Agilent 708-DS Dissolution Apparatus

BETTER DESIGN, BETTER RESULTS

Agilent Technologies

THE NEW STANDARD

In collaboration with global pharmaceutical customers, Agilent has developed a platform that establishes the standard for dissolution instrumentation: the 708-DS Dissolution Apparatus. Simply put, this instrument offers you the flexibility to handle all of your Apparatus 1, 2, 5, and 6 testing needs. The modular design allows you to handle manual sampling, and with additional accessories, modify your instrument for fully automated sampling.

Conforming to internationally harmonized pharmacopeia specifications for Apparatus 1 (basket) and Apparatus 2 (paddle), the 708-DS can easily test tablets, capsules, or a variety of other dosage forms. The 708-DS also meets regulatory standards for Apparatus 5 (paddle over disk), Apparatus 6 (rotating cylinder), and intrinsic configurations. The flexible design allows a variety of vessel sizes to be used; the adjustable manifold can be configured for any of the vessel diameters.

Tailored to Your Needs

The 708-DS Dissolution Apparatus features a smooth-operating, motorized lift for reproducibility and integration with automated systems. Easily configure your apparatus with features that meet your laboratory requirements:

- Media temperature monitoring (AutoTemp)
- Dosage delivery (DDM)
- Automated sampling
- Variety of vessels, baskets, paddles, and shafts
- Integrated printer

Agilent 708-DS Dissolution Apparatus

Enhancements for Improved Performance

Sampling

- **Manual** – Accessibility to your vessels is important when sampling manually. The apparatus' recessed drive unit provides vertical and horizontal accessibility, offering clearance from the vessel plate and simplifying manual sampling through the evaporation cover port. A manual sampling bracket can be added to ease sample removal and ensure sampling position consistency from test to test. This option can be used with the automated manifold or resident probes.
- **Automated** – The automated sampling manifold and depth presets in the firmware manage hands-free sampling automatically. This provides precise non-resident sampling in a repeatable manner for each test. Agilent also offers resident cannula kits for the 708-DS to support your existing dissolution methods.

Temperature Monitoring

- **Handheld Probe** – Verify and automatically record media vessel temperature as needed with the easy-to-use, optional temperature probe. Individual temperatures can be measured and printed before, during, and after each dissolution test.
- **Precise In-vessel Monitoring** – Focus on other laboratory tasks while the optional AutoTemp feature accurately monitors and documents media temperatures. The individual vessel values may be documented initially, at each pre-programmed time point, and after the test has concluded.

Workflow Enhancements

- Perform other laboratory tasks while your media heats. Upon reaching the preset temperature, the AutoTemp feature:
  - Can notify you to begin a manual test or the automated start function initiates the method.
  - Prompts the optional DDM to deliver the dosage form (for Apparatus 2).
  - Uses non-resident probes to monitor and record vessel media temperature at pre-programmed timepoints.
  - Documents initial and final temperatures for accurate recordkeeping.
- Meet regulatory guidelines and ensure maximum productivity. The Autosampling option, in combination with the Agilent 850-DS Dissolution Sampling Station or online UV dissolution system:
  - Lowers the sampling cannulas into the media and withdraws samples at a programmed depth (based on vessel size, apparatus installed, and media volume), ensuring reproducibility.
  - Enables completely unattended dissolution testing when used with the AutoTemp and DDM options.

Top to bottom: manual sampling, resident sampling and automated non-resident sampling options.

DESIGNED FOR ULTIMATE FLEXIBILITY

With versatility in mind and years of industry expertise to draw from, Agilent has delivered an unrivaled range of features to enhance your dissolution experience. A variety of standard and optional features contribute to the superior performance of the 708-DS Dissolution Apparatus.

Apparatus Features and Options		708-DS	
		Standard	Optional
1	Color touchscreen for easy interaction and real-time feedback	●	
2	Storage of up to 40 dissolution methods	●	
3	Shaft locking collar to maintain stable height settings	●	
4	Real-time display of instrument status	●	
5	Motorized manifold to control precise sampling location		●
6	Split covers to minimize evaporative loss and simplify cleaning	●	
7	Ring indicator for repeatable vessel orientation	●	
8	Interchangeable shafts with Certificates of Conformity (COC)	●	
9	Vibration dampening feet for limiting environmental impact	●	
10	Bench saving isolated heater/circulator with energy-save control	●	
11	Angled water bath for complete draining and cleaning	●	
12	Quick-connect water bath drain to simplify bath emptying	●	
13	TruAlign vessels – available in 100, 200, 1000, and 2000 mL	●	
14	Automated Dosage Delivery Module (DDM)		●
15	In-vessel Temperature Monitoring (AutoTemp)		●
16	Sampling bracket for simplified, repeatable manual sample removal		●
17	User levels for controlled instrument access	●	
18	Alarms for sampling and periodic maintenance	●	
19	Automated sampling using the 850-DS Dissolution Sampling Station		●
20	Built-in printer for dissolution test documentation		●

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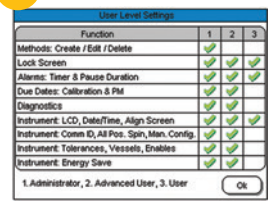

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IMPROVING THE DISSOLUTION WORKFLOW

The 708-DS Dissolution Apparatus is perfect for manual sampling as well as varying levels of automation. With automated dosage delivery, precise sampling position control, and temperature monitoring, it's easy to increase productivity and reduce analyst variability through an automated, repeatable sampling solution.

Manual Dissolution Testing

Increased method storage and easy sampling through evaporation covers make manual sampling easy with the 708-DS.

Attach the convenient manual sampling bracket for easy, repeatable sampling (for use with the motorized manifold or resident probes).

The Dosage Delivery Module (DDM) can be activated manually or automatically for convenient, repeatable dosage form introduction.

The 708-DS supports small and large vessel volumes in manual, semi-automated and online system solutions.

Semi-Automated Dissolution Testing

The 850-DS Dissolution Sampling Station includes an integrated syringe pump, media replacement, and optional filtration capabilities of 0.2 or 0.45 µm.

- Automate sampling and filtration using the 850-DS Dissolution Sampling Station and optional filtration module.
- Reduce variability and improve sample throughput efficiency.
- Collect samples into test tubes, HPLC vials or well plates for subsequent analysis.
- Eliminate manual vial transfer using Agilent HPLC sample trays.
- Enhance compliance and go paperless with the Dissolution Workstation Software.

Online Dissolution Testing

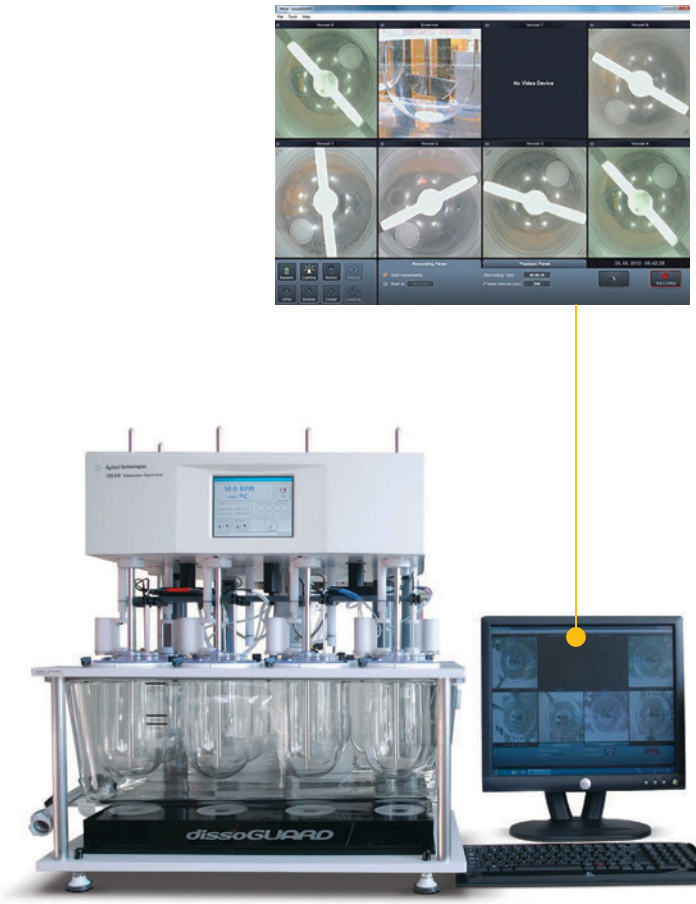
The Cary 8454 or Cary 60 UV-Vis Spectrophotometer can be utilized with the 708-DS in an online UV dissolution system, depending on your analytical preference.

- The Cary 8454 UV Dissolution System can control up to 4 dissolution apparatus, and enable multicomponent analysis with powerful UV ChemStation software.
- The Cary 60 Spectrophotometer can be coupled with the 850-DS for sample archival or offline HPLC sample collection in a single- or dual-system flow cell setup.
- Select fiber optic capabilities for enhanced dissolution profiles and *in situ* dissolution sample analysis.
- Automated calculations and report generation options enhance compliance and efficiency, all from a single-source provider.

SIMPLIFIED VIDEO SURVEILLANCE WITH DISSOGUARD®

Agilent offers a unique hardware and software package to upgrade any 708-DS for video surveillance. The dissoGUARD system contains multiple cameras mounted in a single enclosure placed beneath the water bath to provide an unobstructed view of the dosage form in the vessels. This space-saving design eliminates individual cameras being placed all around the apparatus. A single external camera is also provided for another viewing perspective.

The importance of visual observation during a dissolution run is well documented. Visibility into the vessel permits the analyst to assess the initial disintegration or physical characteristics of the dosage form during the dissolution process. This surveillance is performed by dissoGUARD, relieving analysts from having to constantly view and manually record their observations. The dissoGUARD software provides a real-time view of what is happening, along with preset recording options. The videos or snapshots can then be marked with key events such as dosage introduction, sampling, or unusual behavior, and exported for later viewing or storage.



Video surveillance with dissoGUARD is ideal for:

- Ensuring the dosage form was introduced
- Verifying the dosage form is in the correct location (center or off-center)
- Hydrodynamics within the vessel
- Particle behavior
- Proper deaeration of dissolution media
- Vessel visibility of light-sensitive products
- Sampling time and position
- Aberrant data investigation
- Documentation of uncharacteristic behavior

Not only does dissoGUARD record events, but it can also provide information regarding key physical parameters such as RPM, vessel-to-shaft centering and wobble. The dissoGUARD Pro software alerts the user of any abnormal status of these parameters during a test, preventing lost time and aiding in eventual failure investigations. An innovative lighting system using white/red LEDs allow for observation of light-sensitive products as well.

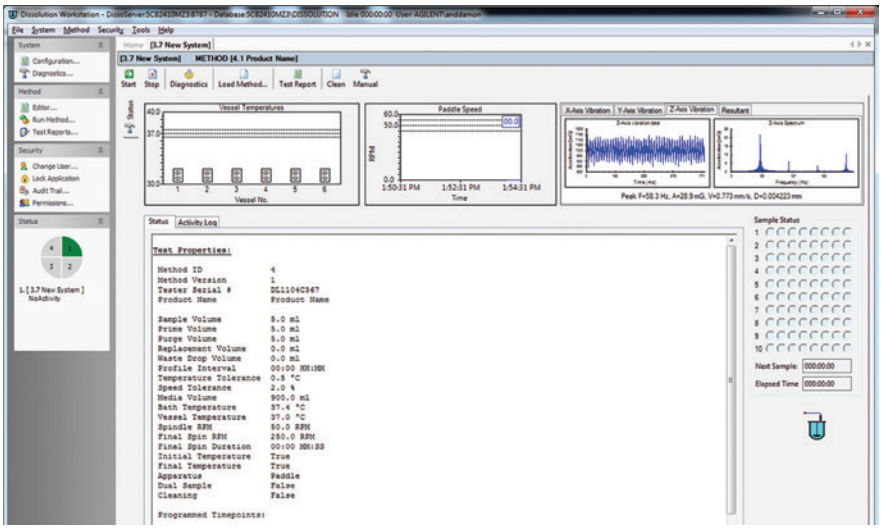
DISSOLUTION WORKSTATION SOFTWARE

Agilent's Dissolution Workstation Software provides complete, integrated control of multiple dissolution systems from a single computer.

Dissolution Workstation Software integrates the 708-DS with automated sampling components, allowing you to simultaneously control up to four systems of any configuration from a desktop PC. This software provides a mechanism for the user to build, edit, search, retrieve, and archive all dissolution methods and test reports from a single interface.

Dissolution Workstation Benefits

- **Timesaving** – Consolidate and maintain your dissolution systems, methods and data in one paperless, centralized database, with various options of exporting information.
- **Compliant** – Be confident knowing the software provides a continuous activity log for the method in use, along with audit trails of method and/or configuration changes for a 21 CFR Part 11 compliant environment.
- **Secure access and organization** – Protect your data using integrated Microsoft® Windows® security. The software includes features designed for easy data export and LIMS or electronic notebook integration.
- **Vibration monitoring** – Record trends related to environmental impact and assist with failure investigation by using the Instrument Module (IM) of the 280-DS Mechanical Qualification System.



Use the 280-DS Instrument Module and Dissolution Workstation Software to monitor vibration during your dissolution tests. Learn more about qualification with the 280-DS at www.agilent.com/lifesciences/280-DS.

DESIGNED TO ENSURE COMPLIANCE

Dissolution results should be based on the performance of the dosage form and should not be impacted by environmental factors. The 708-DS has been designed to minimize or eliminate variability. Regulatory requirements suggest performing either an enhanced mechanical qualification (MQ) or a verification of the physical parameters coupled with the USP Performance Verification test (PVT). The 708-DS was engineered along with the patented 280-DS Mechanical Qualification System (MQS) to simplify the qualification system.

The Agilent 280-DS MQS easily verifies all physical parameters. The accompanying software prompts the user through each measurement with easy-to-follow instructions. Once the vessel module is installed, innovative sensing technology enables hands-free, non-contact measurements with no guesswork involved; the values are automatically recorded in a fraction of the time routinely associated with this procedure.

Access to the vessel is critical to inserting the vessel module. The sampling manifold is easily removed; the evaporation covers slip off and the head is moved with the touch of a button. Once inserted in the vessel, no further adjustment is required to measure all the parameters for that particular position.

To make it easy to perform the qualification, the 280-DS can be integrated with any Windows-based laptop. The software takes control of the 708-DS, eliminating the need to manually activate rotation for spindle speed, wobble, or vibration measurements.

Visit Agilent.com or speak with your Agilent representative for more information about the 280-DS MQS.

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.

280-DS Instrument Module

- Level
- Vibration
- Temperature

280-DS Vessel Module

- Spindle speed (RPM)
- Basket/shaft wobble
- Basket/paddle height
- Vessel-to-shaft centering
- Vessel verticality
- Shaft verticality

YOUR LABORATORY PARTNER

Service and Qualification

Focus on what you do best and let Agilent's experienced, well-trained engineers and chemists provide you with installation and familiarization, hardware and software training, and complete qualification services.

We can develop a service offering that meets your specific needs for:

- Instrument maintenance and repair
- Regulatory compliance
- Software and data systems
- Training and educational services

Dissolution Exchange

Learn. Solve. Discuss.

Agilent's Dissolution Exchange provides a one-stop repository of links to current industry information and guidance:

- Free, online dissolution 1-on-1 self-paced training with assessment and certification
- Dissolution Discussion Group (DDG): free dissolution peer network
- Resources: webinars, white papers, posters, newsletters, and articles
- Contacts for dissolution-related questions, instrument selection, qualification, method development, and more

www.agilent.com/chem/dissolution

Agilent CrossLab

From Insight to Outcome

Agilent CrossLab combines the innovative laboratory services, software, and consumables competencies of Agilent Technologies and provides a direct connection to a global team of experts who deliver vital, actionable insights at every level of the lab environment. Our insights drive improved economic, operational, and scientific outcomes.

www.agilent.com/crosslab

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