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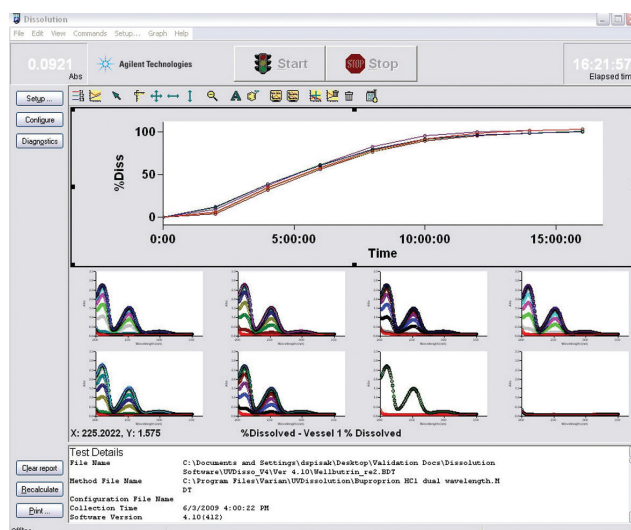
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WinUV Dissolution Software— Are You Making Use of All the Features You Have?

Dan Spisak, Product Manager, Dissolution

The Cary WinUV dissolution software that powers Agilent's online UV-dissolution systems has withstood the test of time. It's proven to be an ideal solution for dissolution laboratories around the world, especially when integrated with the compliance manager software in highly regulated environments. With so many features, however, you could be missing out on some key capabilities that could further enhance your dissolution workflow.



Cary WinUV dissolution software

Here are five examples of useful software elements that are often overlooked:

Did you know... *that dissolution samples collected offline—either manually or with a semiautomated system—can be fully processed using the software?*

While most systems that utilize the WinUV dissolution software are online, the data processing function can process samples acquired from any dissolution system in your lab. Samples are read directly by the Cary 60 with the press of a button and the software does the rest. This automates the analysis and reporting while streamlining many compliance aspects that are difficult to achieve with “offline” practices.

Standalone 708-DS: samples collected manually can be read by the Cary 60 and processed by the WinUV dissolution software.

Semiautomated 708-DS with 850-DS system: samples automatically collected and filtered by the 850-DS can be manually transferred to the Cary 60 for analysis and data processing.



708-DS with 850-DS

UV-Visible Product Update—the End of an Era

With over 20 years of robust performance and production, the diode-array based UV-Visible spectrophotometer from Agilent will no longer be manufactured. Production of the current 8454 model ended in September 2019.



Standalone systems can be replaced by the Cary 60, which will continue to provide an online UV-Dissolution solution in multicell or fiber optic configurations.

Agilent understands the impact this may have on your organization and is ready to assist you with any challenges that arise due to this product discontinuation. Agilent is committed to delivering the highest level of customer care and is offering the End of Production seven-year guaranteed support period as well as the 10-year **Agilent Value Promise**.

Did you know... that the software can support dissolution methods requiring HPLC analysis?

This is online UV-dissolution software, yes, but do all your methods require UV-Vis analysis? For most laboratories, that answer is no. To achieve maximum utilization of your instrumentation, the system can control an 850-DS to:

1. Move samples from the 708-DS to the Cary 60 for online UV-Vis analysis.
2. Collect (archive) samples in test tubes or vials from UV-Vis methods for troubleshooting or investigation purposes.
3. Collect samples from LC methods in vials for eventual (manual) transfer to the LC for analysis.

By including an 850-DS as part of this system, you are now able to store ALL of your dissolution methods in the software—not just the ones requiring UV-Vis analysis. The increased efficiency and compliance are valuable benefits of this solution.



708-DS with 850-DS and Cary 60

Did you know... that a pretest scan can be built in to your dissolution method?

Standard practice dictates that prior to UV-Vis analysis of dissolution samples, the maximum wavelength of the standard solution is identified. To avoid this extra step in a separate application (that is, Scan), this confirmation can be added to the pretest sequence of each dissolution test. The software gives the user the option to adjust the analytical wavelength or continue without changes. The scan data and user actions are documented on the final test report.

Did you know... that you can program an automated system clean when the dissolution test has finished?

Any online UV-dissolution system configured with an 850-DS can take advantage of the automated cleaning function of this sampling station. As soon as the final samples are analyzed, the entire flow path and cells are flushed with rinsing solution according to the user-selected conditions specified in the method. This keeps the system running smoothly while preparing the system for the next test, all without any user intervention.

Did you know... that your % or mg dissolved results can be calculated at any number of wavelengths?

While most sample analysis is performed at a single wavelength, the WinUV dissolution software includes a recalculation feature that can process results at any wavelength where absorbance data has been collected throughout the experiment. There are several ways to set up the specific analysis and correction conditions, online and offline standard measurements, and volume correction parameters that make the software flexible enough to handle most, if not all, of your internal analysis requirements.

These are just a few examples of the benefits of the WinUV dissolution software. Many times, as software is upgraded through the years, some key items are neglected or forgotten, especially as a new generation of users are introduced to existing solutions.

If you have a unique method or just a simple question, please don't hesitate to let us know. For additional details, or a software "refresh" training, you can contact your local Agilent representative or reach out to the Dissolution Hotline at dissolution.hotline@agilent.com. Thoughts and ideas can also be shared on the Dissolution section of the [Agilent Community](#). Come and be a part of the ongoing discussion!

280-DS Dissolution Workstation Software Validated to Be Win10 Compatible

Karen Krauel-Göllner, Product Manager, Dissolution Systems



With the latest release of our 280-DS Workstation Software, Agilent provides you with a fully compatible Windows™ 10 version and supports your upgrade to the Win10 operating system.

The 280-DS instrument is Agilent's solution to perform mechanical qualification of your dissolution apparatus and helps make qualifying dissolution apparatus easy.

The 280-DS instrument comes with a dissolution workstation software package, which allows you to choose from a variety of methods with preselected specifications (for example, FDA, ASTM) for your mechanical qualification procedure. You can keep track of serial numbers for your accessories and, most importantly, have full traceability of your mechanical qualification through audit trail, run log, and signable report.

Apart from the Win10 compatibility, the latest release contains an upgrade to the Microsoft SQL Server that is used to manage the database security within the software. Further, we added a preloaded method to follow the requirements when performing qualification according to the Chinese NMPA (National Medicine Product Administration), formerly Chinese FDA.

For further information, please contact your Agilent account manager or send us an email at: dissolution.hotline@agilent.com

The Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Bryan Crist, Scientific Affairs Manager, Dissolution

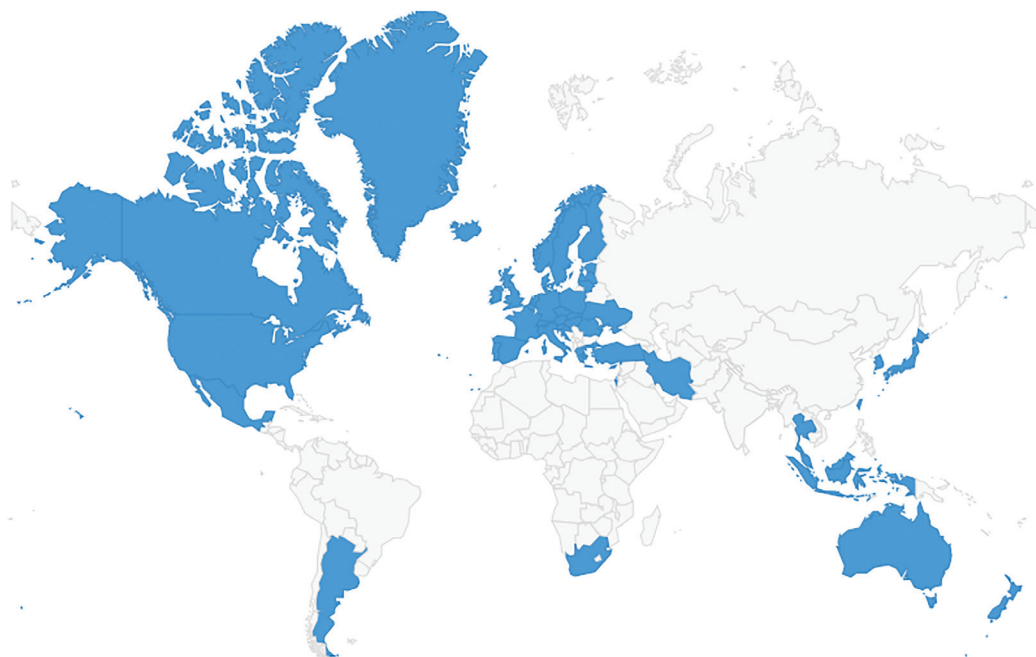
The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide an active and constructive co-operation in the field of GMP.

PIC/S' mission is "to lead the international development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."

This is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international organizations.

There are currently 52 PIC/S Participating Authorities worldwide, including the U.S. FDA. Present members are primarily from North America, the European Union, and Southeast Asia.

For an overview on PIC/S' history, role, members, publications, and activities, visit: www.picscheme.org



PIC/S Participating Authorities by continent

Before a regulatory authority can become a member of the PIC Scheme, a detailed assessment is undertaken to determine whether the authority has the arrangements and competence necessary to apply an inspection system comparable to that of current PIC/S members. This is referred to as the accession procedure, which includes pre-accession—a voluntary assessment including a gap analysis. And then it moves on to the accession activities, a time-consuming process in which a formal application is completed and submitted. This entire process must be completed within six years.

This assessment involves an examination of the authority's inspection and licensing system, quality system, legislative requirements, inspector training, etc., and is followed by a visit by a PIC/S delegation to observe inspectors carrying out actual GMP inspections.

The reason this is so important to dissolution is that the harmonized GMP focuses heavily on the laboratory

instrumentation along with the routine maintenance, calibration, and system suitability tests that ensure the instrumentation is performing as intended and producing accurate and precise results. In dissolution, two processes exist for the ongoing performance qualification (PQ) of the dissolution apparatus: the USP performance verification test and the enhanced mechanical qualification process endorsed by the U.S. FDA and ASTM International. PIC/S places heavy emphasis on the routine calibration procedures, and inspectors are trained to ensure that the instruments are maintained in a qualified state. Internationally, the two methods mentioned above are the most commonly used to qualify dissolution apparatus and either will be satisfactory to meet GMP when performed as recommended.

PIC/S GMP Guides and resources may be found at:

<https://picscheme.org/en/publications>

Are You a Member of the Dissolution Community?

Allan Little, Director of Marketing, Dissolution

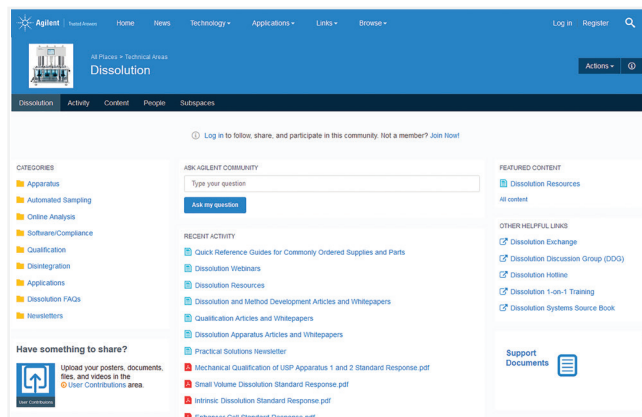
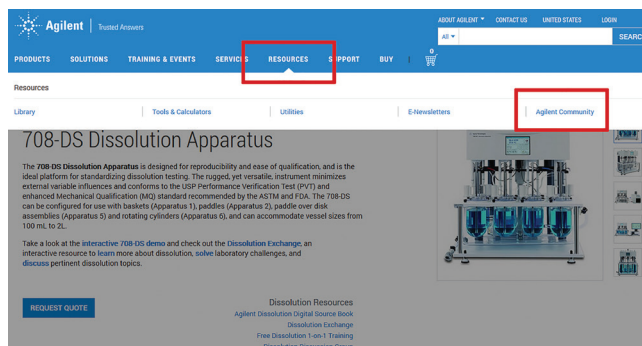
Agilent is committed to providing you with all the information you need to use and maintain our equipment. We've created an **Agilent Dissolution Community** accessible from the Agilent Community on Agilent.com.

The recently launched Dissolution Community gives you access to Agilent application and technical support. You can search for product information, review frequently asked questions, or post a question on the bulletin board.

To join, visit Agilent.com today. Simply click RESOURCES and then Agilent Community.

From there you can join the Agilent Community and the Dissolution Community section, and solicit help on not only dissolution, but many other product areas as well.

The Agilent Community is dedicated to owners of Agilent instrumentation and software. To post a question (or search the archive) of the dissolution community at large, visit the **Dissolution Discussion Group**.



Questions You Asked

- Q.** I am working with dissolution medium containing sodium lauryl sulfate (SLS) and have quite a problem with bubbles that make measurement of media difficult. We also seem to have a problem with air bubbles on the vessel and paddle shaft.
- A.** Most of the problem with surfactants is that they foam excessively when handled and you may wish to determine the density of your medium and weigh the equivalent amount of dissolution media instead of measuring it volumetrically. Second, surfactant-containing media may be easily degassed by preparing the media with everything except the SLS and de-aerating it. Then, remove about 200 mL of media, weigh the SLS into a weigh boat, and add enough media to make a slurry. Use the rest of the 200 mL of media to quantitatively transfer the wetted SLS to the de-aerated media and stir, check pH, and dilute to the final volume.

Learn more:

www.agilent.com/lifesciences/dissolution

Agilent Community:

<https://community.agilent.com/>

Register to receive the e-newsletter quarterly by email:

<https://www.agilent.com/en/promotions/practical-solutions>

Buy online:

www.agilent.com/chem/store

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