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DISSOLUTION

UV Dissolution

SEAMLESS INTEGRATION FOR MULTICELL & FIBER-OPTIC UV-VIS ANALYSIS





VARIAN, INC.

Automation, Convenience, Confidence

High Throughput and Precision with Online UV Dissolution

Precise and accurate determination of dissolution samples is achieved with UV methods. These remain among one of the most common analytical techniques for dissolution samples. Varian's UV Dissolution System integrates dissolution testing with online UV analysis to provide a single-source, automated performance testing solution.

As a leader in dissolution and spectroscopy, and through collaboration with our customers, Varian developed both an online Multicell and a Fiber-Optic UV Dissolution System that save you time and increase your laboratory's productivity and throughput. Backed by industry-leading experience in instrumentation, support, training and qualification, Varian provides the tools you need to gather your data more accurately and efficiently.

Varian's UV Dissolution System Enables You to:

- Obtain real-time results through a single software package, reducing analysts' time and effort, and shortening decision timelines for critical projects.
- Automate dissolution and analytical finish testing to eliminate handling errors commonly associated with manual sampling, filtration and dilution, which can lead to costly investigations and retesting.
- Collect and retain samples for immediate or subsequent analysis.
- Save time with easy-to-navigate user interface screens that allow you to create, retrieve, edit and store online dissolution methods.
- Customize final reports with a complete summary of the data acquisition using comparison and statistical evaluation tools, data tables and dissolution profiles.

A Complete Dissolution and UV-Vis Spectroscopy Solution

Seamless Integration of Dissolution and UV Analysis

Varian's UV Dissolution System combines Varian's industry-leading dissolution instruments with the award-winning Cary™ 50 UV-Vis spectrophotometer to create a flexible solution that supports a wide range of methods and products.

Dissolution Instrumentation — features and options to support your laboratory and method requirements.

- Apparatus for paddle, basket, paddle over disk and rotating cylinder dissolution testing
- Options for single- or dual-dissolution apparatus configurations
- Apparatus automation options for dosage delivery, vessel media temperature monitoring and sampling
- Accommodations for UV sample filtration from 0.45 to 70 μm with the multicell system; or, pump and tubing-free *in situ* sample analysis with the fiber-optic system
- Incorporation of the VK 8000 Dissolution Sampling Station with the multicell system for flexible offline analysis, or sample archiving for subsequent testing requirements

UV-Vis Instrumentation — superior optics with the Cary 50 spectrophotometer, which features:

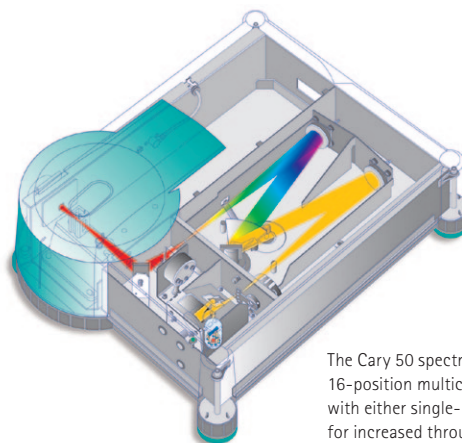
- A long-lasting, no warm-up time Xenon lamp that flashes only when taking a measurement
- No degradation of photosensitive active drug components associated with continually burning lamps
- Virtual immunity to room light, reducing noise and allowing for a linear absorbance range up to 3.3 AU



Varian Multicell UV Dissolution System including 0.45- μm Filter Changer, Syringe Pump and VK 8000 Dissolution Sampling Station for sample archiving.

Cary 50 for Online Multicell UV Analysis

- Flow cells provide analytical precision for 0.2 to 10 mm cell path lengths
- 16-position accommodations for flow cells (8 for each dissolution apparatus) allow for a blank, a standard and the analysis of the 6 samples. Or, run with two sets of flow cells with different path lengths for dual path length, single-bath configurations



The Cary 50 spectrophotometer with 16-position multicell changer integrates easily with either single- or dual-apparatus operation for increased throughput and automation.

Cary 50 with UV Fiber-Optic Multiplexer

- Excellent optical transmission and reproducibility over the entire extended wavelength range of the Cary 50
- Extended linear photometric range ideally suited for fiber-optic analysis
- Precise and rapid position-to-position movement of the multiplexer to decrease time needed between sample points



Probes use silica fibers for optimal performance. Interchangeable tips make cleaning and replacement easy. Tip path lengths from 1 to 20 mm are available to accommodate expected absorbance ranges.

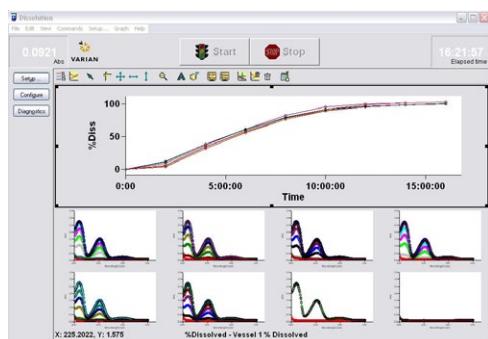
Powerful and Flexible UV Dissolution Capabilities

Choose the UV System to Meet Your Needs

Both the multicell and fiber-optic options are designed for R&D and QC laboratories. Each provides advantages that should be considered when deciding between them for your applications.

Advantages of Multicell UV Dissolution

- Best for dissolution testing where sample filtration down to 0.45 μm and sample archiving are required, via a filter changer and VK 8000 Dissolution Sampling Station
- Bracketing standard and blank readings taken during each timepoint
- Software automatically corrects sample results for volume and analyte loss when the VK 8000 is used for sample collection
- Each vessel position is configured for its own flow cell and tubing, eliminating cross-contamination



Progression of a UV Dissolution profile as data is acquired.

Advanced Software Capabilities

The UV software generates accurate and robust data and accommodates a wide variety of dissolution samples and methods. The software:

- Integrates the pump, filter changer and autosampler for accurate preparation of clean samples
- Controls apparatus features such as dosage delivery, automated sampling and vessel temperature monitoring
- Generates 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 multicomponent analysis, second derivative analysis, baseline correction and more, to work with challenging spectra

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 media, which eliminates possible contamination, carryover and dilution of samples
- Compensates 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 long-term costs

Typical UV Dissolution Hands-On Time (in Minutes)*

Event	Manual A	Semi-Automated B	Fully-Automated C
Dissolution Media Preparation	45	45	45
Standard Preparation	30	30	30
Dissolution Apparatus Preparation	10	10	10
Dissolution Method Setup	5	5	5
Sample Collection/Filtration**	80	8	0
UV Method Setup	10	10	15
Sample Analysis	60	60	0
System Cleanup/Turnover	15	15	15
Calculations/Report Summary	45	45	0
Total	300	228	120
% Time (Savings)	-	24%	60%

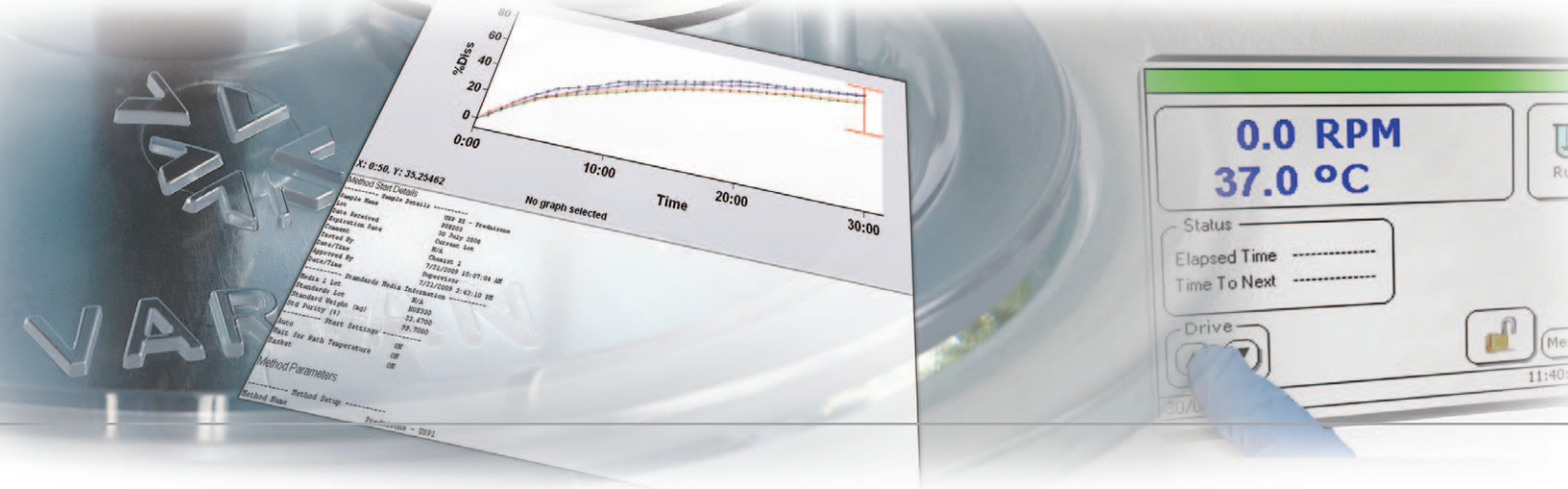
* Based on dissolution method with 8 timepoints

** Sample collection/filtration for manual test includes: pulling/filtering of sample, labeling of test tubes, preparing syringes/cannulas, storing samples = 10 minutes/timepoint

The table above displays the comparison of manual, semi-automated and fully automated online UV testing to demonstrate time savings with Varian's integrated dissolution systems. The studies highlight the benefits of automatic sampling and online automation for a UV analytical finish.



Varian Fiber-Optic UV Dissolution System.



Key Software Functionalities

- Advanced UV-Vis options include single wavelength and scan for method development
- Allows two independent methods to be run simultaneously when using a dual-apparatus configuration
- Online or offline testing of standards for percentage (%) and milligrams (mg) dissolved calculations
- Immediate notification of out-of-specification results
- Supports complete or partial media change methods
- Hardware configuration files stored separately from method and data files for quick retrieval and reduced turnaround times
- Dissolution profiles and customizable reports are available in real time
- Manual data entry and recalculation provides flexibility and enables standalone UV analysis
- Diagnostics module allows for manual intervention when necessary

Multicomponent Analysis Capability

Varian partners with CAMO Software Inc. to integrate The Unscrambler®, the industry's leading multicomponent analysis package, into Varian UV Dissolution Software. The result is an easy-to-use package for multicomponent drug product analysis, without the disadvantages associated with diode array detection.

- Offers powerful statistical tools for analyzing spectroscopic data from single or multiple dissolution runs
- Provides dissolution results for multiple drug components

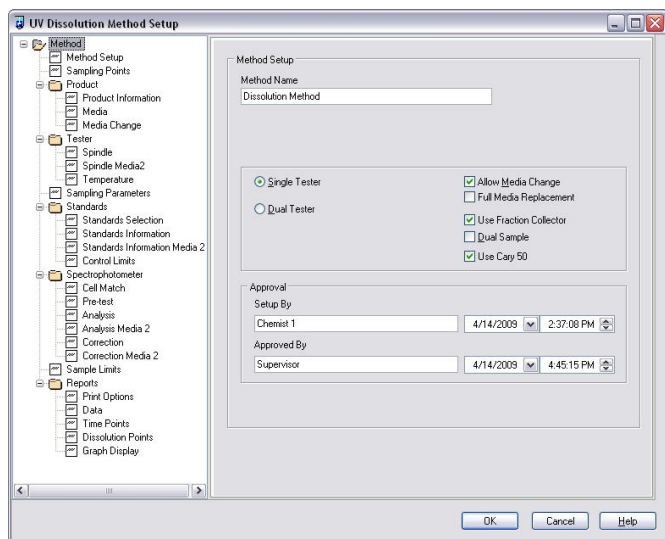
Quality and Value Beyond the System



Varian offers much more than just innovative dissolution products. Varian 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 Varian Care Program offers a flexible menu of comprehensive support 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 Varian's 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).



A comprehensive Method Setup utility is at the core of Varian UV Dissolution Software.

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Varian offers robust instrumentation, application-based consumables, and customer-focused services, backed by our global team of product and applications experts, ready to help you solve your analytical challenges. Whether you're monitoring impurities in drinking water, designing new therapeutic drugs, or developing cleaner fuels, our solutions deliver the sensitivity, flexibility and productivity your laboratory requires.



Varian Care Program

Our goal is to help you increase your productivity, maximize your uptime and achieve the highest return possible on your investment. Our experienced and highly-qualified support organization is strategically located throughout the world to ensure rapid response.

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