

AGILENT TECHNOLOGIES PRACTICAL SOLUTIONS NEWSLETTER

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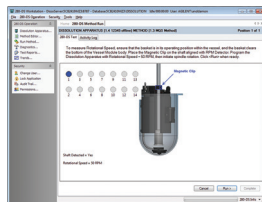
Agilent Sites and Services

DAN SPISAK, PRODUCT MANAGER—DISSOLUTION, AGILENT TECHNOLOGIES INC.

AGILENT 280-DS MQS CAPABILITIES EXTENDED

The measurement device that has taken the dissolution industry by storm now has even more capabilities. The **280-DS Mechanical Qualification System (MQS)** provides laboratories with a solution to rethink how qualification of USP Apparatus 1 and 2 is managed.

- What if instrument qualification only required 15 min of analyst's time?
- What if the system was so innovative, results obtained were user-independent?
- What if you could quickly and easily perform qualifications more frequently than every 6 months?



The powerful 280-DS MQS gives laboratories the freedom to think about ways to redefine their internal laboratory procedures. By making the physical parameter measurement simple and reliable, instrument integrity is vastly improved and failure investigations as a result of qualification failure are limited, if not entirely avoided. The accompanying

software guides the user step-by-step through the qualification process and even trends instrument data to reveal potential problems *before* they become out-of-tolerance.



Agilent Technologies

Compatible since its initial 2012 release with all Agilent, Varian, and VanKel models (as well as most open-head designed systems from various manufacturers), the 280-DS is now even more flexible. Minor modifications to the Vessel Module—including add-on spacers and an arm extension—have expanded the range of vessel heights where the 280-DS can be utilized. All units purchased in early 2017 will contain these improvements, and existing units may be easily upgraded at the time of recalibration.

See if the dissolution apparatus in your laboratory are compatible with the 280-DS. For complete details, contact your Agilent representative, or email us at the Dissolution Hotline: dissolution.hotline@agilent.com.



For more information about how the 280-DS MQS can change your perspective on qualification, visit www.agilent.com and search “280-DS.”

dissoGUARD®—KNOW WHAT HAPPENED!

dissoGUARD® is a powerful dissolution surveillance system that offers a real-time view of your dissolution vessels. A dedicated camera is located beneath each vessel location, and illumination is controlled via the software. The system gives you the ability to store videos, export pictures, and archive videos for future analysis, and to track the position of dosage forms, the timing and location of sampling cannulas, the behavior of particles in-vessel, and more. An additional external camera can be deployed for a different viewing angle.

dissoGUARD® is specifically designed for the Agilent 708-DS. By extending the legs, the camera housing can fit neatly beneath the vessels. No additional bench space is required—except for the PC and monitor. In addition to monitoring what is happening in each vessel, the PRO software package also enables users to evaluate physical parameters such as centering, wobble, and paddle rotation speed. The dissoGUARD® system can be retrofitted to any Agilent 708-DS.

For a limited time, you can purchase the dissoGUARD® system at up to a 50% discount with the purchase of any 708-DS dissolution apparatus. This special offer includes the PRO software package!

To learn more about this offer, contact your Agilent representative.

For more information about dissoGUARD®, visit www.dissoguard.com.

You can also check out the following article in Dissolution Technologies for a real-world application:
<http://www.dissolutiontech.com/issues/201611/DT201611A03.pdf>

SAYING GOODBYE... AND LOOKING AHEAD

It's never too soon to think about the future. That's why Agilent is announcing the End-of-Guaranteed-Support (EoGS) for many legacy dissolution apparatus with plenty of advance notice. Some of these models originated at VanKel Technology Group over 20 years ago and are still operating in many dissolution laboratories today.

You have come to know Agilent Technologies products for their quality, performance, and reliability, giving you many years of useful service. Agilent no longer has the ability to guarantee that we will be able to repair and maintain the following systems; as a result, we may not offer service contracts or assure per-incident repair. Official documentation is available from Agilent detailing this information.

Model	End of Production	End of Guaranteed Support
VK 7000 Dissolution Apparatus	30-Jun-2011	30-Jun-2018
VK 7010 Dissolution Apparatus	30-Jun-2011	30-Jun-2018
VK 7025 Dissolution Apparatus	30-Apr-2011	30-Apr-2018
VK 7030 Dissolution Apparatus	30-Aug-2010	30-Aug-2017



This announcement is meant to allow for appropriate planning to ensure the continuity of your business. We strive to provide timely and complete information regarding end-of-guaranteed-support for all Agilent products. Until the EoGS date is reached, you can still take advantage of all the services you have come to expect for your Agilent dissolution system, including:

- Consumables/Accessories
- Maintenance/Repairs/Qualification
- Consulting/Training/e-Seminars

To help you plan an EoGS transition, contact your Agilent representative, who can provide an upgrade path for your laboratory. The 708-DS Dissolution Apparatus has been the primary Agilent model for the better part of this decade and continues to provide leading-edge solutions for dissolution laboratories worldwide.

If you need more information about improving your workflow with a future-proof solution, please visit <http://www.agilent.com/en-us/promotions/dissolution-sourcebook> or contact your local Agilent representative, who will be happy to assist you. Several trade-in based incentives are available, so be sure to take advantage of these limited time offers!

DAN SPISAK, PRODUCT MANAGER—DISSOLUTION, AGILENT TECHNOLOGIES INC.

850-DS FILTER PLATES—PVDF MEMBRANES AVAILABLE

GE Healthcare (GEHC) continues to add to the filter plate membrane options available for use with the 850-DS Sampling Station. Building upon the already diverse selection, polyvinylidene difluoride (PVDF) filters are now available in 0.45 and 0.2 μm pore sizes.

As discussed at length in Practical Solutions Issue 16.2, analysis of dissolution samples is increasingly carried out by HPLC and UHPLC analysis. This increases the need for filters at finer pore sizes to ensure proper sample cleanup.



850-DS Filter Plates

NEW

The following table displays the current 850-DS filter plate offerings from GEHC:

GE Part Number	Pore Size (μm)	Membrane Material
7707-3000	0.45	Polytetrafluoroethylene (PTFE)
7707-3100	0.45	Nylon
7707-3200	0.45	Polyethersulfone (PES)
7707-3300	0.7	Glass Microfiber (GMF)
7707-3400	0.2	Polytetrafluoroethylene (PTFE)
7707-3500	0.2	Nylon
7707-3600	0.2	Polyethersulfone (PES)
7707-3700	0.2	Polyvinylidene difluoride (PVDF)
7707-3800	0.45	Polyvinylidene difluoride (PVDF)

You may visit www.gelifesciences.com and simply search “850-DS” for more information. Chemical resistance and other product information is available on the website.

Agilent has also created a useful **Filter Validation Protocol** to guide you through selection and validation of the proper filter for your dissolution method. Visit www.agilent.com/lifesciences/filter_validation for this free download.

Additional questions regarding the 850-DS filter plates, or filter validation in general, may be submitted to the Dissolution Hotline at dissolution.hotline@agilent.com

DAN SPISAK, PRODUCT MANAGER—DISSOLUTION, AGILENT TECHNOLOGIES INC.

DISSOLUTION VESSELS— THE TRUALIGN DIFFERENCE



Verified Vessel with included
Certificate of Conformance

High quality vessels are critical to obtaining good results. Past studies, including those performed by the United States Pharmacopeia (USP)¹, describe how minimizing vessel irregularities can lead to decreased result variability with sensitive products such as prednisone. As the

dissolution industry continues to trend toward mechanical qualification (MQ) and away from the USP Performance Verification Test (PVT), vessel quality is now under increased scrutiny. With no standardized chemical testing, how are vessel irregularities—most of which are invisible to the naked eye—detected?

A properly manufactured vessel can reduce variability when performing qualification using prednisone.² For laboratories implementing MQ, a better quality vessel decreases the risk associated with a lack of chemical qualification.

Regardless of your qualification procedure or daily dissolution testing needs, Agilent's dissolution vessels are the preferred choice to ensure consistent, repeatable results with limited variability. The high-quality TruAlign vessels used for the [708-DS Dissolution Apparatus](#) are manufactured to the same time-tested standard of the past VanKel and Varian vessels. In addition, a collar is incorporated onto the vessel to maintain accurate centering and verticality alignment with the dissolution apparatus. An indicator tab on the collar provides reproducible vessel orientation while the serial number offers easy identification.



2L 708-DS Dissolution Apparatus

TruAlign vessels for the 708-DS are available in 100 and 200 mL, as well as 1- and 2-liter sizes. Converting between the larger and smaller volume sizes requires no special tools and can be easily performed by the user. Low actinic (red), Peak, and Verified versions are also available for select volumes.

The Verified vessels include an individual Certificate of Conformance that documents the exact measurements of the vessel as required by MQ.

VF Molded TruAlign Vessels

Agilent also offers molded TruAlign vessels which are vacuum formed (VF) and provide the tightest precision available, to reduce position-to-position variability and improve uniformity. With specifications over 10 times more stringent than standard vessels, this option eliminates inconsistencies and puts the focus on the dosage form. The VF vessels are offered as 1L clear glass only and are available with or without a Certificate of Conformance. For more information on VF vessels, take a look at the technical overview at www.agilent.com/lifesciences/vfvessels.

Visit www.agilent.com or contact your Agilent representative for more information. You may also contact us at the Dissolution Hotline—dissolution.hotline@agilent.com—to speak with one of our dissolution experts.

¹ Liddell, M. et al. "Evaluation of Glass Dissolution Vessel Dimensions and Irregularities". *Dissolution Technologies*. February 2007, 28-33.

² Tanaka, M. et al. "Effect of the Irregular Inner Shape of a Glass Vessel on Prednisone Dissolution Results". *Dissolution Technologies*. December 2005, 15-19.

QUESTIONS YOU ASKED

Enhancer Cell Sample Amount

Question: For the Enhancer Cell, if just 2 ml sample is needed, which sizes are available? It also appears that there are different types of surface area for the cells: 4 cm, 2 cm, and 0.5 cm.

Answer: You can add a specific weight if you would like to, since the Enhancer Cell (Immersion Cell in USP <1724>) has one body size with an adjustable floor plate within the cell. It is adjustable by raising and lowering with the adjustment tool, so it should easily hold the amount suggested in your message. Your question has two parts however, because sample volume is somewhat independent of surface area.

First, performance testing of ointments, creams, and gels with the Enhancer Cell works differently than most dissolution tests in that it only tests the rate of diffusion of the product through a membrane; it does not test the extent of dissolution. By this I mean that it will not be used to determine that all of the drug has released from the amount of formulation added to the cell. Secondly, there are various surface areas of the Enhancer Cell that are available to replicate the surface area for diffusion and also to allow more or less surface area depending on the concentration and permeability of the ointment, cream, or gel under test. We have also produced an instructional video for the use of the Enhancer Cell that can be viewed on the Agilent Dissolution Exchange site, or by following this link:

<https://www.youtube.com/watch?v=K9eiVPOLoNM>

Carry-Under in Manual Sampling of Dissolution Samples

Question: I have experienced some unexplained low results that are also variable when using the same syringe, cannula, and filter for each subsequent time point. I am getting 99% standard recovery from my filter so I don't think the active is binding to the filter. Do I need a separate syringe, cannula, and filter for each time point?

Answer: "Carry-under" may be occurring. It is important to protect the integrity of the samples you take at each time point. If you pull sample with residue from the previous time point, you could dilute the sample you pull through; this is called "carry-under" (as opposed to carryover). My suggestion is to

use the same six syringes with their respective cannulas and filters, while ensuring that you are not getting carry-under for each subsequent sample. There is no need to use a new filter or cannula for each time point, since 4 time points would impractically result in 24 sets of syringes, cannulas, and filters.

You can resolve carry-under by prerinsing with the fresh sample. Whenever you re-use a cannula, syringe, and filter for subsequent time points, you risk diluting the sample. To avoid multiple sets of sampling equipment for each time point, use the original six sampling systems. Here's how:

1. Pull the sample (3-5 mL)
2. Disconnect the cannula
3. Discard syringe contents
4. Re-attach the cannula
5. Pull the sample for collection

In your calculations, you should account for sample volumes during rinsing and collecting. It is also essential to perform the sampling within the $\pm 2\%$ window required in the USP <711> Dissolution chapter. Rinsing steps may warrant a staggered start to accommodate any additional time that may be required to collect your samples.

Timely sampling, as well as the prevention of carry-under and carryover, are good reasons to automate dissolution. Dissolution systems automatically prime and rinse each line with the fresh sample *before* the valve opens and drops sample into a vial or test tube.

Agilent Sites and Services for Your Dissolution Workflow



Agilent Dissolution Systems Digital Source Book

www.nxtbook.com/nxtbooks/agilent/dissolution_sourcebook/index.php

Dissolution Exchange

www.dissolution.chem.agilent.com

Dissolution 1-on-1 Training

www.dissolution.chem.agilent.com/learndissolution-1-on-1

Dissolution Hotline (Email Address)

dissolution.hotline@agilent.com

Dissolution Discussion Group (DDG)

www.dissolution.com

Learn more

[**www.agilent.com/chem/dissolution**](http://www.agilent.com/chem/dissolution)

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