

Agilent 280-DS Mechanical Qualification System

REDEFINE DISSOLUTION QUALIFICATION

The Measure of Confidence



Agilent Technologies

SIMPLIFY MECHANICAL QUALIFICATION

Maximize Laboratory Efficiency and Data Integrity

The Agilent 280-DS Mechanical Qualification System (MQS) will change your perspective on dissolution qualification. Using the 280-DS's two devices – an Instrument Module (IM) and a Vessel Module (VM) – all critical physical parameters of the dissolution apparatus are verified with unprecedented simplicity. The modules are powered by the intuitive Agilent 280-DS Workstation Software that steps the user through each measurement with easy-to-follow directions. Consolidation of measurement devices backed by a streamlined software package, the Agilent 280-DS offers a perfect opportunity to improve accuracy and efficiency as well as the freedom to increase qualification frequency for added integrity.

A Product Combination to Improve All Aspects of Your Dissolution Testing

Agilent has developed an unrivaled device to undoubtedly save you time and increase your laboratory's productivity. Backed by industry-leading experience in instrumentation, support, training and qualification, Agilent provides the tools you need to gather your data more accurately and with confidence.

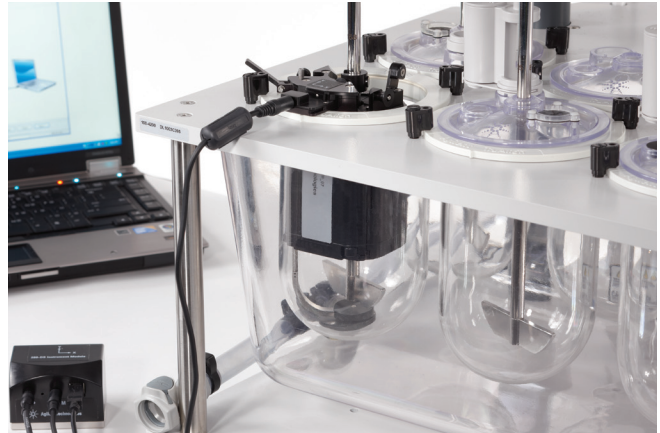
The Agilent 280-DS Mechanical Qualification System provides quantitative values for all physical parameters of the dissolution apparatus. It is designed to take accurate measurements at the proper locations as prescribed by current industry regulations. The innovative design of the modules not only simplifies the procedure, but acts to remove the guesswork of interpreting values obtained with individual manual gauges. Once positioned, the innovative sensing technology enables hands-free, non-contact measurements to be performed in seconds – a fraction of the time routinely associated with such readings.



Lightweight, robust and durable measurement devices can be trusted over time. The Agilent 280-DS comes with a custom-insulated carrying case for safe and secure portability.



The 280-DS Instrument Module positioned on the vessel plate to measure level (X and Y axes) and vibration (X, Y and Z axes).



The 280-DS Vessel Module can be utilized on any open-head dissolution apparatus, but has distinct advantages when used with an Agilent model such as the 708-DS.

The 280-DS Modules

The Instrument and Vessel Modules are all that is necessary to perform any required measurement during mechanical qualification of your dissolution apparatus.

The 280-DS Vessel Module measures:

- Spindle speed (RPM)
- Shaft and basket wobble
- Shaft and vessel verticality
- Vessel centering (upper and lower)
- Basket and paddle height

The 280-DS Instrument Module measures:

- Vessel plate level
- Vibration

The 280-DS Instrument Module also includes an attachment for a temperature probe and provides connections for the 280-DS Vessel Module, as well as a USB cable for the PC.

Dissolution Instrumentation for Use with the 280-DS

Agilent's dissolution instrumentation, as well as any other manufacturer's equipment with an open-head design, can be tested with the 280-DS. This compatibility is a result of module adjustments and snap-on spacers to accommodate various vessel sizes. The vessel module is inserted into a vessel and expands to contact the interior wall. The basket or paddle shaft is not in contact with the vessel module, so no unnecessary force is applied that might bend the shaft.

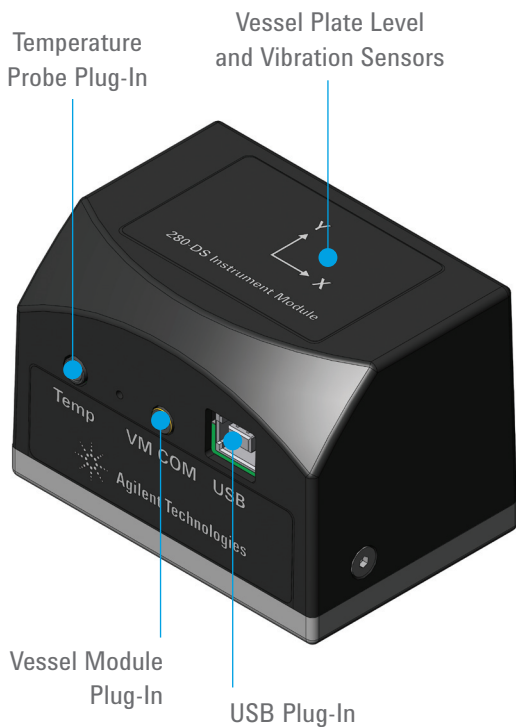
Additional benefits are recognized with an Agilent model – the 280-DS includes an online testing mode that enables the software to control the apparatus. This further speeds up the procedure by automatically activating spindle rotation for measurements such as wobble, spindle speed and vibration.

THE NEW STANDARD FOR DISSOLUTION QUALIFICATION

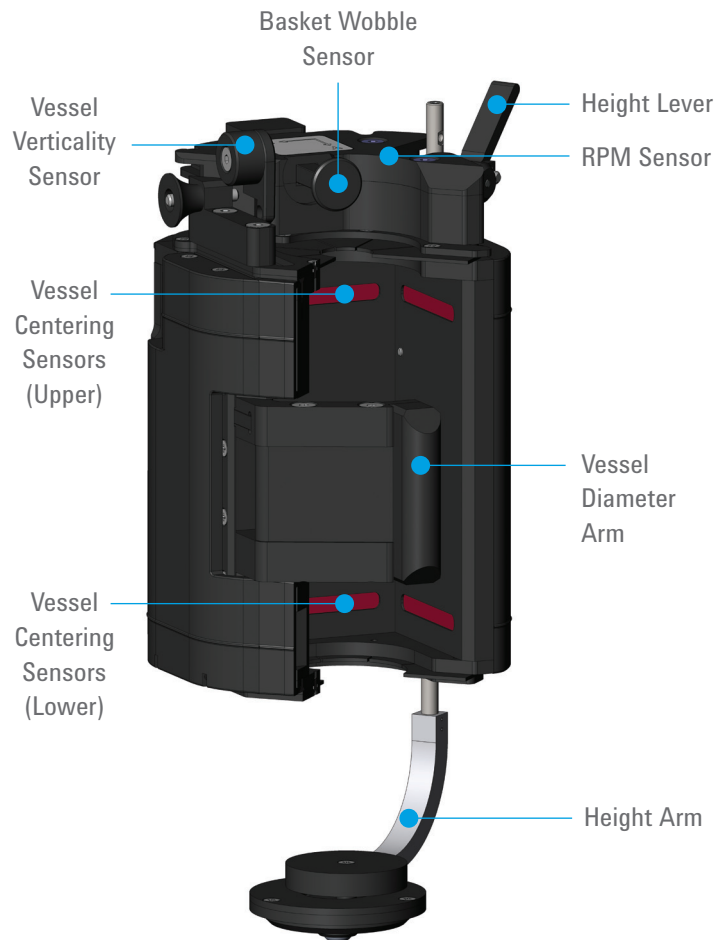
How the Agilent 280-DS Works

The innovative design of the 280-DS modules provide accurate and repeatable measurements with limited hands-on interaction required. These images illustrate the position of the various sensors included in each module.

280-DS Instrument Module



280-DS Vessel Module



Leading the Mechanical Qualification Revolution

The Agilent 280-DS is the latest tool of its kind. Whether it be efficiency, data integrity or everyday verifications, this tool provides instant value to every dissolution laboratory.

280-DS Hardware Highlights

No more calibration of individual measurement gauges.

The 280-DS replaces all of the individual tools you're currently using to verify physical parameters. Now you can conveniently return the all-in-one system to an Agilent calibration center for a complete and traceable certification.

Reduce your qualification time by as much as 50%!

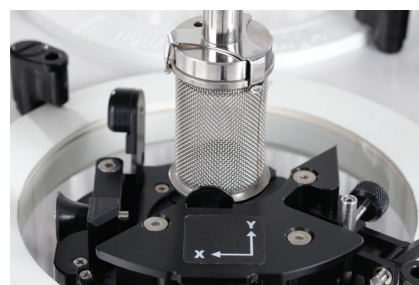
The 280-DS has been shown to cut the time taken to measure and record all values by more than half the time it takes with currently available solutions. This creates greater laboratory efficiency and the freedom to increase qualification frequency for added apparatus integrity.

Eliminate all uncertainty, interpretation and variability with hands-free measurements.

Once properly positioned, the 280-DS modules do all the work – providing you with reliable, repeatable measurements using innovative sensing technology. Quantitative values for each parameter are recorded and visible in real-time through the software.

For use with almost all manufacturers – added bonus with Agilent!

The 280-DS is compatible with all open-head dissolution apparatus and includes snap-on spacers and adjustments for various vessel sizes. The software can take control of an Agilent apparatus eliminating the need to manually activate rotation for spindle speed, wobble or vibration measurements.



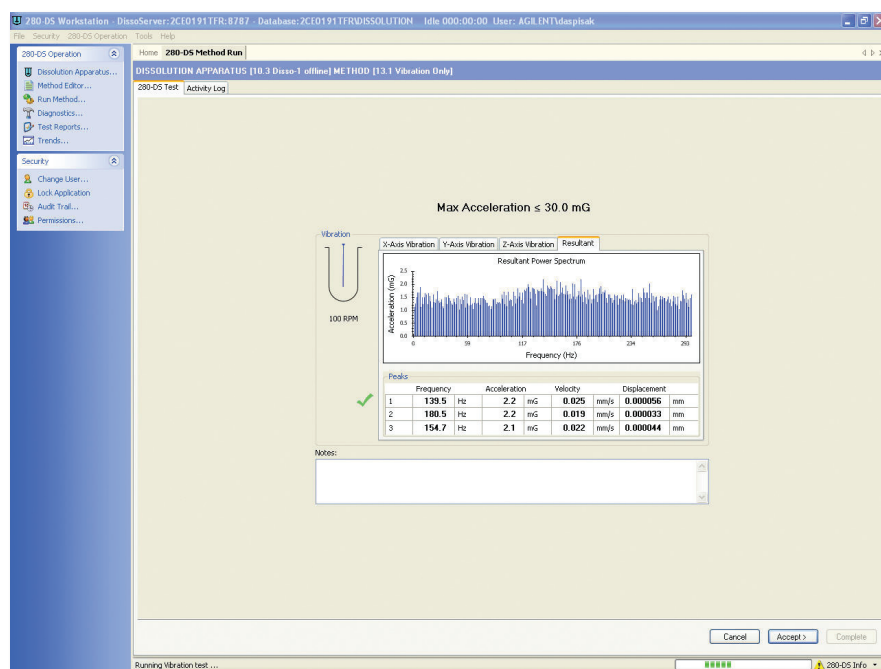
The versatile 280-DS Vessel Module taking basket height (top) and basket wobble (bottom) measurements.

Impacts of Vibration

Agilent understands the impact vibration can have on a dissolution run. The industry has struggled for years to define how to measure and report vibration in a manner that is practical for routine use.

Agilent incorporated a tri-axial accelerometer into the 280-DS that simultaneously measures the vibration in 3 independent axes – namely X, Y and Z. We use the term resultant vibration to represent the square root ($X\text{-axis vibration}^2 + Y\text{-axis vibration}^2 + Z\text{-axis vibration}^2$).

The resultant vibration represents the magnitude of the vibration experienced by the dissolution apparatus. The data for each individual axis can be examined to determine the direction of the dominant vibration experienced (external) or induced (internal) by the apparatus.



The 280-DS Workstation Software displays vibration in 3 axes (X, Y, Z), as well as the resultant values.

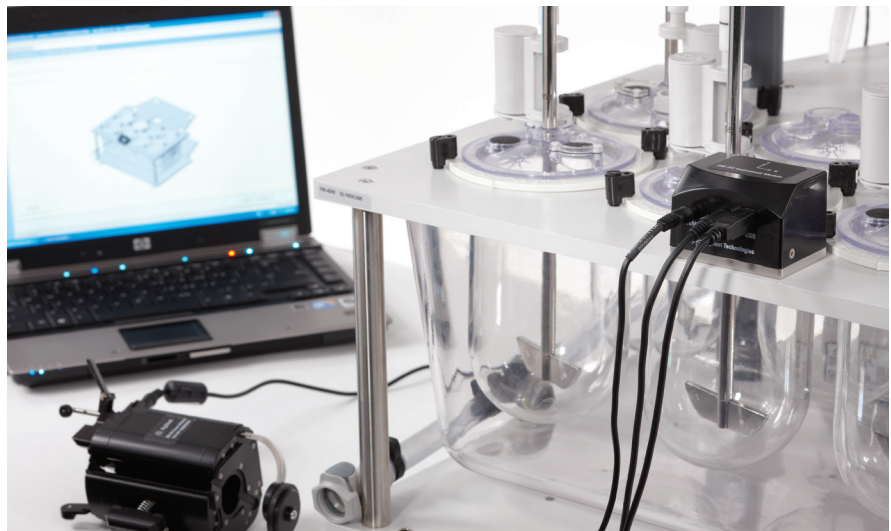
ENHANCED COMPLIANCE AND CAPABILITIES

Designed to Meet Current Regulations and Improve Failure Investigations

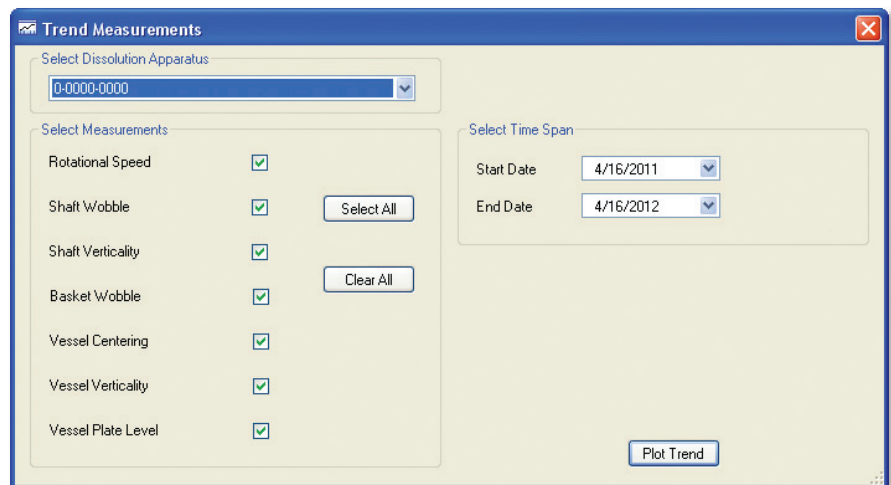
The 280-DS Workstation Software is an integral part of this measurement system and serves to separate the 280-DS even further from its predecessors. The software naturally progresses the user through a customized series of measurements in a 21 CFR Part 11 compatible environment. All relevant information about the dissolution apparatus and measurement gauges is conveniently stored and visible on the final report.

Key Software Functionalities

- Configuration files maintain all relevant apparatus data including serial numbers and certificates of critical components.
- Method files may be chosen from a pre-loaded list or customized based on specific internal requirements.
- All necessary controls available for use in a 21 CFR Part 11 environment including user groups, audit trails, and so on.
- Text directions as well as helpful graphics instruct the user how and when to perform each measurement.
- All results generated are stored within a database that may be created locally or on a network.



Text and graphics step the user through each measurement when using the 280-DS Workstation Software.



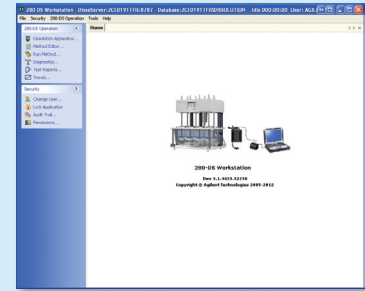
The 280-DS Workstation Software has the ability to plot data from each apparatus to help in failure investigations.

Advanced Software Capabilities

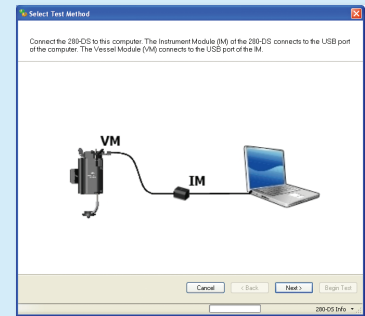
- Inspect individual position measurements using the data trending feature.
- Select specific positions to be tested for quick investigations.
- Record exact orientation of vessel within the data file.
- Filter past reports using various criteria including dates, operator, apparatus, and so on.
- Conveniently monitor system and/or method changes with built-in audit trail reports.

Step-by-Step Mechanical Qualification with the 280-DS

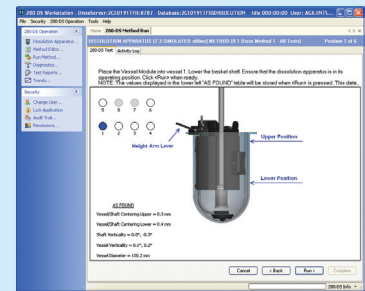
1 Open the 280-DS Workstation Software.



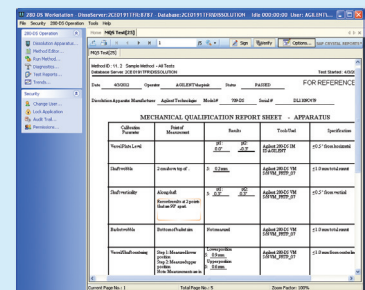
2 Select apparatus and test method from previously created and securely stored files.



3 Execute test procedure.



4 Review results.



280-DS Workstation Software Highlights

Current regulatory methods are preloaded for quick setup and execution.

The software of the 280-DS includes traditional parameters and tolerances as well as the flexibility to create a custom protocol to meet your laboratory's requirements. Revisions to the software are easily managed meaning the 280-DS will always be up to date.

Easily search and retrieve data files from a secure database.

Records for every 280-DS test can be viewed using various filtering criteria to simplify report recovery. Complete reports can be searched by serial number, operator and date just to name a few.

Intuitive, user-friendly interface built on familiar and established software platform.

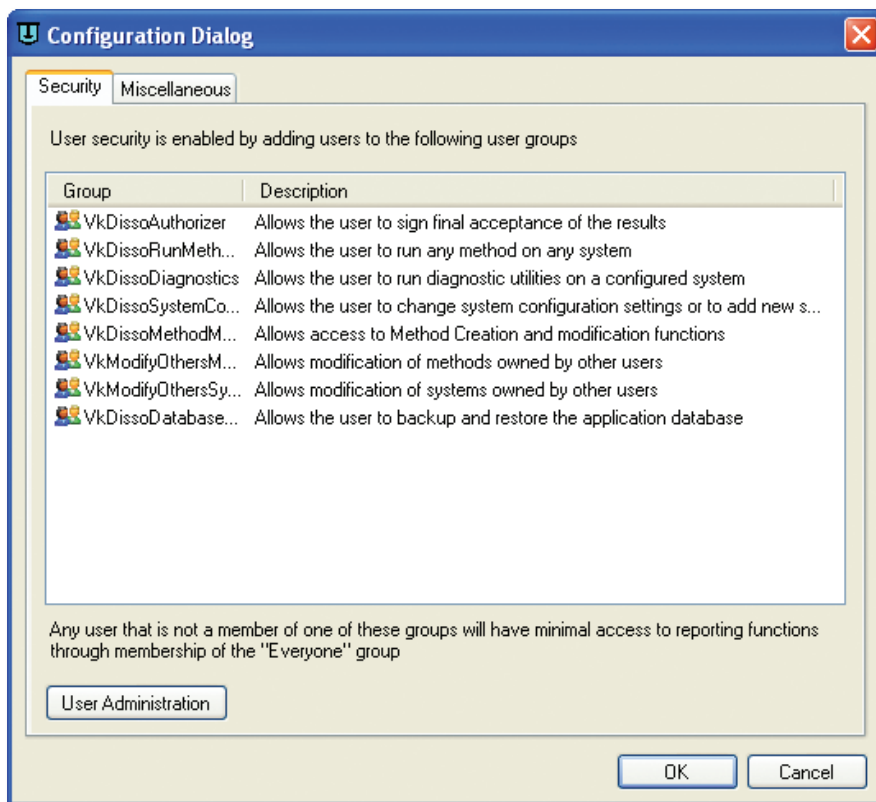
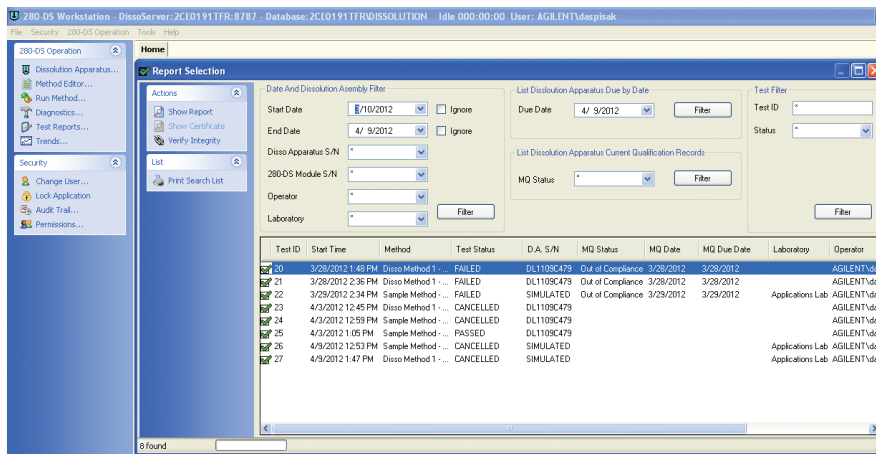
A few clicks to select your dissolution apparatus and method and you can begin testing using Agilent's 280-DS Workstation Software. The software steps you through each measurement with easy-to-follow text and graphical assistance.

Software designed for compliance and enhanced capabilities.

The software includes all necessary controls for a 21 CFR Part 11 including restricted user levels, audit trails and electronic signatures to name a few. The unique ability to trend the measurement data for each apparatus improves root cause investigation for unexplained dissolution data.

Certificates for all components stored with apparatus file.

Easily find and recall the individual certificates associated with vessels, shafts and baskets required for mechanical qualification.

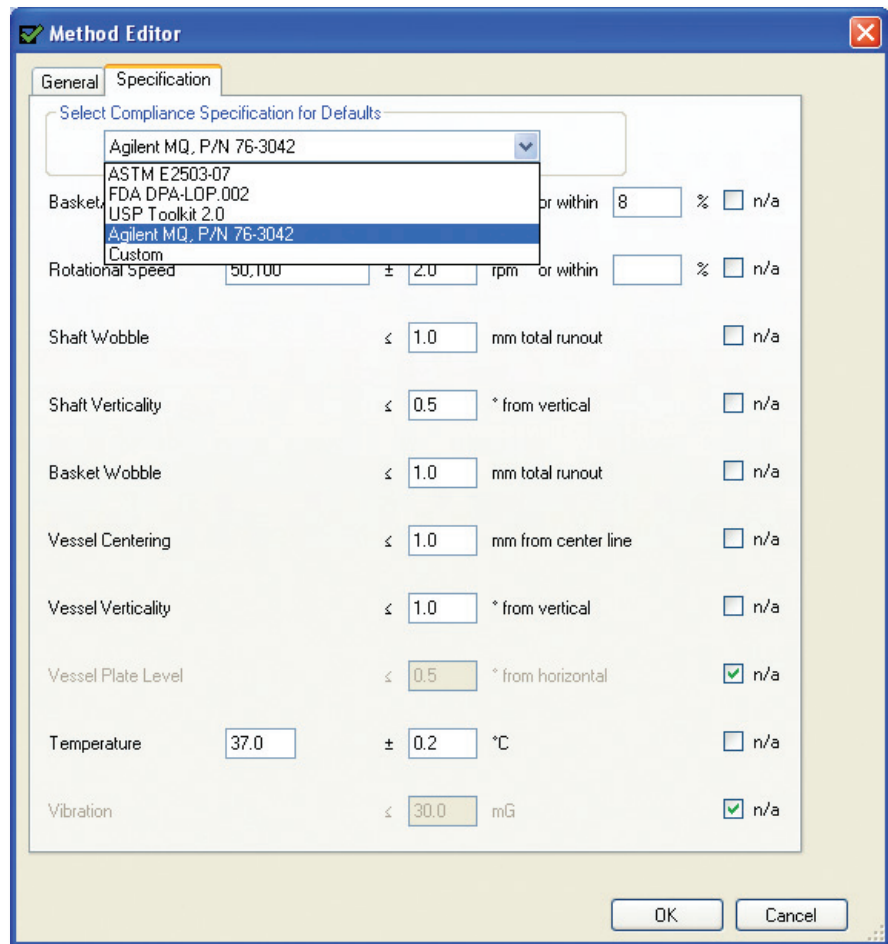


The 280-DS Workstation Software includes multiple options for filtering past reports and several levels of access to control specific user privileges.

PVT or MQ for Dissolution Apparatus Qualification?

The ongoing debate concerning the best method for periodic qualification of dissolution apparatus continues to attract attention. While the USP endorses enhanced mechanical qualification, in addition to the Prednisone acceptance test, the enhanced mechanical calibration procedure, prescribed by the FDA and ASTM – endorsed by guidance’s from ICH and FIP – continues to gain acceptance throughout the dissolution industry.

Regardless of which procedure is performed in your laboratory, the Agilent 280-DS can be utilized productively to verify the critical physical parameters of your dissolution apparatus. The biggest advantage comes from the time needed to perform the measurements. In fact, the ease of use, data storage and trending capability of the software may have you asking yourself why periodic calibration is typically performed ONLY every six months. Increasing qualification frequency facilitates better monitoring of instrument performance and a smaller interval of data to fall under investigation in case of failure. If a complete qualification can be performed in as little as 30 minutes, why wait for 6 months of data to accumulate?



The Method Editor in the 280-DS Workstation Software allows you to customize which qualification method measurements you want qualified by the 280-DS.

Learn More about Dissolution Qualification!

Agilent supports your options for qualification. Learn more about implementation of Mechanical Qualification and Performance Verification Testing through our recently published white papers.

www.agilent.com/lifesciences/MQwhitepaper
www.agilent.com/lifesciences/PVTwhitepaper



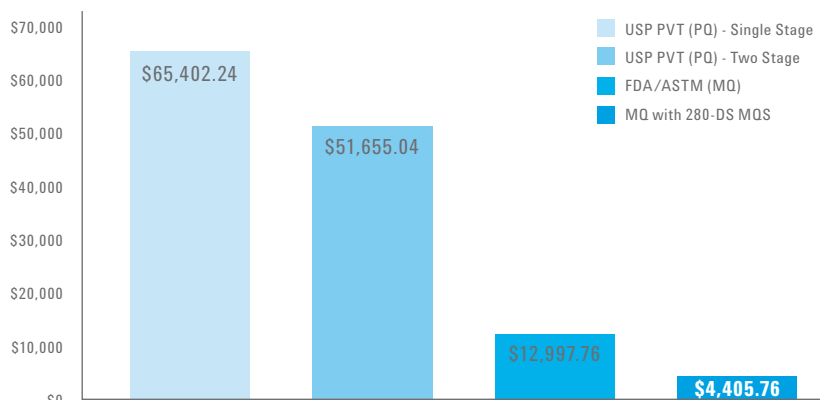
UNIVERSAL QUALIFICATION SOLUTION

Recognize Cost Savings and Maximize Efficiency

Curious to see just how much you could save by incorporating the 280-DS Mechanical Qualification System into your laboratory's dissolution qualification repertoire?

See the following table for some examples and then visit Agilent's 280-DS webpage to perform your own savings estimate: www.agilent.com/lifesciences/280-DS_calculator

Combine this savings with qualification frequency flexibility and added dissolution data integrity, and you're sure to be rewarded.



Annual Cost Estimate of Periodic Dissolution Qualifications (8 dissolution apparatus, 2 times/yr.)

Agilent 280-DS Savings Calculator – Examples

| Type of periodic qualification performed for your dissolution apparatus (USP Apparatus 1 - Baskets and USP Apparatus 2 - Paddles) | USP PVT (PQ) - Single Stage | USP PVT (PQ) - Two Stage | FDA/ASTM (MQ) | MQ with 280-DS MQS |
|---|-----------------------------|--------------------------|--------------------|--------------------|
| Approximate time (in. hrs) to complete qualification for each USP Apparatus (i.e., Basket OR Paddle methods) | 8 Hours | 8 Hours | 2 Hours | 30 minutes |
| % of USP PVT procedures requiring Stage 2 testing (i.e., n=12) | 100% | 25% | 0 | 0 |
| % of qualifications requiring failure investigation (e.g., failed Stage 2, failed MQ) | 5% | 5% | 5% | 5% |
| Average hourly labor rate for dissolution analyst | \$32.00 USD/hr. | \$32.00 USD/hr. | \$32.00 USD/hr | \$32.00 USD/hr |
| USP Apparatus qualified per dissolution apparatus | Both | Both | Both | Both |
| Number of dissolution apparatus qualified per year | 8 apparatus | 8 apparatus | 8 apparatus | 8 apparatus |
| Frequency of periodic dissolution qualification | 2 times/yr. | 2 times/yr. | 2 times/yr. | 2 times/yr. |
| Your estimated annual cost of periodic dissolution qualification | \$65,402.24 | \$51,655.04 | \$12,997.76 | \$4,405.76 |
| Your estimated yearly savings by using the 280-DS MQS and enhanced Mechanical Qualification | \$60,996.48 | \$47,249.28 | \$8,592.00 | |
| Your estimated savings percentage (current vs. 280-DS MQ) | 93.3% | 91.5% | 66.1% | |

*Cost savings estimates based on 8 dissolution apparatus qualified twice per year

*Instrument downtime cost of \$100.00/hr. included in estimate

*Cost of calibration of measuring device(s) included in estimates = \$2,000.00 USD/yr.

*Cost of Prednisone tablets (5 tests/bottle) and standard (10 tests/bottle) added to USP PVT estimates

*Fully burdened cost – wage plus benefits – added to labor rate (35%)

*Failure investigations add 4 times total test time accounting for root cause analysis and retesting

*Stage 2 testing assumes 50% of total time per test

*280-DS MQS estimates are based on 30 minutes per USP Apparatus per dissolution apparatus

Agilent's Dissolution Compliance 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. Agilent streamlines compliance procedures across your entire enterprise to save you time and money with a solution that's compatible with instruments from all leading vendors.

Hardware and Software Support Services

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). Enterprise Edition is a single comprehensive service for IQ/OQ/PQ/MQ qualifications delivered by the company that leads the compliance services industry.

Quality Assurance and Regulatory Compliance are Essential to the Success of Your Business

The Agilent 280-DS and Enterprise Edition services combine to form a powerful solution for dissolution system qualification. Measurement data captured by the 280-DS is entered directly into the patented Agilent Automated Compliance Engine (ACE) software to improve efficiency and ensure data integrity and traceability. Agilent Enterprise Edition harmonizes qualification protocols, streamlines compliance management and increases confidence

that you're audit-ready. The single-protocol Enterprise Edition approach ensures consistent and accurate verification of system performance to simplify qualification and minimize risk. Our all-electronic, paperless compliance delivery solution is compatible with US FDA 21 CFR Part 11 requirements for electronic signatures. And Enterprise Edition built on ACE provides reliable instrument qualification that's fully compliant with GMP predicate rules. ACE ensures adherence to protocol – so we deliver what you approve – and is flexible to integrate fully into your company's SOPs.

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.

DDG DISSOLUTION DISCUSSION GROUP

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Dissolution Resources

Reference Links

Recent Posts

Stella,
Please find an article I wrote on PVT, it pertains to the previous lot, but it should hold true for the current lot as well.
http://www.chem.agilent.com/Library/...e_Paper_D1.pdf
New USP Lot - Q0H398
KBoda Today, 08:09 AM

Dear All,
Good evening, We have also tested this new lot and one of our instruments failed all 3 times we performed the dissolution (two times)
New USP Lot - Q0H398
stella Today, 07:43 AM

DISSOLUTION DISCUSSION GROUP (DDG)

Free DDG Online Meeting: The Role of Dissolution in Quality
Published on 03-28-2012 08:23 AM
Categories: Meetings

The Dissolution Discussion Group is pleased to announce the next free DDG Online Meeting, *The Role of Dissolution in Quality*.

In 2011, we transitioned our meeting approach from face-to-face meetings to the online format to better accommodate your schedules and travel restrictions due to leaner economic times. Our content remains rich and covers the latest regulatory issues affecting dissolution and dosage testing.

Register today for this FREE online meeting.

Date and Time: Thursday, May 24th, 2012
10:30 am
Eastern Daylight Time: New York, GMT-04:00

DDG Online Meeting Recordings/Replays
Published on 12-21-2011 09:32 AM

If you could not participate in our online meetings, free recordings/replays of each meeting are available. We will keep this list up to date as more meetings are offered:

- February 16th, 2012: The Dissolution Method Transfer
- November 17th, 2011: The Dissolution Laboratory Audit
- August 18th, 2011: Do f1 and f2 Tell the Whole Story?
- May 19th, 2011: Best Practices for Success with the USP Dissolution Performance Verification Test (PVT)
- March 15th, 2011: Mechanical Calibration: ASTM vs USP; Impact of ICH on Dissolution; QBD and PAT

Visit www.dissolution.com to register and discuss dissolution issues with industry peers and experts.

Learn more

www.agilent.com/lifesciences/280-DS

Find an Agilent customer center

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