### Practical Solutions Newsletter



Year 2022, Volume 4

# from the New Dissolution Center of Excellence

#### Access granted

Agilent proudly announces the opening of the facility that serves all areas of the dissolution testing business, especially our customers.

Page 2



# Stay Audit Ready with New DWS 1.8

You deserve a stressfree lab. Learn how you can effortlessly meet regulatory requirements.

Page 5



# New Community Blog for Dissolution

Get your questions answered and regular updates on all dissolution topics.

Page 6



#### Questions You Asked



Need help with dissolution investigations? Learn how traceability can help.

Page 7

# Opening of Center of Excellence for Dissolution

Dan Spisak, Dissolution Marketing Manager

Agilent is proud to announce the opening of the Dissolution Center of Excellence (CoE) facility in the United Kingdom (UK). The newly modernized premises will house the core of the Agilent dissolution testing business, including research and development, quality, support, applications, marketing, and more.



# Expanding our customer support

The site has nearly doubled in size to prepare for the next generation of dissolution testing innovation. It also has upgraded capabilities for the ongoing manufacturing of Agilent gel permeation chromatography and evaporative light scattering detector products.

At the center of this expansion is the new dissolution testing CoE laboratory. The space will be utilized as the worldwide hub for education, training, application development, and both onsite and virtual demonstrations.

The new facility creates the ideal environment to foster continuous improvement and connection. This investment supports Agilent in our commitment to providing industry-leading solutions for dissolution testing products and software, both now and into the future.







"Growth in the Agilent dissolution testing business created the need for a larger facility. Our new flagship site will enable us to develop a truly unified approach for the future. The center will also foster greater collaboration, innovation, and manufacturing capabilities to support Agilent digital lab initiatives."

> Site Director, Agilent Craven Arms



For more information about the Agilent dissolution testing portfolio, or assistance with your current workflow, please reach out to our team at dissolution.hotline@agilent.com to schedule a meeting or demonstration.

## Always Audit Ready with New Dissolution Workstation Software 1.8

#### Lorraine Kay, Global Product Manager-Dissolution Systems

Help is at hand to meet your regulatory requirements with Agilent Dissolution Workstation Software (DWS) version 1.8. DWS enables dissolution testing laboratories to securely curate a digital ecosystem of knowledge that is always audit ready. Pharmaceutical contract development and manufacturing companies, and laboratories that perform dissolution testing on generic drug dosage forms have experienced the immediate benefits already.

DWS organizes all your dissolution methods and test data, enables complete operational control and automation, offers structured user-level permissions and access, and has multilevel e-signature reporting. It is configurable to suit your needs, giving you the ultimate flexibility with control.

All e-signatures are permanently linked to the test results; any attempt to sign a set of results using either an invalid user identification or password is automatically recorded in the system audit trail. Digital security enables users to successfully work in a compliant environment and ensures data integrity.

Using DWS to automate your dosage introduction, sampling, and media replacement also relieves you from being bound to the bench. Realize results faster with end-to-end operational control and complete system automation, and buy yourself more time to think, plan, and breathe.

DWS offers to dissolution testing laboratories a reliable way to satisfy regulatory requirements for data storage and traceable digital records.



#### Your needs answered-new DWS 1.8 features include:

- Compatibility with Microsoft Windows 10 and 11
- Data security when connection to a server is lost
- Improved Agilent NanoDis System workflow and automation

DWS keeps your digital ecosystem of dissolution knowledge secure, and is always audit ready.

Request your quote or demonstration today from your Agilent representative, or message us at: dissolution.hotline@agilent.com

## New Community Blog for Dissolution

Karen Krauel-Göllner, Global Product Manager-Dissolution Systems

Are you interested in enhancing your knowledge on key dissolution topics? Come and visit the new dissolution blog in the Agilent Community.



The Agilent Community is a free resource developed and maintained by in-house experts at Agilent to provide you with the latest advice on your instruments and techniques, all in one place. The dissolution specialists have now created a blog containing short, easy-to-digest posts based on relevant, trending topics in the industry.

So far, you can read about overcoming coning issues (with apex/peak vessels), Agilent USP Apparatus 3 (Reciprocating Cylinder) method development, and how to select the right dissolution filter for your method. And this is just the beginning, with new topics appearing frequently.

True to the nature of a blog, you are also able to comment on a post and start a collaborative conversation with the author and other readers. Participation comes at no cost, and Agilent complies with General Data Protection Regulation (GDPR) so you can be sure that your registration details are safe and secure. Simply follow the Dissolution Blog to receive notifications when new articles are posted.

Get answers. Share insights. Build connections. Come and join the Agilent Community for the latest information at:

www.agilent.com/chem/dissolution-community

#### Questions You Asked

#### Lee Dowden, Global Product Manager-Dissolution Systems

#### Traceability is vital—and often required for efficient dissolution investigations

- Why is it important to keep dissolution accessories in the same location for each test? How can I ensure this is done correctly?
- A Let's assume that out of your previous 10 dissolution tests, four of them had out-of-specification results for a single position, and that position differed for each test. After a great deal of time and investigation, it was determined that the cause of the failure was a slightly bent paddle shaft that resulted in excessive wobble and higher percent dissolved values. By having dedicated positions for each accessory, this investigation would have been much easier; the problem would have identified itself since the issue would have appeared in the same position for each test.

In addition to simplified investigations, dedicating positions will ensure you have consistent dissolution environments, and should lead to fewer dissolution run failures and better repeatability. Whether your laboratory performs the USP Performance Verification Test or the enhanced mechanical qualification approach for routine qualification, the accessory for each position is defined.

The result of that qualification means each location on the dissolution instrument meets the requirements for the test based on the parts installed. If any of the parts are moved to another location on the instrument, you are no longer using the dissolution tester in the same way as it was qualified.



Version 2.0 of the USP Dissolution Toolkit<sup>1</sup> states that:

"All vessels and individual parts of the stirring elements (shafts, baskets, paddles, or paddle blades) should be uniquely identified, documented, and kept in the same position in the same test assembly for all dissolution runs."

Dedicating dissolution accessories is one of the greatest corrective and preventive actions that can be done in the lab. To simplify this, access to the information should be convenient and visible to the user. This could be done with software, or a card attached to the instrument itself. Such cards are available for the Agilent 708-DS Dissolution Apparatus. Contact dissolution.hotline@agilent.com for more information or to obtain your own cards for accessory tracking.

<sup>1.</sup> Prednisone Task Force Team, US Pharmacopeia. Dissolution Toolkit, Procedures for Mechanical Calibration and Performance Verification Test, Apparatus 1 and Apparatus 2, Version 2.0. (accessed 2022-07-28).

Learn more:

www.agilent.com/chem/dissolution

Agilent Dissolution:

www.agilent.com/chem/dissolution-community

Register to receive the e-newsletter quarterly by email:

www.agilent.com/chem/practical-solutions

Buy online:

www.agilent.com/chem/store

Contact dissolution chemists:

dissolution.hotline@agilent.com

U.S. and Canada

1-800-227-9770

agilent\_inquiries@agilent.com

Europe

info\_agilent@agilent.com

India

india-lsca\_marketing@agilent.com

Asia

pacificinquiry\_lsca@agilent.com

