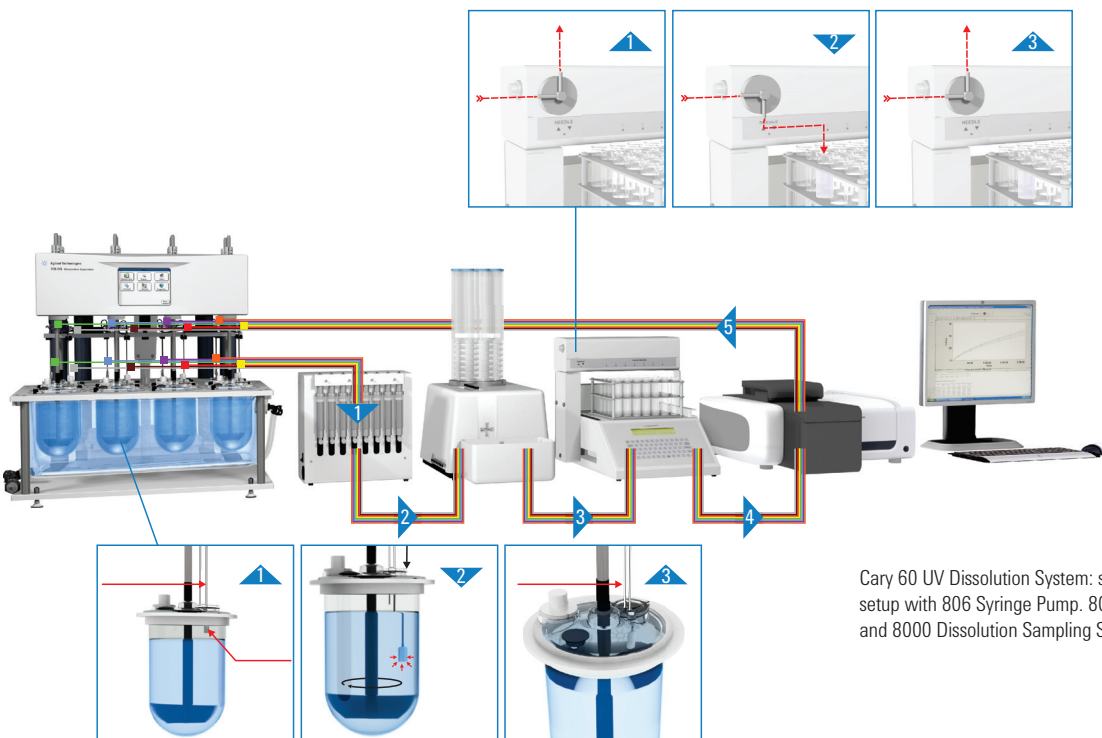
Cary 60 UV Dissolution System: single apparatus setup with 810 Peristaltic Pump.

Cary 60 UV Dissolution System: single apparatus with 806 Syringe Pump, 808 Filter Changer and 8000 Sampling Station

The multicell system is ideal for providing repeatable results, especially when 0.45 micron filtering or sample archival is required, via the 808 Filter Changer and 8000 Dissolution Sampling Station. Integrating the Agilent 8000 with the Cary 60 allows you the flexibility of online UV analysis and offline collection for those methods requiring an LC finish.

Flow Configuration (as shown below)

1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the 806 Syringe Pump simultaneously.
2. The pump then moves the sample through the filters of the 808 Filter Changer.
3. As the volume moves to the 8000 Dissolution Sampling Station, the samples are collected for archival.
4. The volume continues on into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
5. After the samples are measured, the sample lines are purged with air and all volume is returned to the dissolution vessels. No volume is lost in this closed-loop system and the sample lines remain empty until the next timepoint.



Cary 60 UV Dissolution System: single apparatus setup with 806 Syringe Pump, 808 Filter Changer and 8000 Dissolution Sampling Station.

Cary 60 UV Dissolution System: single or dual apparatus with online fiber optic dissolution



Cary 60 UV-Visible Spectrophotometer with 12-position multiplexer

The Cary 60 UV-visible Spectrophotometer offers excellent optical transmission and reproducibility, and the extended linear photometric range is ideally suited for superior fiber optic analysis. The fiber optic multiplexer ensures precise and rapid position-to-position movement to decrease time needed between sample timepoints.

The fiber optic system utilizes a 12-position multiplexer, to read samples sequentially. A single spectrophotometer can be used with two dissolution apparatus. The fiber optic probes can be mounted on a movable manifold that lowers the probe to the correct sampling height in the vessel. The sample is read and the probe is raised either entirely out of the media or held just under the surface of the media to minimize turbulence, bubble formation and prevent drying on the optical surfaces of the tip.

Fast Facts: Advantages of Fiber Optic UV Dissolution

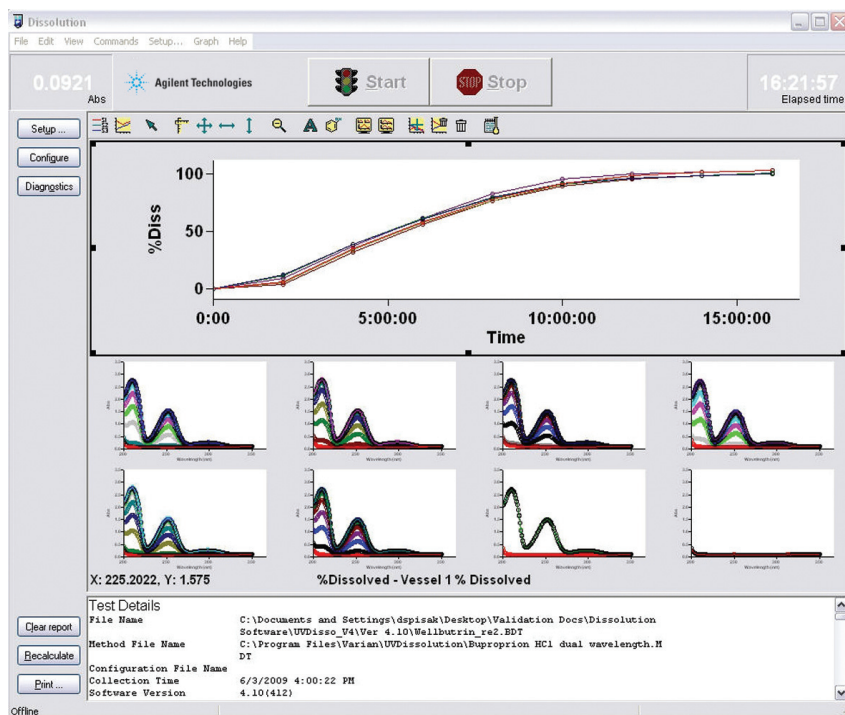
- Ideal for rapid timepoint requirements with the ability to take readings as often as every 45 seconds.
- Samples are read directly in the dissolution vessel, instead of moving the sample to the spectrophotometer.
- Compensates for samples with excipient and background interferences: ideal for micro- and nano-particle dissolution applications.
- Optical tips provide path lengths up to 20 mm, double the conventional 10 mm length, allowing the reading of lower concentration samples.
- Cleaning is simple, requiring only rinsing and wiping of the fiber optic probes and tips.
- Fewer moving parts and consumables reduce cost of ownership.

Cary WinUV Dissolution Software: supports both Agilent's multicell and fiber optic online UV dissolution systems

WinUV dissolution software generates accurate and robust data and accommodates a wide variety 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.

Fast Facts: Advantages of Cary WinUV Dissolution Software

- Can integrate a peristaltic pump or syringe pump, along with a filter changer and autosampler for accurate preparation of samples and archival.
- 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.
- Accommodates media change methods, capsule shell corrections and infinity spins required for various methods.
- Includes advanced UV capabilities, such as second derivative analysis, baseline correction and more, to allow alternative data processing capability.
- Compliant with 21 CFR Part 11 requirements.



Progression of a UV dissolution profile as data is acquired.

Your Laboratory Partner



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).



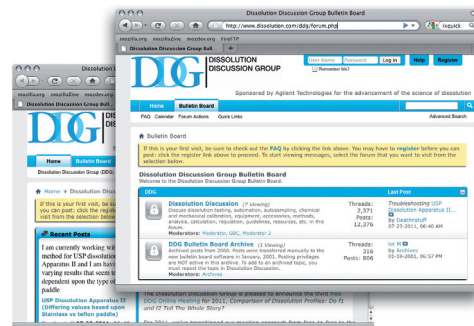
Maintaining the proper instrument and qualification documentation is essential. To ensure you meet the cGMP requirements, Agilent provides qualification guides for all our dissolution and physical testing instrumentation. Our qualification guides include installation qualification (IQ), operational qualification (OQ), and in the case of Apparatus 1, 2 and 3, a performance qualification (PQ) based on the USP Performance Verification Test (PVT). A mechanical qualification (MQ) guide is also available. Our PQ guide contains current USP practices for qualification with current acceptance criteria. Similarly, the MQ guide accurately reflects the current specifications and tolerances for physical parameters contained in the ASTM and FDA procedures. These guides are included with service purchases or can be ordered separately. Our dedicated compliance group strives to ensure this documentation remains current according to the ever-changing industry regulations.

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.

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.

Visit the DDG at: www.dissolution.com



Dissolution Discussion Group (DDG)

Dissolution Hotline

Dissolution chemists are always available to assist with questions about finding the instrument that best supports your laboratory, method development and regulatory support.

Contact our team at:

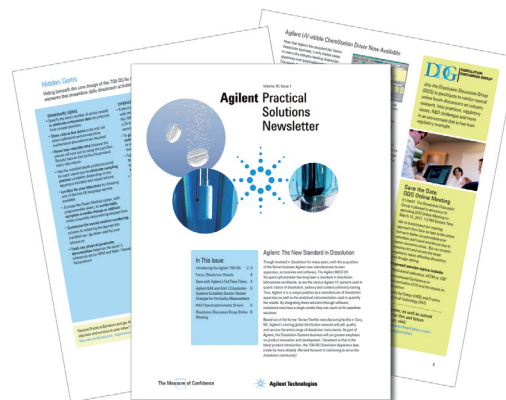
dissolution-hotline.pdl-ext@agilent.com

Practical Solutions Newsletter

You can have Agilent's dissolution-specific newsletter delivered to your inbox! With the latest on our dissolution products, services and the ever-evolving regulatory environment, this is your resource to stay informed.

Register for your copy at:

www.agilent.com/lifesciences/dissolution_registration



Practical Solutions Newsletter

Cary 60 UV Dissolution System

Agilent is known for developing state-of-the-art technology and exceptional products. With the 2010 addition of Varian Inc., we now offer an even greater range of instrumentation, as well as the most comprehensive columns and supplies portfolio in the market. Just as important are the best-in-class service and technical support teams with deep expertise focused on finding solutions for our customers.

Our customers are engaged in a broad range of endeavors, from performing routine tests to addressing complex scientific challenges that will impact the way we live. At Agilent, we understand that all scientists, regardless of their specific area of focus, share a common need for answers they can trust. This universal need is summed up in a word: Confidence.

Confidence means having tools that are precise, consistent, and utterly reliable. It means access to expert support to ensure that those tools run with optimal performance. Above all, this means knowing Agilent, now with the strength of the people and products from Varian, provides the technology—and the Measure of Confidence—you need to be successful.

For more information on Cary 60 UV Dissolution Systems please go to: www.agilent.com/lifesciences/dissolution

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