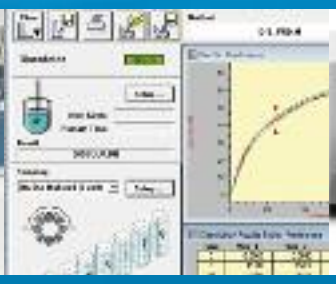
Dissolution Testing and Analysis

DISSOLUTION SYSTEMS SOURCE BOOK

2014-2015 Edition

The Measure of Confidence


Agilent Technologies


Agilent Technologies
Certificate of Conformance

Welcome

Agilent Technologies, Inc. is well known within the pharmaceutical community for its broad portfolio of instruments and supplies, and now offers a variety of dissolution and pharmaceutical testing equipment. Agilent's unique position as a leader in analytical instruments allows us to meet all your needs for equipment, software and reporting packages, qualification documentation and services, training and post-sale support – anywhere you operate around the globe.

The latest edition of the Dissolution Source Book provides a detailed view of this portfolio, including dissolution apparatus, automated systems, calibration and verification tools, dissolution software, analytical UV-Vis and HPLC integration and physical testing. Here you will find in-depth product descriptions, regulatory information, useful tips, specifications and ordering details for thousands of Agilent dissolution products.

Agilent chemists are always available to assist you with dissolution questions. Contact our Dissolution Hotline at **dissolution.hotline@agilent.com**. More information is available by visiting **www.agilent.com/lifesciences/dissolution** or by contacting your local Agilent representative.

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Market Solutions

Agilent Solutions for the Pharmaceutical Industry

About Agilent

Agilent Technologies is the world's premier measurement company. Through the company's acquisition of Varian, Inc. in 2010, we expanded our already extensive product portfolio for the pharmaceutical industry. The former VanKel Technology Group, which Varian acquired in 2001, offered many instruments for testing and evaluating pharmaceutical dosage forms including dissolution and disintegration. These products and accessories are now fully integrated in the worldwide Agilent distribution network.

Agilent's history spans back to 1939 when Bill Hewlett and Dave Packard started HP and helped shape the technology industry from what is now Silicon Valley in California. Agilent began operating in 1999 as an independent company, but retained the historical HP commitment to innovation and contribution, uncompromising integrity, teamwork, trust and respect for the individual.

Practical Solutions for Pharmaceutical Testing

With a rich history in supporting the pharmaceutical industry, Agilent offers solutions for drug discovery, development and manufacturing. The addition of the dissolution business furthers Agilent's support of the pharmaceutical industry through a portfolio of leading dissolution instrumentation and services. Being part of a company that provides the leading UV-Vis and HPLC solutions to the pharmaceutical industry allows us to offer complete workflow solutions, from dissolution apparatus, sampling devices, analytical instruments and the software to control them.

We manufacture dissolution instrumentation to test nearly every dosage form produced. Our staff of application chemists can assist you in selecting the right apparatus and accessories for your method. Whether in R&D or QA/QC, when it comes to analyzing those samples, we offer industry leading UV-Vis technology through the Cary 60 and Cary 8454 spectrophotometers. We can help you automate your workflow with offline or online solutions. Should your methodology require HPLC analysis, we have you covered there as well. The Agilent 1200 LC Series, with its flexible, modular design, ensures configurations ideally suited to meet your application requirements.

Workflow Enhancements

We strive to provide solutions for every type of dissolution user, from routine applications to early drug development. Our equipment is designed to be easy to use, flexible and modular in nature. As the workload increases, we offer greater degrees of automation, both in the dissolution test run and sample collection as well as the data analysis and reporting. Purchasing a dissolution system from Agilent ensures you have one vendor to turn to should you have questions or require assistance, so you have less downtime and better utilization of your equipment.

Quality

At Agilent, we believe that our customers define quality. They do this every day with the products and services they purchase. Customers buy based on perceived value – that is, they measure the benefits against the costs and select the product and experience that provides superior value. We, therefore, define quality as customer-perceived value.

Agilent products are designed to meet or exceed current published pharmacopeia, as well as FDA and ASTM, requirements at the time of manufacture. Our goal is to supply you with the highest quality pharmaceutical testing solutions on the market. Agilent's quality management system provides you the assurance that our company has the requisite quality system in place to support your activities around the globe.

More Than Great Products

Quality equipment is just one component of your work. We believe education is critical to ensuring correct results. For this reason, we offer numerous educational programs geared to various functions within your company. See page 168 for more information.

Agilent Technologies Quality Policy

Agilent will earn customer loyalty by providing products, services and interactions of the highest quality and greatest value. To achieve this result, we will:

1. Ensure that all of our products comply with applicable safety and regulatory requirements.
2. Ensure our products meet or exceed their published specifications.
3. Maintain and continually improve the effectiveness of our product and service business management systems to conform at a minimum to ISO 9001 Quality Management Standard or more stringent or legally required standards as dictated by specific markets.
4. Continually monitor and improve customers' total experience.
5. Establish quality requirements for suppliers, partners and contractors and hold them accountable to comply.
6. Treat customers in accordance with Agilent's Standards of Business Conduct and Privacy policies.

The Agilent Service Advantage: Helping You Focus On What You Do Best

Agilent brings a worldwide network of highly skilled, experienced professionals committed to your success. Our factory-trained field service engineers combine regulatory training along with product maintenance and support knowledge to properly install and qualify your dissolution apparatus. Whether it is Installation or Operational Qualification (IQ/OQ), Performance Verification Testing (PVT, or PQ), or Mechanical Qualification (MQ), we can assist you with initial installations or routine qualification services. We offer customized service agreements based on your specific needs and supported by one of our 65 global service centers.

Industry Information

Apparatus, Pharmacopeia and Regulatory Affairs Overview

The design of dissolution apparatus is specified by the various pharmacopeias from around the world. In addition, both the FDA and ASTM have called for tighter mechanical specifications. The apparatus is routinely operated in facilities regulated by federal agencies, such as the US Food and Drug Administration, which require laboratories to operate under good manufacturing practices (GMPs).

Agilent's dissolution apparatus are developed to operate under GMP environments which require installation, operational, and ongoing performance or mechanical qualifications to verify that the systems are operating as intended. Agilent offers extensive documentation and services that provides full instrument qualifications, including the most recent guidance on mechanical qualification of dissolution apparatus.

We provide the instruments and accessories to test essentially all types of dosage forms, including tablets, capsules, semisolids, transdermal patches, microspheres, implants, etc. Our equipment is designed to easily work with immediate, modified, delayed or extended release products. Our designs adhere to the compendial guidelines. We also offer some non-compendial designs when the traditional methodologies are not suitable for some unique drug release characteristics.

For more regulatory information from the world's pharmacopeias and international pharmaceutical agencies, visit: **www.agilent.com/lifesciences/regulatory_disso**

Applications and Testing Capabilities of Agilent Dissolution Apparatus

Dissolution Apparatus	Description	Common Products Types
Stirred Vessel Methods – The basket and paddle dissolution apparatus are the most commonly used throughout the world. These methods traditionally require the placement of individual dosage forms into 1L glass vessels containing a fixed volume of fluid referred to as dissolution medium.		
Agilent 708-DS and 709-DS Dissolution Apparatus for Rotating Basket (USP Apparatus 1)	Shaft with attached mesh basket fabricated from 316 stainless steel; the dosage form is contained within the basket, lowered into media and rotated typically at 50-100 rpm.	• Capsules • Tablets • Floating dosage forms • Modified release products • Beads • Suppositories
Agilent 708-DS and 709-DS Dissolution Apparatus for Rotating Paddle (USP Apparatus 2)	Paddle blade fixed to the bottom of a shaft fabricated from 316 stainless steel or PTFE coating; the dosage form is introduced directly to the media and the shaft is rotated typically at 50-75 rpm.	• Tablets • Capsules • Hydrogels • Powders • Suspensions • Microparticles
Agilent 708-DS and 709-DS Dissolution Apparatus for Paddle over Disk (USP Apparatus 5)	Rotating paddle apparatus (above) with the addition of a transdermal system attached to a stainless steel screen and ring assembly; placed at the bottom of the vessel.	• Transdermal patches
Agilent 708-DS and 709-DS Dissolution Apparatus for Rotating Cylinder (USP Apparatus 6)	Rotating dissolution apparatus that utilizes a rotating cylinder upon which a transdermal patch is placed; cylinder provides mixing by convection principles.	• Transdermal patches
Reciprocating Methods – The dosage form is placed within a chamber through which media flows in alternating directions, or on/within numerous holders specifically designed for novel extended release dosage forms. The cylinders or holders typically reciprocate in 300 mL vessels although both larger and smaller outer vessels are available.		
Agilent BIO-DIS Reciprocating Cylinder Apparatus (USP Apparatus 3)	Mimicking the pH changes of the GI tract, glass cylinders containing the dosage form between capped screens of varying mesh sizes reciprocate 10 cm within 300 mL vessels containing media for a designated time period before the dosage form is transported to another row of media (six rows are available).	• Capsules • Beads • Chewables • Veterinary products • Enteric coated products • Extended, modified or sustained release formulations
Agilent Reciprocating Holder Apparatus and 400-DS Dissolution Apparatus (USP Apparatus 7)	Holders designed for sustained or extended release, including small-volume products, reciprocate through a distance of 2 cm in volumes ranging from 300 mL to 3 mL per sample row or time point.	• Transdermal systems • Osmotic pumps • Implants • Drug-eluting stents • High-potency, low-dose systems
Alternative Applications – Additional configurations were developed to provide drug release information for the API and topical formulations.		
Agilent Intrinsic Apparatus	Stainless steel die containing a pellet of pure drug substance with a constant surface area to determine the intrinsic dissolution rate; used in early drug development for API characterization.	• Pure drug substances
Agilent Enhancer Cell for Diffusion Cells Testing	Cells consists of a chamber containing dosage form with synthetic or natural membrane representing skin to test biorelevance using small-volume vessels and miniature paddles.	• Ointments • Creams • Gels • Transdermal
Agilent Peak Vessel	The Peak Vessel contains an inverted peak in the base of the vessel to displace disintegrated particles in the unstirred zone, preventing cone formation.	• Beads • Products exhibiting coning problems

Apparatus 1, 2, 5, 6 and Intrinsic

708-DS Dissolution Apparatus

Agilent 708-DS Dissolution Apparatus

The 708-DS Dissolution Apparatus now features many new enhancements, solidifying our commitment to provide an ideal platform for laboratories to standardize their dissolution testing. This instrument is designed to deliver consistent performance and results while conforming to current internationally harmonized pharmacopeial specifications for basket, paddle, rotating cylinder, paddle over disk and intrinsic dissolution tests.

The instrument's versatile dissolution platform can be configured for your needs today as well as tomorrow. The intelligent design accommodates all requirements from basic manual testing to automated configurations for high-throughput sampling and online analysis. The 708-DS is designed to be easily configured to accommodate a variety of vessel sizes and accessories based on the dosage form being tested. The apparatus allows for advanced usage options including automated dosage delivery, in-vessel temperature monitoring, automated sampling and in situ fiber optic analysis. The 708-DS comes in an 8-position configuration, and can be used for either 6- or 8-position testing based on your application.

See the 708-DS and 709-DS in Action!

View the electronic demo and find out how your laboratory can be more productive!
www.agilent.com/lifesciences/dissolutiondemo

Interactive Demo: 708-DS and 709-DS Dissolution Apparatus

Hands-free evaporation cover suspension supports easy media addition.

Providing a new standard for reliability and reproducibility in dissolution testing, the rugged platform conforms to either the USP Performance Verification Test (PVT) or the most rigorous enhanced mechanical qualification (MQ) standards as recommended by the ASTM and US FDA. The advanced design serves to minimize or eliminate variability, allowing for monitoring subtle changes attributed to dosage forms, not the dissolution apparatus. In fact, particular attention was given to simplifying the measurement of critical parameters, allowing for optimal alignment while minimizing vibration.

- Flexible sampling options: easy access to all vessels ensures quick, simple manual sampling through the evaporation cover. or the convenient manual sampling bracket. Alternatively, automate your sampling using the programmable, hands-free manifold and the 850-DS Dissolution Sampling Station.
- Accurately measure and record individual vessel temperatures manually with the handheld temperature probe or automate this process with AutoTemp.
- Automate your dosage delivery with the Dosage Delivery Module (DDM), or introduce samples manually with helpful on-screen prompts through the evaporation cover port. Using the DDM feature allows you to precisely drop samples simultaneously or sequentially at a predetermined interval.
- Customize your instrument with interchangeable dissolution accessory components, including paddles, baskets, rotating cylinder, and small-volume mixing options. The common upper shafts support interchangeable baskets and paddles, yet maintain the correct height to save time when switching configurations.
- Easily navigate the touch screen panel to setup, store and operate up to 40 methods on the easy-to-read color display. The intuitive interface with screen-locking security features also offers multiple languages, including English, Spanish, Japanese, Hungarian, Russian and Chinese.

Newly-added 708-DS Enhancements

- Expanded method storage
- Power saving function
- User access levels
- Visual guidance for manual dosage introduction

- Hands-free evaporation cover suspension offers a simple way to add media to the vessels, place dosage forms in the vessel, manually sample and measure physical parameters. The evaporation covers automatically travel with the apparatus drive unit using either the alignment posts or DDM assemblies.
- Ensure proper vessel alignment with the 708-DS's TruAlign vessel. The incorporated collar allows for better centering and vessel verticality than traditional glass-lipped vessels. There is an indicator tab on the collar allowing for greater reproducibility for every test.
- Decrease cleaning time with the quick-connect fittings and angled water bath that supports complete draining.
- The heater/circulator is freestanding to minimize vibration. The self-priming unit is quiet and designed to fit beneath the base plate in order to conserve valuable bench space.
- Conserve energy by programming an automatic sleep schedule for the heater/circulator when not in use.
- Control access and prevent unwanted changes to instrument settings and methods with the different user levels provided by the 708-DS firmware.
- The 708-DS is designed to accept 100 and 200 mL vessels (with optional conversion kits), the 250 mL Chinese Pharmacopoeia vessel, and standard 1L vessels. The 2L model can incorporate a 2L vessel as well as the smaller sizes.

21 CFR Part 11 Compliance

Agilent's Dissolution Workstation Software provides control of up to four dissolution apparatus from one PC. This software can operate any Agilent dissolution apparatus and sampling systems, as well as systems from Varian and VanKel. See page 86 for more information about the Dissolution Workstation Software.

Designed with Compliance in Mind

The recessed head with unobstructed access on the 708-DS makes setting and verifying physical parameters easier than ever, which is especially critical for Mechanical Qualification.

Agilent has not only raised the standard for dissolution instrumentation with the 708-DS, but the 280-DS Mechanical Qualification System simplifies the apparatus qualification procedure. Our solution also includes the traditional AIQ compliance services and electronic documentation consisting of IQ, OQ, PQ and/or MQ using Agilent's ACE software platform. In addition to these traditional offerings, Agilent provides training and familiarization, SOP templates and guidance, educational seminars, technical and application related support, and much more.

Online Dissolution and Analysis

Modular detection and automation components can easily be integrated to accomplish a UV analytical finish during dissolution testing. Agilent offers online UV Dissolution capabilities with the Cary 8454 and Cary 60 UV-Vis Spectrophotometers with either multicell or fiber optic configurations. See page 96 for more details.

Multicell UV Dissolution System, including the 708-DS Dissolution Apparatus, 850-DS Dissolution Sampling Station and Cary 60 UV-visible Spectrophotometer.

Did You Know?

When recording the physical parameters of the dissolution apparatus, during Mechanical Qualification, for example, it is important to measure parameters with the actual shafts and vessels used when performing the dissolution tests. Record the accessory serial numbers and position within the apparatus.

Agilent's 708-DS and 709-DS do not require the use of surrogate shafts or vessels to perform these measurements during an OQ, PQ, or MQ.

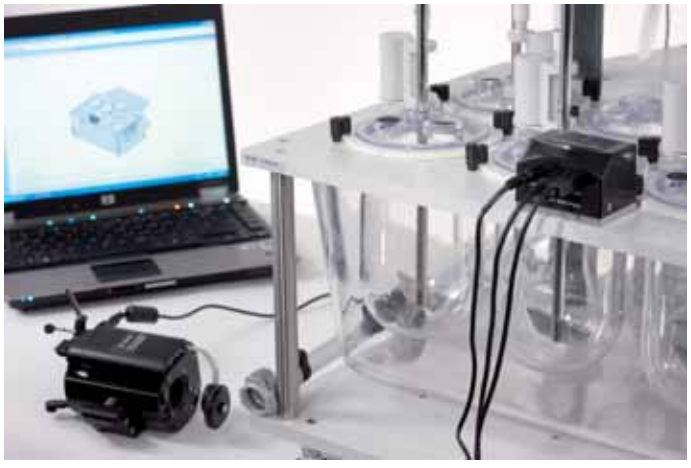
Standard 708-DS Configuration

Because the 708-DS is designed for configurability, you have the ability to select the exact options you need for your instrument. A standard 708-DS includes:

- 708-DS Dissolution Apparatus
- Vessel plate level adjustment tools
- Receptor shafts with locking collars (6 or 8)
- Evaporation covers (6 or 8)
- Verified basket / paddle shafts and height setting devices
- Baskets (6 or 8)
- Vessels (6 or 8)
- Level
- Heater / circulator
- Safety manual and technical documentation CD

Optional features include:

- Dosage Delivery Modules (DDM)
- AutoTemp In-vessel Temperature Monitoring
- Autosampling with automated manifold
- Low actinic - red vessels / evaporation covers
- Individually verified vessels and baskets
- VF molded vessels
- Built-in printer



Take physical parameter measurements on the 708-DS using Agilent's 280-DS Mechanical Qualification System. See page 90 to learn more about the 280-DS.

Dosage Delivery Modules (DDM)

Dosage Delivery Modules

Equip your 708-DS or 709-DS with DDM to simplify dropping your dosage form when using paddles. Methods can be programmed to automatically start simultaneously or sequentially. The DDM option saves analyst time and prevents costly timing errors. This feature is especially valuable when automated sampling systems are configured. See page 21 for information on the 709-DS.

708-DS Dissolution Apparatus Bundles

In order to simplify ordering, product numbers are available for the most common 708-DS configurations. Each bundle includes a 708-DS, 1-Liter TruAlign clear glass vessels, interchangeable paddle and basket shafts, and baskets. Options to further customize each apparatus by adding or deleting various options give you the flexibility to support your specific testing needs.

Equip your 708-DS with DDM to simplify dropping your dosage form when using paddles. Other options to consider are AutoTemp, sampling manifold, verified components, and optional built-in printer. Should you have any questions about configuring your apparatus, contact your local Agilent representative or contact us directly via our Dissolution Hotline at **dissolution.hotline@agilent.com**.

708-DS Dissolution Apparatus, 6-position

Description	Part Number
708-DS Dissolution Apparatus, 1L, 6-position	G7910A
Includes Printer, Handheld Temperature Probe, 1L Vessels, Interchangeable Verified Electropolished Paddle and Basket Shafts, Baskets, Evaporation Covers and complete accessories for 6 positions.	
Options for G7910A	
Dosage Delivery Modules (DDMs)	G7910A #101
DDMs and sampling manifold	G7910A #102
DDMs, sampling manifold and temperature monitoring	G7910A #103
Sampling manifold without temperature monitoring	G7910A #104
Sampling manifold with temperature monitoring	G7910A #105
Note: Only one (1) selection may be chosen from options #101-105 for G7910A (not a required selection).	
Low actinic - red evaporation covers and vessels	G7910A #110
Delete handheld temperature probe	G7910A #115
Delete basket shafts and baskets	G7910A #120
Delete paddle shafts	G7910A #125
PTFE-coated paddle shafts	G7910A #126
PEEK paddles	G7910A #127
Note: Only one (1) selection may be chosen from options #125-127 for G7910A (not a required selection).	
VF molded vessels	G7910A #130
708-DS Dissolution Apparatus, 2L	G7910A #140
Verified accessories	G7910A #145
Delete 708-DS printer	G7910A #890

Did You Know?

Agilent's 708-DS can also support transdermal testing using USP Apparatus 5 and 6 accessories. This includes setup and storage of precise sampling manifold locations in the firmware based on vessel volume and the assembly installed. The 708-DS is easily converted to smaller volumes typically associated with transdermal testing as well. See page 32 for information about 708-DS volume conversion kits, and page 59 for more on Apparatus 5 and 6.

708-DS Dissolution Apparatus, 8-position

Description	Part Number
708-DS Dissolution Apparatus, 8-position	G7911A
Includes Printer, Handheld Temperature Probe, 1L Vessels, Interchangeable Electropolished Paddle and Basket Shafts, Baskets, Evaporation Covers and complete accessories for 8 positions.	
Options for G7911A	
Dosage Delivery Modules (DDMs)	G7911A #101
DDMs and sampling manifold	G7911A #102
DDMs, sampling manifold and temperature monitoring	G7911A #103
Sampling manifold without temperature monitoring	G7911A #104
Sampling manifold with temperature monitoring	G7911A #105
Note: Only one (1) selection may be chosen from options #101-105 for G7911A (not a required selection).	
Low actinic - red evaporation covers and vessels	G7911A #110
Delete handheld temperature probe	G7911A #115
Delete basket shafts and baskets	G7911A #120
Delete paddle shafts	G7911A #125
PTFE-coated paddle shafts	G7911A #126
PEEK paddles	G7911A #127
Note: Only one (1) selection may be chosen from options #125-127 for G7911A (not a required selection).	
VF molded vessels	G7911A #130
708-DS Dissolution Apparatus, 2L	G7911A #140
Verified accessories	G7911A #145
Delete 708-DS printer	G7911A #890

708-DS Dissolution Apparatus: 8-position, 2L model with motorized lift

Temperature Monitoring

Verify and monitor individual vessel temperatures prior to starting a test with the AutoTemp option, which records all the vessel temperatures at once, or via the handheld temperature probe to measure and record the vessel temperatures one at a time. When using the AutoTemp feature, once the set temperature is reached, the apparatus can initiate the test without analyst intervention.

Documentation Options

When configuring a system, consider what other equipment it will be integrated with in your laboratory. If you plan to include an 850-DS, there is no need to duplicate a printer on both instruments. If the 708-DS could also be used for manual sampling, you may include G7912A #880 to add this option. The thermal printers used with the 708-DS and 709-DS utilize a medical grade paper that lasts for more than 10 years!

The 708-DS Dissolution Apparatus can pair with Agilent sampling, pumping, filter and UV analytical instrumentation to create an automated solution for your laboratory. The 708-DS and 850-DS Sampling Station below provides an unattended, repeatable semi-automated solution for your laboratory. See page 96 for online UV dissolution options.

708-DS and 850-DS Sampling Station

Description	Part Number
708-DS Dissolution Apparatus and 850-DS Sampling Station	G7913A
Includes 708-DS Dissolution Apparatus with DDMs, sampling manifold, vessels, paddles, baskets, accessories and 850-DS Sampling Station with 16x100 mm sample tray.	
Options for G7913A	
Add temperature monitoring to 708-DS	G7913A #105
Low actinic - red evaporation covers and vessels	G7913A #110
Delete basket shafts and baskets	G7913A #120
Delete paddle shafts	G7913A #125
PTFE-coated paddle shafts	G7913A #126
PEEK paddles	G7913A #127
Note: Only one (1) selection may be chosen from options #125-127 for G7913A (not a required selection)	
VF Molded Vessels	G7913A #130
708-DS Dissolution Apparatus, 2L	G7913A #140
Verified accessories	G7913A #145
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7913A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7913A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7913A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7913A #213
Add Dissolution Workstation Software cable kit	G7913A #220
Note: Dissolution Workstation Software (G4974AA) or Software Bundle with PC (G9264AA) ordered separately (see page 86).	
Add 708-DS printer	G7913A #880
Add printer to 850-DS	G7913A #881

Need an Upgrade?

If you're looking to improve productivity and automate your 708-DS, an upgrade kit is available to add the components necessary. Contact your Agilent Service representative and reference part number K1002-02045 for more information.

708-DS Dissolution Apparatus – Upgrade Options

Description	Part Number
708-DS Dissolution Apparatus – Printer Option	
Thermal printer assembly, for use with 708-DS and 709-DS	K1005-05160
708-DS Dissolution Apparatus – Options	
708-DS/709-DS, manual kit, without DDM and alignment posts, 6-position	K1005-01871
708-DS/709-DS, manual kit, without DDM and alignment posts, 8-position	K1005-01876
708-DS/709-DS alignment post kit, without DDM, evaporation cover, 6-position	K1005-01872
708-DS/709-DS alignment post kit, without DDM, evaporation cover, 8-position	K1005-01875
708-DS/709-DS DDM kit, 6-position	K1005-01873
708-DS/709-DS DDM kit, 8-position	K1005-01874
708-DS/709-DS DDM kit, 8-position, for UV dissolution (6 DDMs)	K1005-01987
708-DS/709-DS alignment post kit, 7-position, for UV dissolution	K1005-01989
708-DS/709-DS DDM kit, 8-position, 200 mL standard, for UV dissolution (6 DDMs)	K1005-01990

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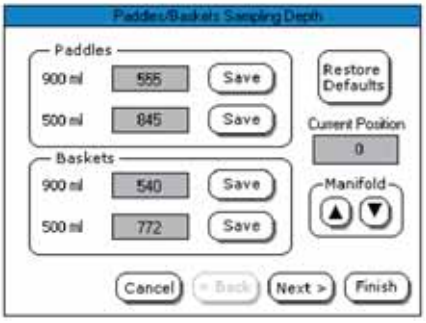
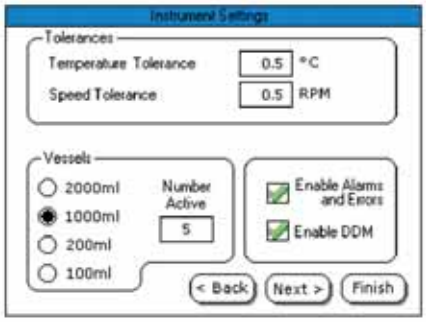


The ability to specify an exact depth for the manifold means that each sample is withdrawn from the same USP location within the dissolution vessel. This adds to the reproducibility and consistency for every test performed – a critical consideration for dissolution testing.



Specific settings and features within the 708-DS firmware – such as tolerances, vessel volumes and alarms – are easily adjusted to meet your laboratory's exact requirements.

Hydrodynamic Disturbances

Avoid hydrodynamic disturbances caused by resident dwelling probes. The sampling manifold only lowers the probes during sampling – lifting the probes between timepoints. By mimicking the manual procedure for sampling, the semi-automated system simplifies your method transfer and validation.

708-DS Dissolution Apparatus – Upgrade Options

Description	Part Number
708-DS Dissolution Apparatus – Motorized Manifold Options	
708-DS temperature kit, 6-position, 1L	K1001-01160
708-DS manifold, temperature only, 6-position, 1L	K1001-01177
708-DS manifold, temperature only, 8-position, 1L	K1001-01178
708-DS manifold, sampling only, 6-position, 1L	K1001-01171
708-DS manifold, sampling only, 8-position, 1L	K1001-01172
708-DS manifold, sampling/temperature, 6-position, 1L	K1001-01183
708-DS manifold, sampling/temperature, 8-position, 1L	K1001-01184
708-DS manifold, sampling only, 8-position, for UV dissolution	K1001-01197
708-DS manifold, sampling/temperature, 8-position, for UV dissolution	K1001-01198
708-DS manifold, 6-position, 1L, for Fiber Optic UV dissolution	K1001-01189
708-DS manifold, temperature only, 6-position, 1L, for Fiber Optic UV dissolution	K1001-01191
708-DS manifold, temperature only, 6-position, 2L	K1001-01181
708-DS manifold, temperature only, 8-position, 2L	K1001-01182
708-DS manifold, sampling only, 6-position, 2L	K1001-01175
708-DS manifold, sampling only, 8-position, 2L	K1001-01176
708-DS manifold, sampling/temperature, 6-position, 2L	K1001-01187
708-DS manifold, sampling/temperature, 8-position, 2L	K1001-01188
708-DS manifold, sampling only, 8-position, 2L, for UV dissolution	K1001-01199

(Continued)

Non-resident sampling cannulas in a TruAlign vessel on the 708-DS.

708-DS Dissolution Apparatus – Upgrade Options

Description	Part Number
708-DS Dissolution Apparatus – Motorized Manifold Options	
708-DS manifold, sampling/temperature, 8-position, for UV dissolution	K1001-01200
708-DS manifold, sampling only, 6-position, 100/200 mL	K1001-01173
708-DS manifold, sampling only, 8-position, 100/200 mL	K1001-01174
708-DS manifold, temperature only, 6-position, 100/200 mL	K1001-01179
708-DS manifold, temperature only, 8-position, 100/200 mL	K1001-01180
708-DS manifold, sampling/temperature, 6-position, 100/200 mL	K1001-01185
708-DS manifold, sampling/temperature, 8-position, 100/200 mL	K1001-01186
708-DS manifold, 6-position, 100/200mL, for Fiber Optic UV dissolution	K1001-01190
Resident sampling kit, 6-position, 900 mL	K1001-01193
Resident sampling kit, 8-position, 900 mL	K1001-01194
Resident sampling kit, 6-position, 500 mL	K1001-01195
Resident sampling kit, 8-position, 500 mL	K1001-01196
708-DS Dissolution Apparatus – Temperature Probe	
708-DS vessel temperature probe, handheld	K1005-01568

Manual temperature measurement using 708-DS temperature probe.

Apparatus 1 and 2 with Bath-free Technology

Agilent 709-DS Dissolution Apparatus

Using the same platform as the 708-DS, the 709-DS Dissolution Apparatus ensures productivity, reproducibility and ease of use combined with the convenience of a bath-free design. The 709-DS reduces media heating time with Direct Vessel Heating (DVH) capabilities while insulating the vessel from environmental factors and eliminating water bath cleaning.

The exclusive design of the chemically resistant, TruAlign DVH vessel incorporates cutting-edge heat-sensing technology in the vessel wall. The unique clear vessel coating offers protection from breakage and containment in the event the glass vessel is damaged. The coating also provides complete visibility of the dosage form within the vessel – a critical component of the dissolution test. The TruAlign vessel collar is fitted in the ground glass groove to ensure every vessel is perfectly centered and the collar is perpendicular to the vessel walls. The DVH controller resides in the rear of the apparatus and requires no additional bench space.

See the 708-DS and 709-DS in Action!

View the electronic demo and find out how your laboratory can be more productive!

www.agilent.com/lifesciences/dissolutiondemo

- The 709-DS can be used for either 6- or 8-position testing based on your application.
- Includes a manifold equipped with AutoTemp In-Vessel Temperature Sensing as standard to ensure each vessel temperature is individually measured and recorded prior to and during the dissolution run.
- Uses 1L DVH vessels and environmental chambers that prevent temperature fluctuations from external air sources such as air conditioning vents. The chambers also provide an added degree of protection in the event a vessel is damaged and the contents are spilled. Reflective bases at the bottom of each chamber enhance visibility of the dosage form.
- Supports testing of light-sensitive dosage forms with low actinic - red environmental chambers and evaporation covers.

709-DS Dissolution Apparatus

Custom basket used for preheating inside a DVH vessel

Bath-free Advantages: How Does it Work?

Each dissolution test performed with the 709-DS involves a preheat cycle to equilibrate vessel temperature. During this cycle, the DVH vessels are heated as the temperatures are monitored closely. Under typical test conditions, the preheat cycle is completed in approximately 10-15 minutes. The combination of DVH technology and the electronic intelligence built into the controller provides vessel temperature stability with ultimate precision.

Due to the unique method of controlling the temperature in the 709-DS, only the use of paddles or baskets is recommended. When using other accessories, such as a rotating cylinder, the temperature of the large metal surface may reduce the media temperature upon introduction of the dosage form. In these cases the recovery time is faster with the 708-DS, and for this reason, the 708-DS is recommended for use with USP Apparatus 6 and the intrinsic dissolution apparatus.

Standard 709-DS Configuration

Designed for configurability just like the 708-DS, the 709-DS offers the ability to select the exact options you need for your instrument. A standard 709-DS includes:

- 709-DS Dissolution Apparatus (6- or 8-position)
- Manifold with AutoTemp
- Vessel plate for level adjustment tools
- Receptor shafts with locking collars (6 or 8)
- DVH vessels and environmental chambers (6 or 8)
- Evaporation covers
- Verified basket / paddle shafts and height setting devices
- Baskets, USP 40-mesh (6 or 8)
- Level
- Safety manual and technical documentation CD

Optional features include:

- Dosage Delivery Modules (DDM)
- Autosampling cannulas
- Low actinic (red) evaporation covers and environmental chambers
- Verified accessories
- Built-in printer

709-DS Dissolution Apparatus, 6-position

Description	Part Number
709-DS Dissolution Apparatus, 6-position	G7915A
Options for G7915A	
Dosage Delivery Modules (DDMs)	G7915A #101
DDMs, sampling manifold and temperature monitoring	G7915A #103
Sampling manifold with temperature monitoring	G7915A #105
Note: Only one selection may be chosen from options 101-105 for G7915A. Manifold with AutoTemp is standard on the 709-DS.	
Delete basket shafts and baskets	G7915A #120
Delete paddle shafts	G7915A #125
PTFE-coated paddle shafts	G7915A #126
PEEK paddles	G7915A #127
Note: Only one selection may be chosen from options 125-127 for G7915A (not a required selection).	
Verified accessories	G7915A #145
Note: All Vessels, Paddles, Basket Shafts and Baskets ordered will come with individual certificates of conformance with this option.	
Delete 709-DS printer	G7915A #890

709-DS DVH vessel

709-DS Dissolution Apparatus, 8-position

Description	Part Number
709-DS Dissolution Apparatus, 8-position	G7916A
Options for G7916A	
Dosage Delivery Modules (DDMs)	G7916A #101
DDMs, sampling manifold and temperature monitoring	G7916A #103
Sampling manifold with temperature monitoring	G7916A #105
Note: Only one selection may be chosen from options 101-105 for G7916A. Manifold with AutoTemp is standard on the 709-DS.	
Delete basket shafts and baskets	G7916A #120
Delete paddle shafts	G7916A #125
PTFE-coated paddle shafts	G7916A #126
PEEK paddles	G7916A #127
Note: Only one selection may be chosen from options 125-127 for G7916A (not a required selection).	
Verified accessories	G7916A #145
Note: All Vessels, Paddles, Basket Shafts and Baskets ordered will come with individual certificates of conformance with this option.	
Delete 709-DS printer	G7916A #890

709-DS with AutoTemp, Autosampling and DDM.

Did You Know?

The 709-DS DVH vessel is layered with the heating elements sprayed onto the glass for maximum heat transfer. It is then covered with a clear protective plastic shield for added safety. These vessels can be cleaned in the same manner as traditional vessel, although extended submersion that could require additional drying time is not recommended.

709-DS and 850-DS Sampling Station

Description	Part Number
709-DS Dissolution Apparatus and 850-DS Sampling Station	G7918A
Options for G7918A	
Low actinic - red evaporation covers and vessels	G7918A #110
Delete basket shafts and baskets	G7918A #120
Delete paddle shafts	G7918A #125
PTFE-coated paddle shafts	G7918A #126
PEEK paddles	G7918A #127
Note: Only one selection may be chosen from options 125-127 for G7918A (not a required selection).	
Verified accessories	G7918A #145
Note: All Vessels, Paddles, Basket Shafts and Baskets ordered will come with individual certificates of conformance with this option.	
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7918A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7918A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7918A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7918A #213
Add Dissolution Workstation Software cable kit	G7918A #220
Add 709-DS printer	G7918A #880
Add printer to 850-DS	G7918A #881

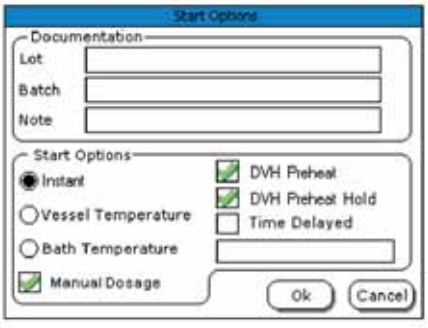
709-DS Dissolution Apparatus and 850-DS Dissolution Sampling Station

Adding Automation or UV Dissolution Capabilities

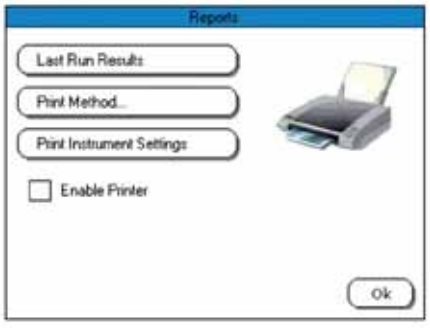
The 709-DS Dissolution Apparatus can pair with Agilent sampling, pumping, filter and UV dissolution instruments to create an automated solution for your laboratory. See page 92 for automated sampling, pumping and filtering options, and see page 96 for automated UV dissolution options.

709-DS Dissolution Apparatus – Upgrade Options

Description	Part Number
709-DS Dissolution Apparatus – Printer Option	
Thermal printer assembly, for use with 708-DS and 709-DS	K1005-05160
709-DS Dissolution Apparatus – DDM Option	
708-DS/709-DS, manual kit, without DDM and alignment posts, 6-position	K1005-01871
708-DS/709-DS, manual kit, without DDM and alignment posts, 8-position	K1005-01876
708-DS/709-DS alignment post kit, evaporation cover, 6-position	K1005-01872
708-DS/709-DS alignment post kit, evaporation cover, 8-position	K1005-01875
708-DS/709-DS DDM kit, 6-position	K1005-01873
708-DS/709-DS DDM kit, 8-position	K1005-01874
708-DS/709-DS DDM kit, 8-position, for UV dissolution (6 DDMs)	K1005-01987
709-DS Dissolution Apparatus – Sampling Option	
Sampling kit, DVH Only, 6-position, 1L, 709-DS	K1001-01160
Sampling kit, DVH Only, 8-position, 1L, 709-DS	K1001-01161



Every test performed with a 709-DS includes a Preheat cycle to equilibrate and stabilize vessel temperatures. The DVH Preheat Hold feature delays the system until the user is ready to initiate the test.



The built-in printer available on the 708 and 709-DS can recover lost data. If the paper expires during a test, the information is stored and can be reprinted once the printer has been replenished.

708-DS and 709-DS Accessories

Two-piece interchangeable paddle/basket shafts with 40-mesh baskets

Baskets, Paddles and Shafts

For Apparatus 1 (baskets) and Apparatus 2 (paddles) dissolution testing, Agilent's variety of quality accessories can support your laboratory's needs while maintaining compliance with regulatory standards.

Two-piece Interchangeable Paddle/Basket Shafts

Switching between paddles and baskets is simple with Agilent's two-piece interchangeable paddle/basket shafts. Rather than resetting the height of the individual shafts when you change between paddles and baskets, the upper receptor shaft stays securely in place, while the lower interchangeable paddle or basket shaft can be switched for your specific testing needs. The paddle and basket shaft assemblies are designed with height offsets so that the proper height is maintained after the changeover.

These shafts are manufactured to meet or exceed the USP specifications and precisely engineered, minimizing the risk of cross threading and ensuring a secure connection. In addition, the attachment area remains out of the media so there is less chance for contamination and corrosion. Further, each component is serialized for traceability.

The 708-DS and 709-DS can also be used with single-piece basket and paddle shafts. The minimum shaft length required is 21 inches. See page 38 for ordering information.

Did You Know?

Agilent's paddle and basket shafts now come as verified Accessories with individual certificates of conformance (COCs) that document actual measured values of all critical dimensions, the measurement device used for certification and its traceability. Additionally, a wide variety of additional Verified Accessories are available, including various baskets, and vessels to meet your needs for Mechanical Qualification. For individual baskets and vessels, many of the verified accessories are denoted with a "V" at the end of the part number.

(Left to right) 40-mesh basket, PTFE-coated basket, gold-plated basket, 20-mesh basket, 10-mesh basket, slotted basket, 3-fin basket, mini basket, and bolus basket

Upper shaft receptor and lower paddle piece

708-DS/709-DS Accessories – Paddles, Basket Shafts and Baskets

Description	Part Number
Two-piece Interchangeable Paddle/Basket Shafts with individual Certificate of Conformance	
Upper Receptor Shafts	
Upper receptor shaft, 21 in.	13-3613
Lower Interchangeable Paddle and Basket Shafts	
Paddle, lower interchangeable, PTFE-coated	13-3602
Paddle, lower interchangeable, electropolished	13-3603
Basket shaft, lower interchangeable, 3-clip, USP	13-3631
Basket shaft, lower interchangeable, O-ring	13-3632
Paddle, lower interchangeable, PTFE-coated, for 2L	13-3604
Paddle, lower interchangeable, electropolished stainless steel, for 2L	13-3605
Basket shaft 3-clip, lower interchangeable, standard USP, for 2L	13-3634
Baske shaft, lower interchangeable, O-ring, for 2L	13-3635
Paddle, lower interchangeable, PEEK	13-3606
Mini basket, lower interchangeable, Durafit, stainless steel, O-ring	13-3636
Mini paddle, lower interchangeable, PTFE-coated	13-3607
Mini paddle, lower interchangeable, electropolished stainless steel	13-3608
Baskets	
Basket, USP, 40-mesh, 381 µm	12-2100
Basket, USP, 40-mesh, 381 µm, with COC certificate	12-2100V
Basket, mini, 40-mesh, 381 µm	12-2102

For a complete listing of available baskets, see table on pages 40-41.

Vessels for 708-DS and 709-DS

Agilent's patented TruAlign vessels for the 708-DS and 709-DS precisely align the vessel every time. Each vessel is individually turned on a lathe to precisely locate the vessel center. Only TruAlign vessels have a collar incorporated onto the vessel around the ground glass groove, maintaining 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.

Using the TruAlign vessel design with a fitted collar, the TruAlign DVH vessels for the 709-DS also incorporate cutting-edge heat-sensing technology into the vessel wall. The heating element is fused to the glass for accelerated heating. The unique clear vessel coating offers protection for less breakage, ensuring long-lasting, durable performance. The coating allows complete visibility of the dosage form within the vessel – a critical component of the dissolution test.

TruAlign vessels for the 708-DS are available in 100 and 200 mL, 1 and 2L sizes. They are available in clear or low actinic – red for light sensitive products. Tru-Align vessels are also available as Peak vessels to prevent cone formation. Individual Certificates of Conformance can be obtained by ordering the verified versions of these vessels.

The TruAlign DVH vessel is available in a 1L clear size only, with low actinic – red environmental chambers and evaporation covers available for light sensitive products.

An individually serialized 1L TruAlign vessel

Learn more about Agilent's VF Molded Vessels

Visit **http://www.agilent.com/lifesciences/vfvessels**

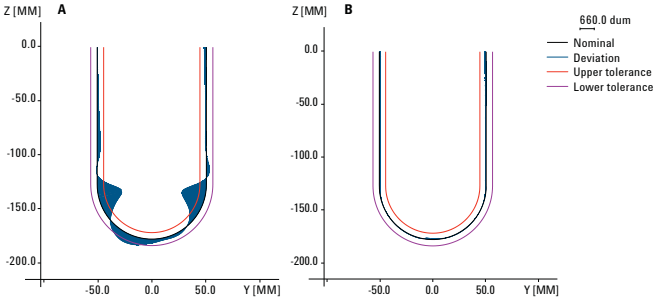
VF Molded Vessels

Agilent has also introduced molded TruAlign vessels which are vacuum formed (VF) and offer 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 removes vessel irregularity as a possible cause for failure. The TruAlign VF vessels are offered as 1-Liter clear glass only (available with or without an individual Certificate of Conformance).

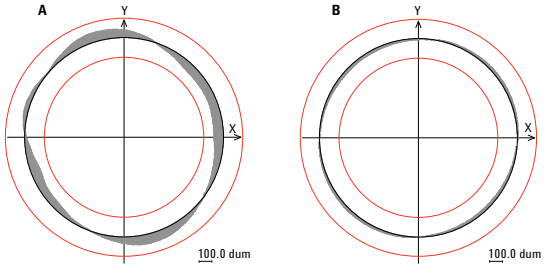
Conversion Kits

The 708-DS Dissolution Apparatus can also be used with a conversion kit for small-volume dissolution. Each position will require a conversion kit to hold the 100 or 200 mL vessel in position, and are designed to be used with either mini paddles, mini baskets, or Enhancer Cells, which are sold separately.

Special conversion kits, available in sets of 6 and 8, are also available for the Chinese Pharmacopeia (CP) 250 mL vessel. These kits include the 250 mL vessel designed according to CP specifications, vessel adapter ring, two-piece mini paddle, evaporation cover, height settting device (15 mm) and manifold conversion block.



Variation in vessel shape between standard vessels tested by Agilent (A) and Agilent VF molded vessels (B), which exceed USP vessel tolerances. The center of the three lines indicates the ideal shape of the cylinder and hemisphere. The two lines drawn on both sides represent ± 0.3 mm from the center line.



Variation in roundness between a standard vessel (A) and an Agilent VF molded vessel (B). The center of the three lines indicates the ideal shape of the cylinder and hemisphere. The two lines drawn on both sides represent ± 0.3 mm from the center line.

708-DS/709-DS Accessories – Vessels and Conversion Kits

Description	Part Number
TruAlign Vessels for 708-DS Dissolution Apparatus	
TruAlign vessel, 100 mL	12-5145
TruAlign vessel, low actinic - red, 100 mL	12-5146
TruAlign vessel, 200 mL	12-5147
TruAlign vessel, low actinic - red, 200 mL	12-5148
TruAlign vessel, 250 mL, for Chinese Pharmacopeia	12-1452
TruAlign vessel, 1L	12-5149
TruAlign vessel, 1L, with certificate	12-5149V
TruAlign vessel, low actinic - red, 1L	12-5152
TruAlign vessel, low actinic - red, 1L, with certificate	12-5152V
TruAlign Peak vessel, 1L	12-5153
TruAlign Peak vessel, 1L	12-5153V
TruAlign Peak vessel, low actinic - red, 1L	12-5154
TruAlign vessel, 2L	12-5157
TruAlign vessel, 2L, with certificate	12-5157V
TruAlign vessel, low actinic - red, 2L	12-5158
TruAlign vessel, low actinic - red, 2L, with certificate	12-5158V
TruAlign Peak vessel, 2L	12-5159
TruAlign vessel, flat bottom, 200 mL (one per position)	12-5170

(Continued)

(Left to right) 1L TruAlign vessel, 1 L low actinic - red TruAlign vessel, 2 L TruAlign vessel and 200 mL TruAlign vessel

708-DS/709-DS Accessories – Vessels and Conversion Kits

Description	Part Number
TruAlign VF Molded Vessels for 708-DS Dissolution Apparatus	
TruAlign VF molded vessel, clear, 1L	12-1501
TruAlign VF molded vessel, clear, 1L with certificate	13-0010
TruAlign DVH Vessels for 709-DS Dissolution Apparatus	
TruAlign DVH vessel, with collar, 1L	12-1500
TruAlign DVH vessel, with collar, 1L, with certificate	12-1500V
Small-volume TruAlign Vessel Conversion Kit for 708-DS Dissolution Apparatus	
TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 6	12-1450
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 8	12-1451
Height gauge sphere, 15 mm, for small volume vessels	K4040-00495

Did You Know?

A 708-DS Dissolution Apparatus can easily convert to a small-volume apparatus. For example, to convert a 6-position, 1L 708-DS for 200 mL testing with paddles, simply order the parts in the table on the right. If installed, a simple adjustment to the sampling manifold is also necessary that requires no additional parts or service call.

Small-volume Conversion Ordering Example

Quantity	Description	Part Number
6	TruAlign vessel, 200 mL	12-5147
6	TruAlign vessel 100/200mL conversion kit (includes vessel adapter and evap. cover)	12-6368
6	Mini paddle, lower interchangeable, electropolished stainless steel	13-3608

Adapting to Changing Needs

Have your laboratory needs changed? Are you ready to upgrade to an automated sampling system? While it's strongly recommended to prepare for this situation when initially ordering your instrument, to add sampling capabilities to your 708-DS or 709-DS, choose the 708-DS Upgrade Kit and Sampling Manifold that best fits your needs based on features and vessel volume. Each kit comes with a sampling manifold, and the features specified in the description. Contact your Agilent representative about scheduling installation of these items: **www.agilent.com/chem/contact**

708-DS and 709-DS Accessories

In addition to vessels, paddles, baskets and shafts, Agilent offers a variety of accessories specific to the 708-DS and 709-DS platform. These accessories include replacement tubing assemblies for sampling and return cannulas, sampling and resident probe sampling manifold kits, evaporation covers and more.

708-DS and 709-DS Accessories

Description	Part Number
708-DS Upgrade Kit	
708-DS internal upgrade for DDM, sampling, temperature	K1002-02045
Replacement Tubing Assemblies for 708-DS Manifold and 709-DS Manifolds	
Tubing assembly, for 1L 708-DS, sample and return cannulas, 6-position	1005-1920
Tubing assembly, for 1L 708-DS, sample and return cannulas, 8-position	1005-1921
Tubing assembly, for 2L 708-DS, sample and return cannulas, 6-position	1005-1922
Tubing assembly, for 2L 708-DS, sample and return cannulas, 8-position	1005-1923
Sampling Manifolds for 708-DS	
708-DS manifold, sampling only, 6-position, 1L	K1001-01171
708-DS manifold, sampling only, 8-position, 1L	K1001-01172
708-DS manifold, sampling only, 6-position, 100/200 mL	K1001-01173
708-DS manifold, sampling only, 8-position, 100/200 mL	K1001-01174
708-DS manifold, sampling only, 6-position, 2L	K1001-01175
708-DS manifold, sampling only, 8-position, 2L	K1001-01176
708-DS manifold, temperature only, 6-position, 1L	K1001-01177
708-DS manifold, temperature only, 8-position, 1L	K1001-01178
708-DS manifold, temperature only, 6-position, 100/200 mL	K1001-01179
708-DS manifold, temperature only, 8-position, 100/200 mL	K1001-01180
708-DS manifold, temperature only, 6-position, 2L	K1001-01181
708-DS manifold, temperature only, 8-position, 2L	K1001-01182
708-DS manifold, sampling/temperature, 6-position, 1L	K1001-01183
708-DS manifold, sampling/temperature, 8-position, 1L	K1001-01184
708-DS manifold, sampling/temperature, 6-position, 100/200 mL	K1001-01185
708-DS manifold, sampling/temperature, 8-position, 100/200 mL	K1001-01186
708-DS manifold, sampling/temperature, 6-position, 2L	K1001-01187
708-DS manifold, sampling/temperature, 8-position, 2L	K1001-01188
708-DS manifold, 6-position, 1L, for Fiber Optic UV dissolution	K1001-01189
708-DS manifold, 6-position, 100/200mL, for Fiber Optic UV dissolution	K1001-01190

(Continued)

708-DS and 709-DS Accessories

Description	Part Number
Sampling Manifolds for 708-DS	
708-DS manifold, sampling only, 8-position, for UV dissolution	K1001-01197
708-DS manifold, sampling/temperature, 8-position, for UV dissolution	K1001-01198
708-DS manifold, sampling only, 8-position, 2L, for UV dissolution	K1001-01199
708-DS manifold, sampling/temperature, 8-position, for UV dissolution	K1001-01200
Sampling Upgrade Kits for 709-DS	
708-DS temperature kit, 6-position, 1L	K1001-01160
Sampling kit, DVH Only, 8-position, 1L, 709-DS	K1001-01161
Resident Probe Sampling Kits for 708-DS	
Resident sampling kit, 6-position, 900 mL	K1001-01193
Resident sampling kit, 8-position, 900 mL	K1001-01194
Resident sampling kit, 6-position, 500 mL	K1001-01195
Resident sampling kit, 8-position, 500 mL	K1001-01196
Evaporation Covers and Accessories for 708-DS and 709-DS	
708-DS evaporation cover, tight seal	1005-1812
708-DS evaporation cover, open seal	1005-1813
708-DS evaporation cover, tight seal, low actinic - red	1005-1899
708-DS evaporation cover, open seal, low actinic - red	1005-1900
708-DS evaporation cover, split, tight seal	K1005-05213
708-DS evaporation cover, split, open seal	K1005-05214
708-DS evaporation cover, split, tight seal, low actinic - red	K1005-05215
708-DS evaporation cover, split, open seal, low actinic - red	K1005-05216
708-DS alignment post, for use in place of DDM	1005-1898
708-DS evaporation cover plug, white, for use in place of DDM	1200-1012
708/709-DS evaporation cover plug, black, flat	12-6365
708/709-DS evaporation cover plug, black, fingertip removal	12-6370
708/709-DS evaporation cover, for blank position	K1400-00210

(Continued)

Split evaporative cover (left), low actinic - red and clear evaporation covers for 708-DS and 709-DS (right)

Did You Know?

A manual sampling bracket option is now available for the 708-DS and 709-DS Dissolution Apparatus. This bracket gives users the ability to sample manually from each vessel position in an efficient and repeatable manner. The bracket attaches to the front of the apparatus and is available with the option to use resident sampling probes (which reside in the evaporation cover) or an existing manifold. The manifold option takes full advantage of the instrument's capability to achieve a reproducible sampling position at each time point.

708-DS and 709-DS Accessories

Description	Part Number
Miscellaneous Accessories for 708-DS and 709-DS	
708-DS Heater/circulator, 115/230V	G7986A
708-DS bath temperature probe	67-0300
708-DS vessel temperature probe, handheld	K1005-01568
DDM assembly, for use with 708-DS and 709-DS	1005-1897
Thermal printer assembly, for use with 708-DS and 709-DS	K1005-05160
Thermal printer paper, for use with 708-DS and 709-DS, 10 rolls/pkg.	12-9988
Thermal printer paper, for use with 708-DS and 709-DS, 100 rolls/pkg.	12-9989
Cannula rinse cup, with shaft clip	17-1340
Cannula rinse cup carrying tray	17-1345
Acrylic rinse tray, for 708/709-DS	17-1351
Storage rack for two-piece paddle/basket shafts	12-1352
Sample tubing rinse kit	17-1341
Storage rack for one-piece paddle/basket shafts	12-1350
Manual sampling bracket, for use with manifold, 708-DS and 709-DS	17-3151
Manual sampling bracket, resident probes, 708-DS and 709-DS	17-3152

Manual sampling bracket for 708-DS and 709-DS manifold

Two-piece interchangeable basket/paddle shaft storage rack

3200P ph Meter

3200P pH Meter

pH is a critical parameter for dissolution testing. Agilent's standard 3200P pH meter is designed for easy operation, even by non-technical users, while still producing the most reliable readings. The meter takes measurements of acid and alkali levels and provides electrode potential (mV) values of relevant ions.

- Unique electrode reference system, backed by our qualified material and manufacturing process, delivers fast, reliable response during meter operation.
- Rugged design stands up to the toughest laboratory conditions
- High-endurance protective glass and multi-layer composite electrodes prevent breakage caused by frequent use, even in demanding environments.

Agilent pH meters are backed by our 3 years replacement warranty. For more information, visit **www.agilent.com/chem/phmeters**

3200P pH Meter

Description	Part Number
3200P Benchtop pH Meter Basic Package, including pH meter, P3211 pH combination electrode, T7111 ATC probe, pH buffer package, and 3200EA electrode holder	G4391A
3200P Benchtop pH Meter Package with 3-in-1 Electrode, including pH meter, P3311 pH triode combination electrode, pH buffer package, and Agilent 3200EA electrode holder	G4392A
P3211 Combination electrode with glass body, refillable, BNC connector, glass bulb measuring tip	5190-3988
P3212 Combination electrode with PC body, not refillable, BNC connector, glass bulb measuring tip	5190-3989
P3311 Combination electrode with glass body, refillable, BNC and miniDIN4 connector, glass bulb measuring tip	5190-3990
P3111 Electrode with glass body, not refillable, BNC connector, glass bulb measuring tip	5190-3991
P3213 Combination electrode with PC body, refillable, BNC connector,flat measuring tip	5190-3992
P3214 Combination electrode with ABS body, not refillable, BNC connector, spear-tipped measuring tip	5190-3993

3200P pH Meter Specifications*

Range	pH	-2.000-20.000 pH
	mV	(-1999.9 - 1999.9) mV
	Temperature	-5.0-110.0 °C
Resolution	pH	0.1/0.01/0.001 pH
	mV	0.1 mV
	Temperature	0.1 °C
Accuracy	pH	0.1 °C
	mV	±0.03% FS
	Temperature	±0.1°C
Temperature compensation	Manual/Auto -5.0-110.0 °C	
Power	Universal AC power adapter 100 V-240 V, 50/60 Hz**	
Dimension (L×D×H)	190 mm × 190 mm × 105 mm	
Weight	1 kg	

*EC Print software for easy and direct printing and EC Firmware software are available for free download at **www.agilent.com/chem/phmeters**

**Shipped with meter

dissoGUARD® System

dissoGUARD®

Merel, an Agilent dissolution partner, offers dissoGUARD®, 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, track the position of dosage forms, timing and location of sampling cannulas, behavior of particles in-vessel and more. The PRO version enables users to evaluate physical parameters such as centering, wobble and paddle rotation speed. dissoGUARD® can be retrofitted to any Agilent 708-DS or 709-DS apparatus.

Designed to support both Agilent's 708-DS and 709-DS Dissolution Apparatus, dissoGUARD® adds unmatched visibility into the dissolution vessel environment. To learn more about this system, visit **www.dissoguard.com**.

Dissolution Accessories

Legacy Products

Agilent continues to support customers with accessories for legacy products. See page 138 for a complete listing of accessories that work with the 705-DS, 7000/7010 and 7025/7030 V-Series.

Ordering

Order Agilent parts and supplies for legacy instruments at **www.chem.agilent.com/store**

Baskets, Paddles and Shafts

For Apparatus 1 (baskets) and Apparatus 2 (paddles) dissolution testing, Agilent's variety of quality accessories can support your laboratory's needs while maintaining compliance with regulatory standards. In keeping with the most current guidance for mechanical qualification, Agilent offers Verified Dissolution Accessories including baskets, paddles and shafts with certificates of conformity with actual component measurements for all critical dimensions using traceable devices.

Basket Shafts

Whether you need electropolished stainless steel, PTFE-coated, gold-plated or Durafit basket shafts, Agilent provides these individually serialized accessories. Basket shaft options include 3-clip shafts to meet standard USP design, O-ring for automated systems, or conical surface to support air bubble dispersion. A range of basket shaft sizes from 14.5 in. for the legacy 7025/7030 apparatus to 24 in. for large volume vessel volume configurations.

Baskets

From the standard USP 40-mesh stainless steel basket, to custom baskets with varying mesh sizes, to baskets specific to small or large dosage forms, Agilent supports your Apparatus 1 needs. Unless otherwise noted, all baskets fit the standard basket shafts.

(Left to right) Standard 3-clip shaft, conical 3-clip shaft, standard O-ring shaft, conical O-ring shaft, PTFE-coated 3-clip shaft, gold-plated 3-clip shaft and mini shaft

Upper shaft receptor and lower interchangeable paddle piece

Paddles

One-piece paddles are serialized and designed to meet USP specifications for Apparatus 2. Select from electropolished stainless steel, PTFE-coated or the biocompatible, chemically inert PEEK (polyetheretherketone) paddles in a range of sizes. Additionally, mini and mega paddles for small- and large-volume dissolution testing are available.

Two-piece Interchangeable Paddle/Basket Shafts

Switching between paddles and baskets is simple with Agilent's two-piece interchangeable paddle/basket shafts. Rather than resetting the height of the individual shafts when you change between paddles and baskets, the upper receptor shaft stays securely in place, while the lower interchangeable paddle or basket shaft can be switched for your specific testing needs. The paddle and basket shaft assemblies are designed with height offsets so that the proper height is maintained after the changeover.

These shafts are manufactured to meet or exceed the USP specifications and precisely engineered, minimizing the risk of cross threading and ensuring a secure connection. In addition, the attachment area remains out of the media so there is less chance for contamination and corrosion. Further, each component is serialized for traceability.

The 708-DS and 709-DS can also be used with single-piece basket and paddle shafts. The minimum shaft length required is 21 inches.

(Left to right) Electropolished stainless steel paddle, PTFE-coated paddle, PEEK paddle, electropolished mini paddle, and PTFE-coated mini paddle

Basket Shafts / Assemblies with individual Certificate of Conformance

Description	Part Number
21 - 24 in. (53 - 61 cm) Basket Shafts for 7000/7010E, 705/708/709-DS	
Basket shaft, USP 3-clip, 21 in.	13-3620
Basket shaft, O-ring, 21 in.	13-3621
Basket shaft, PTFE-coated, 21 in.	13-3622
Basket shaft, O-ring, Conical, 21 in.	13-3623
Basket shaft, 3-clip, Conical 21 in.	13-3624
Basket shaft, USP 3-clip, 24 in.	13-3629
Basket shaft, for bolus basket, 24 in.	13-3630
Baskets	
Basket, USP, 40-mesh, 381 µm	12-2100
Basket, USP, 40-mesh, 381 µm, with COC certificate	12-2100V
Basket, mini, 40-mesh, 381 µm	12-2102
Mini basket only, 20-mesh, 864 µm	12-2103
Mini basket only, 10-mesh, 1905 µm	12-2104
Basket, gold plated, 40-mesh, 381 µm	12-2105
Basket, PTFE-coated, 40-mesh	12-2110
Basket, 3-fin assembly, 40-mesh, 381 µm	12-2115
Basket, 20-mesh, 864 µm	12-2120
Basket, 20-mesh, 864 µm, with certificate	12-2120V
Basket, 10-mesh, 1905 µm	12-2125
Basket, slotted, for suppository testing	12-2130
Basket, 450x2750-mesh, 1 µm	12-2140
Basket, 400x2800-mesh, 2 µm	12-2145

(Continued)

Close up of standard 3-clip shaft and conical 3-clip shaft

Basket Shafts / Assemblies with individual Certificate of Conformance

Description	Part Number
Baskets	
Basket, 325x2300-mesh, 5 µm	12-2146
Basket, 200x1400-mesh, 10 µm	12-2148
Basket, 165x800-mesh, 20 µm	12-2149
Basket, 325x325-mesh, 43 µm	12-2150
Basket, 270x270-mesh, 53 µm	12-2151
Basket, 150x150-mesh, 104 µm	12-2152
Basket, 100x100-mesh, 140 µm	12-2154
Basket, 50x50-mesh, 280 µm	12-2155
Bolus basket, 20x20-mesh, 864 µm	12-2180
Bolus basket, 40x40-mesh, 381 µm	12-2185
Basket, Metformin Vertical Sample Holder, Large	12-2165
Basket, Metformin Vertical Sample Holder, Small	12-2170
Stationary Baskets and Shafts	
Stationary basket shaft (basket sold separately)	12-2065
Stationary basket, Felodipine quadrangular	12-2069

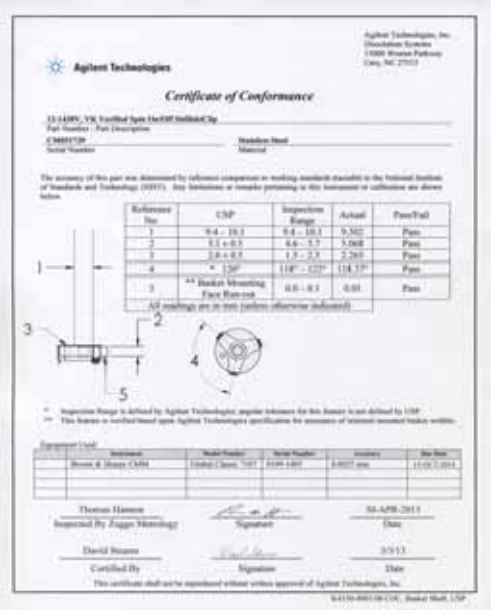
(Left to right) 40-mesh basket, PTFE-coated basket and gold-plated basket

Certificates of Conformity

There is some confusion regarding what constitutes a Certificate of Conformance or Certificate of Analysis (COC, COA). Simply stating a component meets USP requirements is not sufficient. Most, if not all, accessory suppliers do some type of batch inspection. According to ASTM E2503: "-3.1 Analyst Responsibilities: Verify the vessel, basket, and paddle dimensions on receipt through measurement or Certificate of Analysis (COA) or Certificate of Conformity (COC)"

- "4.3 Apparatus Setup: During apparatus installation or after replacement of parts or components, verify that the descriptions and critical dimensions for each part meets the original description and dimension." After this statement, a more detailed description is given for vessels, paddles and basket/shaft dimensions.
- "4.3.3 Paddle Dimensions: In the absence of a COA or COC, an appropriate measuring device is used to measure the relevant dimensions of the paddle. Examples of dimensions to be determined on each paddle should include but are not limited to: shaft diameter, blade height, blade thickness, total blade length, length of flat portion on bottom of blade, radius of the angle on the top outer edge of the top of the blade, radius of the outside edge of the blade, difference between the distance from the midline of the shaft to the top outer edge for the two sides, and difference between the heights of both sides of the paddles at the outside top."

Verification in GMP applications means documentation. If you measure it, you document it. Without documentation (of the actual measurements) you cannot prove anything.



Agilent Technologies

Certificate of Conformance

Certificate of Conformance for an Agilent basket shaft

Two-piece Interchangeable Paddle/Basket Shafts

Description	Part Number
Two-piece Interchangeable Paddle/Basket Shafts with individual Certificate of Conformance	
Paddle, lower interchangeable, PTFE-coated	13-3602
Paddle, lower interchangeable, electropolished	13-3603
Basket shaft, lower interchangeable, 3-clip, USP	13-3631
Basket shaft, lower interchangeable, O-ring	13-3632
Basket shaft, lower interchangeable, conical	13-3633
Upper receptor shaft, 15 in.	13-3612
Upper receptor shaft, 21 in.	13-3613
Upper receptor shaft, 24 in.	13-3614
Paddle, lower interchangeable, PTFE-coated, for 2L	13-3604
Paddle, lower interchangeable, electropolished stainless steel, for 2L	13-3605
Basket shaft 3-clip, lower interchangeable, standard USP, for 2L	13-3634
Basket shaft, lower interchangeable, O-ring, for 2L	13-3635
Paddle, lower interchangeable, PEEK	13-3606
Mini basket, lower interchangeable, Durafit, stainless steel, O-ring	13-3636
Mini paddle, lower interchangeable, PTFE-coated	13-3607
Mini paddle, lower interchangeable, electropolished stainless steel	13-3608
Shaft Accessories	
Storage rack for one-piece paddle/basket shafts	12-1350
Storage rack for two-piece paddle/basket shafts	12-1352
Shaft locking ring, for 705-DS, 708-DS, 709-DS, 7025/7030	12-2096

Storage rack for one-piece paddle/basket shafts

Paddle Shafts with individual Certificate of Conformance

Description	Part Number
21 - 24 in. (53 - 61 cm) Paddle Shafts for use with 7000/7010E, 705/708/709-DS	
Paddle, PTFE-coated, 21 in.	13-3594
Paddle, PTFE-coated, 24 in.	13-3596
Paddle, electropolished, 21 in.	13-3595
Paddle, electropolished, 24 in.	13-3597
Paddle, PEEK, 24 in.	13-3598
Mini paddle, PTFE-coated, 24 in.	13-3599
Mini paddle, electropolished, 24 in.	13-3600
Mega paddle, electropolished stainless steel, 24 in.	13-3601

Dissolution Vessels

Agilent provides a variety of dissolution vessels for use with Agilent dissolution apparatus, as well as other equipment manufacturers. A wide variety of vessel types and volumes are available. Agilent's vessels are designed meet regulatory specifications, ensuring quality and consistency.

TruAlign vessel for the 708-DS with Certificate of Conformance (COC)

Verified Dissolution Accessories

Do you need vessels that are individually certified to meet with Mechanical Qualification guidelines? Agilent offers Verified Dissolution Accessories with a certificate of conformance that documents the actual measured values of all critical dimensions, the measurement device used for certification, and its traceability.

TruAlign Vessels

The TruAlign vessels for the 708-DS and 709-DS have a collar 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.

The TruAlign DVH vessel for the 709-DS also incorporates cutting-edge heat-sensing technology in the vessel wall. The unique clear vessel coating offers protection for less breakage and complete visibility of the dosage form within the vessel – a critical component of the dissolution test.

TruAlign vessels for the 708-DS are available in 100 and 200 mL, and 1 and 2 L sizes. Low actinic - red, Peak, and Verified versions are also available for select volumes. The TruAlign DVH vessel is available in a 1L size only, and low actinic - red environmental chambers and evaporation covers are available for light sensitive products.

VF Molded Vessels

Agilent also offers a molded vessel - in EaseAlign, TruCenter and TruAlign form - 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 our technical overview at **www.agilent.com/lifesciences/vfvessels**

1L TruAlign VF Molded Vessel

Did You Know?

The Peak vessel was introduced to solve coning problems. Some dosage forms form a cone in the bottom of the vessel. The result is the media only comes in contact with the outer layer, slowing the dissolution process. Typically results are lower than anticipated. The Peak vessel disperses the cone exposing greater surface area. While the Peak vessel is not included in USP guidance, multiple methods using this accessory have been accepted by the FDA. As with any non-compendial accessory, proper justification is required for use.

TruAlign Vessels for 708-DS and 709-DS

Description	Part Number
TruAlign Vessels for 708-DS Dissolution Apparatus	
TruAlign vessel, 100 mL	12-5145
TruAlign vessel, low actinic - red, 100 mL	12-5146
TruAlign vessel, 200 mL	12-5147
TruAlign vessel, low actinic - red, 200 mL	12-5148
TruAlign vessel, 250 mL, for Chinese Pharmacopeia	12-1452
TruAlign vessel, 1L	12-5149
TruAlign vessel, 1L, with certificate	12-5149V
TruAlign vessel, low actinic - red, 1L	12-5152
TruAlign vessel, low actinic - red, 1L, with certificate	12-5152V
TruAlign Peak vessel, 1L	12-5153
TruAlign Peak vessel, 1L, with certificate	12-5153V
TruAlign Peak vessel, low actinic - red, 1L	12-5154
TruAlign vessel, 2L	12-5157
TruAlign vessel, 2L, with certificate	12-5157V
TruAlign vessel, low actinic - red, 2L	12-5158
TruAlign vessel, low actinic - red, 2L, with certificate	12-5158V
TruAlign Peak vessel, 2L	12-5159
TruAlign vessel, flat bottom, 200 mL (one per position)	12-5170
TruAlign VF molded vessel, clear, 1L	12-1501
TruAlign VF molded vessel, clear, 1L with certificate	13-0010

(Continued)

1L TruAlign Peak vessel

TruAlign Vessels for 708-DS and 709-DS

Description	Part Number
TruAlign DVH Vessels for 709-DS Dissolution Apparatus	
TruAlign DVH vessel, with collar, 1L	12-1500
TruAlign DVH vessel, with collar, 1L, with certificate	12-1500V
Small-volume TruAlign Vessel Conversion Kit for 708-DS Dissolution Apparatus	
TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 6	12-1450
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 8	12-1451

Conversion Kits

Sink Condition Requirements

In any dissolution test, it is imperative that there is sufficient media to meet sink requirements. The dissolution rate should not be inhibited by saturation. At the same time you must consider the detection limits of your analytical technique. Vessel volume adjustments can help to meet the appropriate conditions for your dissolution method.

Small-volume Kits

Small-volume conversion kits are an excellent, cost-effective way to use your existing equipment for testing that requires a smaller volume of media. Each position will require a conversion kit to hold the 100 or 200 mL vessel in position. These kits can also be used with Online UV dissolution systems when preparing standards for automated analyses. In this configuration, a single conversion kit is used in position 7 of the dissolution apparatus. The smaller volume allows you to prepare a smaller amount of standard, saving you money. The conversion kits are designed to be used with either mini paddles or mini baskets, which are sold separately.

100 and 200 mL conversion kits are available for the 708-DS, as well as the legacy 705-DS, 7000/7010, and 7025 Dissolution Apparatus. Note that if you intend to use automated sampling options for these instruments with a small-volume conversion kit, you may need a modified or new sampling manifold to accommodate the change in vessel diameter and sampling position.

Small-volume conversion kits, sold individually or in packages, typically require:

- Mini vessel(s)
- Mini paddle(s) or mini-basket and basket shafts
- Evaporation cover(s)
- Centering ring assembly(ies) or adapter

Shaft lengths and diameters, as well as vessel types, are noted with the part number descriptions.

708-DS conversion kit, 200 mL vessel with mini paddle

Legacy Products

Agilent continues to support customers with accessories for legacy products. See page 138 for a complete listing of accessories that work with the 705-DS, 7000/7010 and 7025/7030 V-Series.

Large-volume Kits

If you could potentially need to test using a larger volume (e.g., 2L), it is recommend to purchase your new 708-DS with this configuration. This configuration gives you the capability to utilize 1 and 2L vessel sizes in the same instrument with only the need to purchase and install the alternate vessels when converting.

Conversion Kits for 708-DS Dissolution Apparatus

Description	Part Number
TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporation cover)	12-6368
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 6	12-1450
TruAlign vessel, 250 mL conversion kit, for Chinese Pharmacopeia (includes vessel, adapter, two-piece mini paddle, evaporation cover and manifold adapter), set of 8	12-1451

2L TruAlign vessel

Capsule Wire, Weights and Sinker Baskets

Capsule wire, weights and sinker baskets are used to retain a solid dosage form at the bottom of the vessel for testing when the dosage form is buoyant. Depending on your dosage form a variety of options are available.

- The flexible capsule wire has a 0.032 in. diameter and is made of made of stainless steel. The USP compendial wire is twisted around the dosage form in order to provide sufficient mass to ensure the dosage form sinks to the bottom of the vessel.
- Sinker baskets are offered in a variety of mesh sizes and made of stainless steel. The press-on caps use O-rings to seal the basket closed once the dosage form is inserted. The Japanese Pharmacopoeia (JP) sinker basket is also available as an alternative.
- A three-prong capsule weight can be used to retain your capsule for testing. These weights fit traditional capsule sizes one through three, and are sold individually.

Capsule weight wire (top row), two versions of wire sinkers and a Japanese sinker (second row), mesh sinkers (third row) and 3-prong sinkers (fourth row)

When to Use a Sinker

Sinkers are used during a dissolution test to sink a dosage form that would otherwise float. The USP specifies that a small piece of non-reactive material, such as not more than a few turns of steel wire, can be attached to the dosage form to prevent floating. Other validated sinkers may also be used for this purpose.

Capsule Wire, Weights and Sinker Baskets

Description	Part Number
Capsule Wire and Weights	
Capsule weight wire, 316 stainless steel, 0.032 in. dia., 50 ft.	12-3000
Capsule weight, 3-prong	12-3050
Capsule weight, robotic type, with magnetic cap	12-3055
Capsule weight, robotic type, with magnetic inserts in legs	12-3056
Sinker Baskets	
Sinker basket, with cover, 10-mesh, 1905 µm	12-3060
Sinker basket, with cover, 8-mesh, 2591 µm	12-3062
Sinker basket, with cover, 20-mesh, 864 µm	12-3063
Sinker basket, with cover, 40-mesh, 381 µm	12-3064
Sinker basket, with cover, 100-mesh, 140 µm	12-3065
Sinker basket, with cover, 60-mesh, 229 µm	12-3066
Sinker basket, with cover, 150-mesh, 104 µm	12-3067
Sinker basket, with cover, 270-mesh, 53 µm	12-3068
Sinker basket, with cover, 325-mesh, 45 µm	12-3072
Sinker basket, Japanese Pharmacopoeia (JP)	12-3070

Did You Know?

Weights and sinker baskets may also be used for sticky dosage forms, as well as powders contained in capsule shells.

Sinker Baskets Dimensions*

Inside diameter	20.3 mm / 0.8 in.
Outside diameter (with cover)	25 mm / 0.98 in.
Inside height	11.7 mm / 0.46 in.
Outside height (without cover)	15 mm / 0.59 in.
Outside height (with cover)	20 mm / 0.79 in.

**Excludes Japanese Pharmacopoeia basket, 12-3070*

Sampling and Temperature Measurement

For a quick, manual sampling solution, Agilent's cannula luer lock assembly is comprised of a bent cannula and a sampling syringe that are best used with the Full Flow Filters. The sampling cannulas are available two in different lengths based on the volume of media, 500 or 900 mL, from which you will sample.

Resident sampling kits for use when there is no automated manifold are available to pull samples through a resident-dwelling probe. Please note that probes left in the media during a dissolution run will alter the hydrodynamics and may affect the rate of release. Therefore, it is critical that resident probe methods are validated against manual sampling to ensure the integrity of the dissolution test is intact.

For automated sampling, the motorized manifold can be programmed to lower and raise sampling cannulas at specific timepoints when used with the 850-DS Dissolution Sampling Station. The manifold supports sampling in media volumes based on the size of vessel installed. The standard sampling manifolds withdraw samples from the proper USP sampling point, halfway between the top of the paddle/basket and the top of the media. Full Flow Filters are recommended for use to prevent undissolved particles from contaminating the sample lines.

Manual sampling on the 708-DS

The legacy 7025 and 7030 Dissolution Apparatus include individual sampling cannulas that may include temperature probes as well. The sampling depth of the cannulas is preset and stored in the firmware of the instrument based on the apparatus installed and volume. The cannulas are only submerged at the time of sampling to minimize hydrodynamic disturbance.

The 708-DS and 709-DS also support an automated, non-resident manifold, which is included in those systems preconfigured for automated sampling. Any unit without the automated manifold can be retrofitted by our service organization. The depth of the manifold is preset and stored in the firmware of the instrument based on the apparatus installed and vessel volume.

Autosampling manifolds can also support the AutoTemp In-Vessel Temperature Sensing System to lower temperature probes at a specifically programmed time. Once the temperature is measured, the manifold removes the probes to avoid hydrodynamic disturbances. AutoTemp makes starting methods easy, particularly when combined with the Dosage Delivery Module (DDM) option. As soon as the desired temperature is reached, the values are recorded and the dosage forms are introduced. Like the Autosampling option, AutoTemp is available on new apparatus and may also be retrofitted to an existing instrument.

Resident cannula kit on the 708-DS

Resident Sampling Kits/Accessories

Description	Part Number
Resident sampling kit, 6-position, 900 mL	K1001-01193
Resident sampling kit, 8-position, 900 mL	K1001-01194
Resident sampling kit, 6-position, 500 mL	K1001-01195
Resident sampling kit, 8-position, 500 mL	K1001-01196
Resident probe sample cannula, 500 mL	17-3330
Resident probe sample cannula, 900 mL	17-3335

Note: Resident sampling kits for the 7000/7010 or 705-DS must be used with the low-loss evaporation cover (12-6328)

For Your Sampling Needs

Agilent offers a variety of height spacers to increase working space when performing manual sampling. See page 151 for Verification Tools, including these spacers. Full Flow Filters are recommended for use with automated sampling options. See page 56 for details.

Manual Sampling Accessories

Description	Part Number
Bent cannula with Luer Lock, for sampling from 900 mL in 1L vessels, 4.75 in.	12-3200
Bent cannula with Luer Lock, for sampling from 500 mL in 1L vessels, 7.75 in.	12-3210
Bent cannula with adjustable gauge, 4.75 in. (900 mL), 708/709-DS	12-3221
Bent cannula with adjustable gauge, 7.75 in. (900 mL), 708/709-DS	12-3222
Adjustable gauge kit, 708/709-DS	12-3223
Cannula, PEEK, for low-volume sampling	12-3219
Filter holder, 25 mm	12-3220
Glass syringe, 20 cc	12-3230
Manual sampling bracket, for use with manifold, 7000/7010	17-3150
Manual sampling bracket, for use with manifold, 708-DS and 709-DS	17-3151
Manual sampling bracket, resident probes, 708-DS and 709-DS	17-3152

Manual sampling bracket for 708-DS or 709-DS Dissolution Apparatus

Filtration

Did You Know?

Through GE-Whatman, Agilent offers filters in a unique plate design for use with the 850-DS filter module. See page 92 for more information.

Automation-ready Roby25 filters for the legacy 808 Filter Changer can also be purchased through GE-Whatman.

Dissolution continues until a sample is filtered, so it is critical to filter at the specified timepoint. When using manual or automated sampling cannulas, you have the option to use one of Agilent's Full Flow Filters or conventional filter tips to ensure the integrity of your dissolution sample.

Full Flow Filters

Made of either ultrahigh molecular weight polyethylene (UHMWPE) or the polyvinylidene fluoride (PVDF), the Full Flow Filter offers increased surface area to optimize filter life and prevent clogging. In those instances where chemical compatibility is an issue with UHMWPE, we offer PVDF filters. These are made of a low protein-binding material that can filter a wide variety of active drug substances. Both UHMWPE and PVDF filters can be used with 1/8 in. diameter cannulas and are available in packs of 100 or 1000.

Conventional Filter Tips

Standard conventional filter tips are made of polyethylene fluoride and can also be used with 1/8 in. diameter cannulas.

Full Flow Filters

Cut Costs and Plan Ahead

Save money by ordering our economical 1000 pack! Same high quality filters, just packaged in bulk.

Filters and Filter Tips for Sampling Cannulas

Description	Part Number
Original Full Flow Filters	
Full Flow Filter, UHMWPE, blue, 10 µm, 100/pkg.	17-4000
Full Flow Filter, UHMWPE, blue, 10 µm, 50/pkg.	17-4001
Full Flow Filter, UHMWPE, blue, 10 µm, 1000/pkg.	17-4005
Full Flow Filter, UHMWPE, white, 35 µm, 100/pkg.	17-4010
Full Flow Filter, UHMWPE, white, 35 µm, 50/pkg.	17-4011
Full Flow Filter, UHMWPE, white, 35 µm, 1000/pkg.	17-4015
Full Flow Filter, UHMWPE, red, 70 µm, 100/pkg.	17-4020
Full Flow Filter, UHMWPE, red, 70 µm, 50/pkg.	17-4021
Full Flow Filter, UHMWPE, red, 70 µm, 1000/pkg.	17-4025
Full Flow Filter, PVDF, green, 10 µm, 100/pkg.	17-4040
Full Flow Filter, PVDF, green, 10 µm, 1000/pkg.	17-4045
Full Flow Filter, PVDF, yellow, 35 µm, 100/pkg.	17-4050
Full Flow Filter, PVDF, yellow, 35 µm, 1000/pkg.	17-4055
Filter Tips	
Filter tip, PE, 2 µm, 100/pkg.	17-4100
Filter tip, PE, 5 µm, 100/pkg.	17-4110
Filter tip, PE, 10 µm, 100/pkg.	17-4120
Inline Filter	
Inline filter, luer lock, 5 µm (for use with BIO-DIS)	3081-0004

Note: PE = polyethylene, PVDF = polyvinylidene fluoride, UHMWPE = ultrahigh molecular weight polyethylene

Evaporation Covers

Evaporation covers maintain volumetric accuracy of the media used during dissolution testing by slowing the amount of media lost to evaporation. A variety of evaporation covers are available to fit your apparatus and vessels. Evaporation plugs are used to minimize evaporation by sealing unused ports in the evaporation covers.

Evaporation Covers and Accessories

Description	Part Number
708-DS evaporation cover, tight seal	1005-1812
708-DS evaporation cover, open seal	1005-1813
708-DS evaporation cover, tight seal, low actinic - red	1005-1899
708-DS evaporation cover, open seal, low actinic - red	1005-1900
708-DS evaporation cover, split, tight seal	K1005-05213
708-DS evaporation cover, split, open seal	K1005-05214
708-DS evaporation cover, split, tight seal, low actinic - red	K1005-05215
708-DS evaporation cover, split, open seal, low actinic - red	K1005-05216
708-DS alignment post, for use in place of DDM	1005-1898
708-DS evaporation cover plug, white, for use in place of DDM	1200-1012
708/709-DS evaporation cover plug, black, flat	12-6365
708/709-DS evaporation cover plug, black, fingertip removal	12-6370
708/709-DS evaporation cover, for blank position	K1400-00210

Low actinic - red and clear evaporation covers for the 708-DS and 709-DS.

Transdermal Delivery Systems – USP Apparatus 5, 6, and 7

Apparatus 5, or Paddle Over Disk, and Apparatus 6, Rotating Cylinder, are commonly used for the testing of transdermal patches per USP General Chapter <724>.

Did You Know?

Agilent's 708-DS can also support transdermal testing using USP Apparatus 5 and 6 accessories. This includes setup and storage of precise sampling manifold locations in the firmware based on vessel volume and the assembly installed. The 708-DS is easily converted to smaller volumes typically associated with transdermal testing as well. See page 49 for more information about 708-DS volume conversion kits.

USP Apparatus 5 – Paddle Over Disk

The Paddle Over Disk assembly is used for the dissolution testing of transdermal patches, and is used with a standard dissolution apparatus and paddles. The assembly is made of a 316 stainless steel disk and PTFE locking ring that holds the removable, replaceable screens in place. Screens are provided with the ring assemblies but are also offered in a variety of other sizes which are sold separately.

Agilent also offers a transdermal patch holder system as an alternative to the traditional Apparatus 5 assembly. Also made of 316 stainless steel, the O-ring assembly eliminates the need for adhesives to hold the patch. The clam-shell design secures the patch in place and exposes only the active release area of patches with an inactive perimeter around the release area.

USP Apparatus 6 – Rotating Cylinder

The Rotating Cylinder assembly uses a 316 stainless steel cylinder and includes four slots at the top for improved media circulation over the transdermal patch. The two-piece design includes a removable extension for testing larger transdermal patches.

USP Apparatus 7 – Reciprocating Holder

Transdermal delivery systems may also be tested with Apparatus 7 using a variety of sample holders. For more information on the instrumentation and holders available from Agilent, see page 73.

(Left to right) Paddle Over Disk assemblies, transdermal patch holders and suspension cup.

Transdermal Delivery, compatible with all apparatus models

Description	Part Number
Paddle Over Disk	
Paddle Over Disk assembly, with 35 mm opening, 40-mesh screen	12-4200
Paddle Over Disk assembly, with 35 mm opening, 40-mesh screen, with certificate	12-4200V
Paddle Over Disk assembly, 125 µm, EP	12-4201
Replacement screens, 125 µm, EP, 100/pkg.	12-4209
Replacement screens, 35 mm openings, 40-mesh, 100/pkg.	12-4210
Disk disassembly kit, for PN 12-4200	12-4211
Paddle Over Disk assembly, with 56 mm opening, 120-mesh screen	12-4230
Replacement screens, 56 mm openings, 120-mesh, 100/pkg.	12-4231
Disk disassembly kit, for PN 12-4230	12-4232
Transdermal Patch Holders	
Transdermal patch holder, 2.5 cm^2	12-4300
Transdermal patch holder, 5.0 cm^2	12-4310
Transdermal patch holder, 7.0 cm^2	12-4320
Transdermal patch holder, 10.0 cm^2	12-4330
Watch glass screen, polypropylene, 6/pkg.	12-4400
Watch glass screen, stainless steel, 6/pkg.	12-4410

Rotating Cylinder and Accessories

Description	Part Number
Lower interchangeable shaft for Rotating Cylinder	12-1371
Lower interchangeable shaft for Rotating Cylinder, with certificate	12-1371V
Rotating Cylinder, 25 mm outside dia., with interchangeable shaft	12-1372
Cuprophan membrane, 126x345 mm, 10 sheets/pkg.	12-1370
Height gauge, Rotating Cylinder, USP	12-7335

PTFE Suspension Cups

For suspensions, the PTFE suspension cup is a weighted holder with a hemispheric bottom designed to sit at the bottom of a standard 1L vessel to control the exposed surface area. The suspension is weighed in the center cup prior to analysis in order to correlate the release rate.

Suspension Cups

Description	Part Number
Weighted holder, 5.72 cm outside dia., 0.52 cm inside dia.	12-4050
Insert cup, 17.5x8.2 mm, use with PN 12-4050	12-4055
Insert cup, 20x8.2 mm, use with PN 12-4050	12-4060

PTFE Suspension Cup

Enhancer Cell

Did You Know?

The Enhancer Cell is now included in the new USP General Chapter <1724> Semisolid Drug Products - Performance Tests.

Enhancer Cell and accessories

Designed for release rate dissolution testing of ointments, creams, gels and topicals

Used in research, quality control and product development laboratories, the Enhancer Cell provides release rate data for topicals using your standard Apparatus 1 or 2 with either a standard 1L paddle method or 200 mL vessel with mini paddle. Also known as the Vertical Diffusion Cell and External Receptor Chamber Type, the Enhancer Cell is a PTFE cell with adjustable volume and retaining cap to eliminate air pockets trapped against the skin or artificial membrane that provide the diffusion barrier. It is a cost-effective alternative to investing in the fragile and more labor-intensive Franz Cells.

- Ideal for testing ointments, creams and gels
- Available in several surface areas, including 0.5, 2.0 and 4.0 cm^2
- Used with traditional dissolution apparatus and a 200 mL flat bottom vessel or 1L vessel
- Meets SUPAC guidelines
- An alignment tool, available in various sizes to match membrane surface area size, is used to hold the membrane in place while eliminating air pockets with the universal adjustment tool. Alignment tools specific to the surface area are sold individually.

Take a look at Agilent's video on the Enhancer Cell at
www.agilent.com/lifesciences/enhancercell

Enhancer Cells and Accessories, compatible with Agilent, Varian and VanKel apparatus models

Description	Part Number
Enhancer Cell, 4 cm^2 surface area membrane (one per position)	12-4000
Enhancer Cell, 2 cm^2 surface area membrane (one per position)	12-4001
Enhancer Cell, 0.5 cm^2 surface area membrane (one per position)	12-4002
Height spacer (1 cm) / alignment tool, for 4 cm^2 Enhancer Cell (one required)	12-4020
Height spacer (1 cm) / alignment tool, for 2 cm^2 Enhancer Cell (one required)	12-4021
Height spacer (1 cm) / alignment tool, for 0.5 cm^2 Enhancer Cell (one required)	12-4022
Adjustment tool, for all Enhancer Cell sizes (one required)	12-4015
Cuprophan membrane, 126x345 mm, 10 sheets/pkg.	12-1370

Enhancer Cell Ordering Example

In addition to your apparatus, the following ordering example describes the items that should be ordered for Enhancer Cell use.

Enhancer Cell Ordering Example: 708-DS conversion, 6 positions, 4 cm^2 Enhancer Cell

Quantity	Description	Part Number
6	Enhancer Cell, 4 cm^2 surface area membrane (one per position)	12-4000
1	Height spacer (1 cm) / alignment tool, for 4 cm^2 Enhancer Cell (only one required)	12-4020
1	Adjustment tool, for all Enhancer Cell sizes (only one required)	12-4015
6	Mini paddle, lower interchangeable, electropolished stainless steel	13-3608
6	TruAlign vessel, flat bottom, 200 mL (one per position)	12-5170
6	TruAlign vessel 100/200 mL conversion kit (includes vessel adapter and evaporative cover)	12-6368

Intrinsic Dissolution Apparatus

The Intrinsic Dissolution Apparatus provides the dissolution rate of a pure active pharmaceutical ingredient (API) by exposing the API to a constant surface area of dissolution medium. The intrinsic rate is determined by rotating the apparatus in a dissolution vessel containing 37 °C media and pulling samples until at least 10% of the API has dissolved. The rate is then calculated by plotting the cumulative amount of API dissolved from the exposed surface area with respect to time.

Based on the modified Woods Apparatus as described in USP <1087>, the design includes threaded rings on the inside of the die cavity to prevent the compacted API from falling out of the die cavity during analysis. The apparatus includes a punch used to compress the API into a pellet with the aid of a laboratory press (not provided by Agilent). The Intrinsic Apparatus includes:

- Stainless steel die cavity with 0.5 or 0.125 cm^2 surface area
- Punch
- Shaft with holder
- Gasket ring

The surface plate, used in conjunction with the punch and a laboratory press, is sold separately and only one plate is required.

Intrinsic dissolution is expressed in terms of mg/time/cm^2, and is useful in studying the solubility characteristics of a pure drug substance.

Intrinsic Dissolution Apparatus and accessories

Intrinsic Dissolution Apparatus

Description	Part Number
Intrinsic Dissolution Apparatus, 0.5 cm^2 exposed surface area, with punch, shaft and holder, for 7000E/7010, 708-DS, 705-DS*	12-4101
Intrinsic Dissolution Apparatus, 0.125 cm^2 exposed surface area*	12-4110
Intrinsic die, 0.5 cm^2 exposed surface area	12-4120
Punch	12-4140
Shaft and die holder only, for intrinsic dissolution	12-4150
Surface plate, for intrinsic dissolution	12-4130

*Surface plate sold separately. Only one plate required for testing.

Note: The Intrinsic Dissolution Apparatus is not recommended for use with DVH models, including the 7030 and the 709-DS.

Intrinsic Dissolution Apparatus Example

In addition to the standard dissolution apparatus, to configure a 708-DS for intrinsic dissolution use, see the following example:

Intrinsic Dissolution Ordering Example: 708-DS, 6 positions

Quantity	Description	Part Number
6	Intrinsic Dissolution Apparatus, 0.5 cm^2 exposed surface area, with punch, shaft and holder, for 7000E/7010, 708-DS, 705-DS	12-4101
1	Surface plate, for intrinsic dissolution	12-4130

Water Baths and Heater/Circulators

708-DS heater/circulator

Agilent offers a number of water baths and replacement parts for the water baths, including fittings, adapters, tubing and clamps, as well as heater/circulators.

- Acrylic fabricated water baths for disintegration testers and BIO-DIS apparatus are made of a three-piece construction with solvent-welded seams.
- The molded high-performance polymer PETG design, utilized on most Agilent dissolution apparatus, provides better chemical and heat stability than standard acrylic baths and the rounded corners make cleaning easier.
- The 708-DS utilizes a universal voltage heater/circulator. It is designed specifically to fit beneath the apparatus housing and minimize vibration.

Water Baths, Heaters/Circulators and Accessories

Description	Part Number
Water Baths and Replacement Parts	
Water bath, for 100 Automated Disintegration Tester, with fittings	60-2120
Water bath, for BIO-DIS, 22.56x20.68x7.5 in.	60-2400
Drain valve for molded bath	62-9000
Bulkhead bath fitting	62-9010
Bath flow deflector	62-9020
Barbed angle adapter	62-9025
PVC tubing with 3/4 in. outer dia., 1/2 in. inner dia., 50 ft.	62-9030
Bath tubing clamps, stainless steel, 4/pkg.	62-9040
Heater/Circulators	
Heater/circulator, 115/230V	G7986A
Note: The heater/circulator can be used with 708-DS, as well as legacy 7000/7010, 7020, 7025 and 705-DS dissolution apparatus, and the BIO-DIS and Apparatus 7.	
Options for G7986A	
Cable for use with 7000/7010/BIO-DIS/Apparatus 7	G7986A #100
Cable for use with 708-DS	G7986A #101

Apparatus 3

BIO-DIS Reciprocating Cylinder Apparatus and Accessories

Extended release-rate dissolution testing that meets requirements of USP Apparatus 3 and EP Reciprocating Cylinder specifications

The Agilent BIO-DIS Reciprocating Cylinder Apparatus is ideal for automatic dissolution testing of dosage forms that require different types of media. Typically used for imitating the pH changes that occur in the body, this instrument is perfectly suited for extended and sustained release dosage forms.

The BIO-DIS can automatically perform a complete media change, simulating the pH change that occurs in the digestive tract. Due to the reciprocating action and the change in pH, the instrument may be used for a variety of applications. Capable of running unattended for extended periods of time, the BIO-DIS can store up to 15 programs and provide direct control over timepoints, agitation rate, sampling rate, movement between vessel rows, hold dip time, and drain time.

The BIO-DIS is designed to meet current USP and EP specifications. The instrument automatically traverses up to six rows of corresponding outer media tubes filled with different media. Custom instruments with additional rows are available as well.

BIO-DIS Reciprocating Cylinder Apparatus

Features include:

- Simulate gastrointestinal conditions with simple programming that allows in vitro dissolution pH profiling with biorelevant agitation rates and retention times.
- Useful for release-rate testing of floating dosage forms, beads and chewables.
- Use one instrument to test and transport a variety of samples, saving valuable bench space. Samples are automatically transported from one medium to the next without operator intervention.
- Be confident knowing the BIO-DIS is compliant with the reciprocating cylinder apparatus, USP Apparatus 3 and EP harmonized specifications.
- Select a standard volumetric reciprocating cylinder option or small and large volume configuration to meet testing needs for low dose or poorly soluble formulations. Other options include a double row instrument for increased testing throughput.

The standard seven-position system includes the following items:

- 3 outer media tube vessel carriers, 14 positions each
- 7 inner sample tubes with upper and lower caps
- 1 sample kit of polypropylene and stainless steel screens
- 42 outer media tubes, 300 mL (USP)
- 1 external heater/circulator

BIO-DIS accessories

Automated Sampling for BIO-DIS

Easily automate the sample collection process for Apparatus 3 using the Agilent 850-DS Dissolution Sampling Station. See page 92 for more details.

Filtration Options

Accomplish manual inline filtration using 5 µm disc filters with Luer Lock fittings found on page 55. Or use the 850-DS Dissolution Sampling Station with optional filter module to automate filtration with innovative Whatman™ filter plates from GE Healthcare that sample down to 0.2 or 0.45 µm pore size. See page 92 for more details.

BIO-DIS Reciprocating Cylinder Apparatus

Description	Part Number
BIO-DIS Reciprocating Cylinder Apparatus, 300 mL	G7970A
Options for G7970A	
Conversion kit, 100 mL	G7970A #100
Conversion kit, 1L	G7970A #105
Conversion kit, double row dip, 300 mL	G7970A #110
Conversion kit, double row dip, 1L	G7970A #115

Conversion/Retrofit Kits

Description	Part Number
Conversion/Retrofit Kits	
Conversion kit, 100 mL	27-6100
Conversion kit, 1L	27-6105
Retrofit kit, double row dip, 300 mL*	27-6201
Retrofit kit, double row dip, 1L*	27-6203
Retrofit kit, double row dip, 1L / 300 mL*	27-6205

*Retrofit kits must be installed by an Agilent representative

Did You Know?

The Dissolution Workstation Software can be used to control up to four (4) systems with the BIO-DIS, a pump, and the 850-DS Dissolution Sampling Station. In fact, the software allows for multiple samples per row and additional media changes beyond the traditional capability of the instrument. See page 86 for more information.

BIO-DIS Reciprocating Cylinder Apparatus and 850-DS Sampling Station

Description	Part Number
BIO-DIS Reciprocating Cylinder Apparatus and 850-DS Sampling Station	G7977A
Options for G7977A	
Conversion kit, 100 mL	G7977A #100
Conversion kit, 1L	G7977A #105
Conversion kit, double row dip, 300 mL	G7977A #110
Conversion kit, double row dip, 1L	G7977A #115
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7977A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7977A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7977A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7977A #213
Add Dissolution Workstation Software cable kit (software ordered separately)	G7977A #220
Add printer to 850-DS	G7977A #880

BIO-DIS Dimensions

Height	Width	Depth	Weight
73.66 cm / 29 in.	68.58 cm / 27 in.	69.85 cm/ 27.5 in.	43.1 kg / 95 lbs, dry without vessels

Did You Know?

Apparatus 3 may also be used for disintegrating dosage forms by using 27-1050 which creates improved mixing for particulates that may pass through the lower screen.

BIO-DIS Reciprocating Cylinder Accessories

Description	Part Number
Inner Sample Tubes (with threaded glass ends)	
Standard inner sample glass tube for 300 mL outer media tube	27-5000
Inner sample glass tube for 100 mL outer media tube	27-5010
Outer Media Tubes	
Outer media tube, USP, 300 mL	27-5100
Outer media tube, 100 mL	27-5110
Outer media tube, flat bottom, 1000 mL	27-5120
Upper and Lower Caps	
Standard upper cap, USP, 300 mL, for use with P/N 27-5000	27-1000
Upper cap, 100 mL, for use with P/N 27-5010	27-1010
Standard lower cap, USP, 300 mL, for use with P/N 27-5000	27-1020
Lower cap, 100 mL, for use with P/N 27-5010	27-1030
Lower cap, wider diameter for improved mixing, for use with P/N 27-5000	27-1050
Replacement Cannulas and Tubing	
Replacement Tubing Kit, BIO-DIS (all tubing, cannulas and fittings included)	27-0126
Return cannula, 2.75 in.	27-6520
Evaporation Caps	
Evaporation cap, USP, for 300 mL tube	27-1500
Evaporation cap, for 100 mL tube	27-1510
Evaporation cap, USP, tinted, for 300 mL tube	27-1520
Vessel Carrier for Outer Media Tubes	
Vessel carrier, for 300 mL tube, 7x2 layout, set of 3	27-6000
Vessel carrier, for 100 mL tube, 7x2 layout, set of 3	27-6005
Vessel carrier, for 1000 mL tube, 1x3 layout, set of 3	27-6010

(Continued)

BIO-DIS Reciprocating Cylinder Accessories

Description	Part Number
Replacement Screens for Inner Sample Tubes	
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 20-mesh, 840 µm	27-2000
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 40-mesh, 405 µm	27-2005
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 56-mesh, 250 µm	27-2007
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 78-mesh, 177 µm	27-2010
Polypropylene screens, 1.25 in. dia. for 300 mL tubes, 100-mesh, 150 µm	27-2015
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 20-mesh, 840 µm	27-2200
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 40-mesh, 405 µm	27-2205
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 78-mesh, 177 µm	27-2210
Polypropylene screens, 0.75 in. dia. for 100 mL tubes, 100-mesh, 150 µm	27-2215
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 10-mesh, 1905 µm	27-2099
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 20-mesh, 864 µm	27-2100
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 30-mesh, 533 µm	27-2103
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 40-mesh, 381 µm	27-2105
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 100-mesh, 140 µm	27-2110
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 200-mesh, 74 µm	27-2115
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 300-mesh, 46 µm	27-2120
Stainless steel screens, 1.25 in. dia. for 300 mL tubes, 400-mesh, 38 µm	27-2125
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 8-mesh, 2591 µm	27-2300
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 10-mesh, 1905 µm	27-2305
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 20-mesh, 864 µm	27-2310
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 40-mesh, 381 µm	27-2315
Stainless steel screens, 0.75 in. dia. for 100 mL tubes, 60-mesh, 229 µm	27-2320
Basket Adapters	
Basket adapter, O-ring, for BIO-DIS	27-2400
Basket adapter, 3-clip, for BIO-DIS	27-2401

BIO-DIS screens

Apparatus 7

Reciprocating Holder Apparatus 7 and Accessories

The Agilent Reciprocating Holder Apparatus 7 is ideal for automatic dissolution testing of dosage forms that require a change of media, a smaller volume or more vigorous agitation. Initially developed for testing transdermal patches, this apparatus now includes many different dosage form holders.

The reciprocating holder has a stroke length of 20 mm and can be programmed to dip between 5 and 40 dips per minute. At the end of a designated time period, the dosage form is automatically transported from one row to the next. Typical products tested include extended release tablets, transdermals, osmotic pumps and arterial stents.

The standard apparatus has seven sample positions with six rows and is available with 100 or 300 mL outer tubes. The firmware can be preprogrammed to automatically move to a fresh row of media for as many as six media changes. For smaller volumes, the instrument is available with 50 mL vessels in a 7-row configuration.

The Dissolution Workstation Software can also be used to control and log events of an Apparatus 7 with an 850-DS Sampling Station. By incorporating PC control, additional media changes can be accommodated by exchanging the vessel racks with fresh media.

Reciprocating Holder Apparatus 7

Dosage Holder Options

Agilent offers a variety of standard and customizable holder options to meet your application needs. These include reciprocating disks, angled disks, and cylinders for transdermal patches. For traditional oral dosage forms, acrylic pointed rods, stent holders and mini baskets are available.

Integration Options for Sampling and Filtration

The 7-position Apparatus 7 (100 or 300 mL) systems can be integrated with the 850-DS Dissolution Sampling Station, with optional built-in filter module to automate filtration down to 0.2 or 0.45 µm pore size. Inline filtration is also possible.

The Reciprocating Holder Apparatus 7:

- Simulates the biorelevant conditions for the skin, gastrointestinal tract and tissue required for transdermal, oral drugs and implants with biorelevant temperature agitation rates and retention times.
- Tests and transports a variety of samples, saving valuable bench space. Samples are automatically transported from one medium to the next without operator intervention, and can run unattended for up to six days.
- Stores up to 15 programs and maintains direct control over timepoints, agitation rate, sampling rate, and movement between vessel rows, hold dip time, and drain time.
- Accommodates a variety of dosage form holders including cylinders, reciprocating disks, angled disks, spring holders, stent holders, and pointed rods.
- Supports typical volume configurations of 20, 50, 100 and 300 mL. Additional conversion kits are available that can transition the instrument to support different volumes.

A standard Apparatus 7 includes the following items:

- Outer media tube vessel carriers
- Outer media tubes
- 1 external heater/circulator
- Built-in printer

Reciprocating Holder Apparatus 7

Description	Part Number
USP Apparatus 7 Reciprocating Holder	G7972A
Options for G7972A	
6-row, 7-sample, 300 mL configuration	G7972A #100
6-row, 7-sample, 100 mL configuration	G7972A #105
12-row, 12-sample, 50 mL configuration	G7972A #110
6-row, 13-sample, 20 mL configuration	G7972A #115
Note: Apparatus 7 Row/Sample Configuration - One (1) selection is required.	
Acrylic pointed rod assembly	G7972A #120
Transdermal holder kit	G7972A #121
Reciprocating disk, 1.6 cm^2	G7972A #122
Reciprocating disk, 2.5 cm^2	G7972A #123
Reciprocating disk, 5.0 cm^2	G7972A #124
Reciprocating disk, 7.0 cm^2	G7972A #125
Reciprocating disk, 10.0 cm^2	G7972A #126
Angled disk holder, 1.98 in.	G7972A #127
Angled disk holder, 1.42 in.	G7972A #128
Mini basket assembly, 40-mesh	G7972A #129
Mini basket assembly, 50-mesh	G7972A #130
Spring holder, 1.45"L x .58"ID x .031" wire ID	G7972A #131
Spring holder, 1.40"L x .31"ID x .040" wire ID	G7972A #132
Spring holder, 0.96"L x .33"ID x .031" wire ID	G7972A #133
Spring holder, 0.60"L x .25"ID x .031" wire ID	G7972A #134
Note: Sample Holder Type - One (1) selection is required.	

Reciprocating Holder Apparatus 7 and 850-DS Sampling System

Description	Part Number
Reciprocating Holder Apparatus 7 and 850-DS Sampling Station	G7978A
Options for G7978A	
6-row, 7-sample, 300 mL configuration	G7978A #100
6-row, 7-sample, 100 mL configuration	G7978A #105
6-row, 7-sample, 50 mL configuration	G7978A #110
Acrylic pointed rod assembly	G7973A #120
Transdermal holder kit	G7978A #121
Reciprocating disk, 1.6 cm^2	G7978A #122
Reciprocating disk, 2.5 cm^2	G7978A #123
Reciprocating disk, 5.0 cm^2	G7978A #124
Reciprocating disk, 7.0 cm^2	G7978A #125
Reciprocating disk, 10.0 cm^2	G7978A #126
Angled disk holder, 1.98 in.	G7978A #127
Angled disk holder, 1.42 in.	G7978A #128
Mini basket assembly, 40-mesh	G7978A #129
Mini basket assembly, 50-mesh	G7978A #130
Spring holder, 1.45"L x .58"ID x .031" wire ID	G7978A #131
Spring holder, 1.40"L x .31"ID x .040" wire ID	G7978A #132
Spring holder, 0.96"L x .33"ID x .031" wire ID	G7978A #133
Spring holder, 0.60"L x .25"ID x .031" wire ID	G7978A #134
Note: Sample Holder Type - One (1) selection is required.	
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7978A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7978A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7978A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7978A #213
Add Dissolution Workstation Software cable kit (software ordered separately)	G7978A #220
Add printer to 850-DS	G7978A #880

Did You Know?

The compatibility table on pages 78-79 provide details on holders and outer tube volumes for your specific testing needs.

Reciprocating Holder Apparatus 7 Accessories

Description	Part Number
Pointed acrylic rod	27-3000
Transdermal patch holder kit	27-3001
Replacement acrylic rod kit	27-3002
1.6 cm^2 reciprocating disk	27-8005
2.5 cm^2 reciprocating disk	27-8010
5.0 cm^2 reciprocating disk	27-8015
7.0 cm^2 reciprocating disk	27-8020
10.0 cm^2 reciprocating disk	27-8025
Angled disk, 1.98 in.	27-8035
Angled disk, 1.42 in.	27-8036
Basket shaft, mini	27-8600
Basket, mini, 40-mesh	27-8620
Basket, mini, 50-mesh	27-8621
Basket assembly, titanium	27-8622
Spring holder, Alza, 1.45 in. L x 0.58 in. ID x 0.031 in. wire ID, spring offset	27-0100
Spring holder, Alza, 1.40 in. L x 0.31 in. ID x 0.040 in. wire ID, spring offset	27-0101
Spring holder, Alza, 0.96 in. L x 0.33 in. ID x 0.031 in. wire ID, spring offset	27-0102
Spring holder, Alza, 0.60 in. L x 0.25 in. ID x 0.031 in. wire ID, spring offset	27-0103
Spring holder, Alza, 1.00 in. L x 0.50 in. ID x 0.031 in. wire ID, spring offset	27-0104
Spring holder, Alza, 1.45 in. L x 0.58 in. ID x 0.031 in. wire ID, spring centered	27-0105
Spring holder, Alza, 1.40 in. L x 0.31 in. ID x 0.040 in. wire ID, spring centered	27-0106
Spring holder, Alza, 0.96 in. L x 0.33 in. ID x 0.031 in. wire ID, spring centered	27-0107
Spring holder, Alza, 0.60 in. L x 0.25 in. ID x 0.031 in. wire ID, spring centered	27-0108
Spring holder, Alza, 1.00 in. L x 0.50 in. ID x 0.031 in. wire ID, spring centered	27-0109
Outer tube, 50 mL	27-5130
Outer tube, calibrated, 50 mL, class B	27-5135
Outer tube, 50 mL, low actinic - red	27-5160

BIO-DIS Reciprocating Cylinder and Reciprocating Holder Apparatus 7 Compatibility Table

		Apparatus 7 - Outer Tube			
Part Number	**Holder**	**50 mL**	**100 mL**	**300 mL (USP)**	**1000 mL**
27-5000	Inner tube (300 mL)	-	-	♦	♦
27-5010	Inner tube (100 mL)	-	♦	♦	♦
12-2100	Basket, USP, 40-mesh, 381 µm	-	-	♦	♦
27-2400	Durafit basket adapter	-	NR	♦	♦
27-2401	Basket adapter with clip assembly	-	NR	♦	♦

Diamond image (♦) = Compatible, Shaded box = Not compatible, NR = Not Recommended,
Asterisk (*) = based on dimension measurements only

(Continued)

Reciprocating Holders

BIO-DIS Reciprocating Cylinder and Reciprocating Holder Apparatus 7 Compatibility Table

		Apparatus 7 - Outer Tube			
Part Number	**Holder**	**50 mL**	**100 mL**	**300 mL (USP)**	**1000 mL**
27-5000	Inner tube (300 mL)	-	-	◆	◆
27-5010	Inner tube (100 mL)	-	◆	◆	◆
27-2400	Durafit basket adapter	-	NR	◆	◆
27-2401	Basket adapter with clip assembly	-	NR	◆	◆
27-8620	Basket, mini, 40-mesh	◆	NR	◆	◆
27-8621	Basket, mini, 50-mesh	◆	◆	◆	◆
27-8600	Basket shaft, mini	◆	◆	◆	◆
27-8622	Basket assembly, titanium	◆	◆	◆	◆
27-3000	Pointed acrylic rod	◆	◆	◆	◆
27-3002	Replacement acrylic rod kit	◆	◆	◆	◆
27-3001	Transdermal patch holder kit	-	-	◆	◆
27-8005	1.6 cm^2 reciprocating disk	◆	◆	◆	◆
27-8010	2.5 cm^2 reciprocating disk	-	-	◆	◆
27-8015	5.0 cm^2 reciprocating disk	-	-	◆	◆
27-8020	7.0 cm^2 reciprocating disk	-	-	◆	◆
27-8025	10.0 cm^2 reciprocating disk	NR	NR	◆	◆
27-6540	Replacement stent holder	◆	◆	◆	◆
27-6541	Stent holder, 8 mm (horizontal)	◆	◆	◆	◆
27-6542	Stent holder, 18 mm (vertical)	◆	◆	◆	◆
27-6543	Stent holder, 30 mm (vertical)	◆	◆	◆	◆
27-0101	Spring holder, 1.40 in. L x 0.31 in. inner dia. x 0.040 in. wire inner dia.	◆*	◆*	◆*	◆
27-0102	Spring holder, 0.96 in. L x 0.33 in. inner dia. x 0.031 in. wire inner dia.	◆*	◆*	◆*	◆
27-0103	Spring holder, 0.60 in. L x 0.25 in. inner dia. x 0.040 in. wire inner dia.	◆*	◆*	◆*	◆
27-0104	Spring holder, 1 in. L x 0.50 in. inner dia. x 0.031 in. wire inner dia.	◆	◆	◆	◆
27-8035	Angled disk, 1.98 in.	-	-	-	◆
27-8036	Angled disk, 1.42 in.	-	-	-	◆

Diamond image (◆) = Compatible, Shaded box = Not compatible, NR = Not Recommended,
Asterisk (*) = based on dimension measurements only

400-DS Apparatus 7

The first compendial small-volume dissolution testing apparatus for novel dosage forms

The 400-DS sets the performance standard for small-volume drug-release testing of medical devices or combination products such as drug eluting stents (DES) or contact lenses that release small amounts of active pharmaceutical ingredients (API) during a long period of time. Also used for testing extractables and leachables, and extended-release pharmaceutical products, the apparatus offers bathless heating, custom sample holders, integrated autosampling, media replacement and liquid handling capabilities.

Systems are available in sample cell sizes of 5 or 10 mL. Dissolution can be performed in volumes as low as 3 mL, providing significant gains in sample concentration for UV or LC analysis while virtually eliminating evaporation even when used with organic solvents. Controlled by its own version of the Dissolution Workstation Software, the 400-DS is capable of storing the operating parameters and method data required for a 21 CFR Part 11 environment. A relational database is used for system, method and test result storage, archival and retrieval. A single PC and software can control up to four systems.

400-DS Dissolution Apparatus

400-DS Sample Cells

Please consider the volume of media your method will require. It is not possible to switch between 5 and 10 mL cells on the same instrument. Keep in mind that the total volume of media the dosage form is exposed to is cumulative, Example: a method using 10 mL of media that has five timepoints and includes a complete media change at each timepoint would have a total volume of 50 mL.

The 400-DS:

- Saves time by simultaneously testing up to 13 samples, or 12 samples and a control or standard, while providing users direct visibility of each dissolution cell
- Maintains temperature control through internal temperature probes and external heating jackets; no water bath is required
- Minimizes evaporation through the fully closed system and the integrated syringe pump and autosampler save valuable bench space
- Offers automated media addition/removal through a port on the bottom of the cell
- Enables sample holder reciprocation through an externally controlled magnetic plate and supports between 1 and 35 dips per minute (DPM) to best match your requirements
- Includes a built-in autosampler that accommodates 12 individual sample rows with either 2 or 4 mL HPLC vials
- Permits to program up to 36 timepoints and five different media types into method
- Automates full or partial media replacement via a built-in fluidics module at every timepoint for each vessel

Items included with a standard 400-DS (software ordered separately):

- 400-DS base unit with built-in syringe pump
- 13 sample cells (5 or 10 mL)
- 13 heater jackets for sample cells
- Sample tray (2 individual rows)
- Sample vials (2 and 4 mL) for volume calibration
- Bottle caps and tubing for dissolution media/waste
- Modified temperature probe (for temperature calibration)
- Sample extraction tool
- Communication/power cables

400-DS cell holder with stent

Dissolution Cell Design

- A glass tube, open at both ends, is placed on top of the fluidics module, and a heating jacket surrounds each tube (no water bath is required). The bottom end is capped by the sampling port, while the top end is sealed after the sample holder is inserted.
- All sampling and media replacement is performed from the sampling port at the bottom of the dissolution cell.
- Temperature is recorded and independently controlled using an integrated temperature probe at the bottom of each cell.
- The 400-DS supports the USP-specified stroke length of 20 ± 1.0 mm required for Apparatus 7.

400-DS Dissolution Apparatus 7

Description	Part Number
400-DS Automated Apparatus 7	G7975A
Options for G7975A	
Note: 400-DS sample cell size (one selection is required).	
400-DS, 5 mL sample cell	G7975A #105
400-DS, 10 mL sample cell	G7975A #110
Note: 400-DS sample holder type (one selection is required).	
5 mL stent holder assembly	G7975A #120
10 mL stent holder assembly	G7975A #121
Basket assembly, PEEK	G7975A #122
Pacemaker lead holder, 1.7 mm	G7975A #123
Basket, 50-mesh, 10 mL	G7975A #124
Basket, mesh end, 20 µm	G7975A #125
Punctal plug, 5 mL	G7975A #126
Contact lens holder, 5 mL	G7975A #127
Flat blank holder, 10 mL	G7975A #128
Contact lens holder, 16 mm, 5 mL	G7975A #129
Basket, 50-mesh, 5 mL	G7975A #130
Contact lens holder, 16 mm, 10 mL	G7975A #131

Note: Software not included. See page 83 for software and PC ordering options.

Internal view of cell holders

400-DS Software and Accessories

Description	Part Number
400-DS Workstation Software, PC not included	G4973AA
400-DS Workstation Software Bundle, with PC, printer and monitor	G9263AA
Dissolution cell, 10 mL	33-9000
Dissolution cell, 5 mL	33-9005
Dissolution cell, 5 mL, low actinic - red	33-9043
Dissolution cell, 10 mL, low actinic - red	33-9044
Heater element with cable assembly, 10 mL	33-9001
Heater element with cable assembly, 5 mL	33-9006
Vial tray row, single, 1.5 mL	33-9013
Vial tray row, single, 4 mL	33-9002
Extraction tool	33-9007
Vial, pre-crimped 12x32, 100/pkg.	33-9010
Glass vial, clear, with PTFE/silicon cap, 15x45, 100/pkg.	17-5030

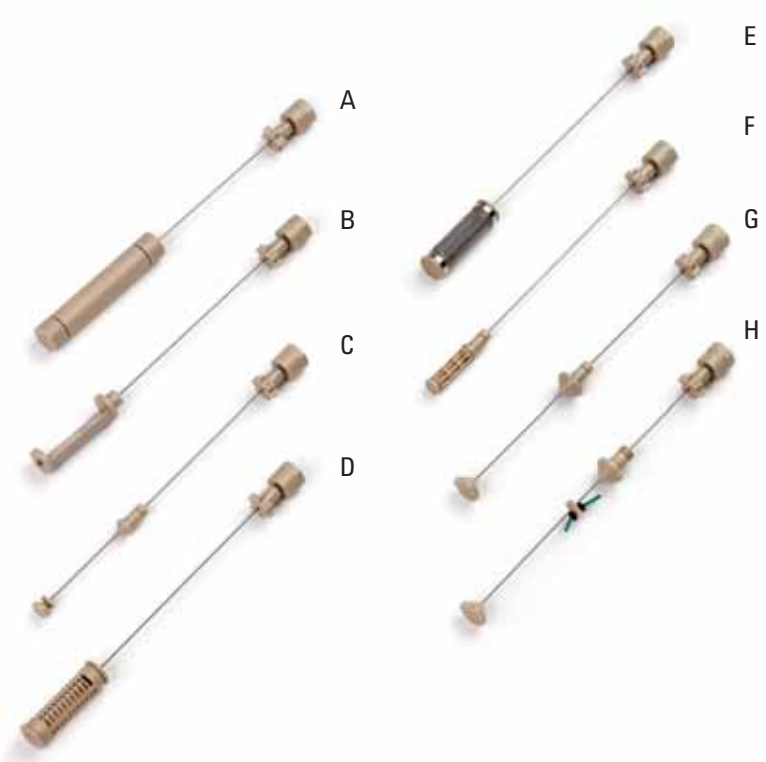
400-DS sample holders

Did You Know?

Agilent offers a variety of standard holders for stents, pacemaker leads, medicated contact lens, wound care products, and more. Contact your Agilent representative for information on custom-designed holders specifically for your testing needs.

400-DS Accessories

Description	Part Number
400-DS Sample Holders	
Stent holder assembly, 10 mL	33-9012
Stent holder assembly, 5 mL	33-9009
Pacemaker lead holder, 1.7 mm, requires stent holder assembly	33-9025
50-mesh basket, 10 mL	33-9029
50-mesh basket assembly, 10 mL	33-9041
PEEK basket assembly	33-9022
PEEK basket	33-9042
Basket, mesh end, 20 µm	33-9046
Punctal plug holder, 5 mL	33-9047
Contact lens holder, 5 mL	33-9048
Flat blank holder, 5 mL	33-9049
Contact lens holder, 16 mm, 5 mL	33-9050
50-mesh basket, 5 mL	33-9051
50-mesh basket assembly, 5 mL	33-9052
Contact lens holder, 16 mm, 10 mL	33-9053



A = P/N 33-9046
B = P/N 33-9049
C = P/N 33-9009
D = P/N 33-9022
E = P/N 33-9052
F = P/N 33-9048
G = P/N 33-9012
H = P/N 33-9025

400-DS Specifications

Reciprocation Length	20.0 ± 1.0 mm
Dip Rate	1-35 ± 0.5% DPM
Temperature	Ambient + 5 to 55 ± 0.2°C
Volume (Media)	3-5 (5 mL cell) or 8-12 (10 mL cell) ± 1%
Volume (Sample)	2 or 4 mL tray ± 1%
Timepoint (Samples)	Specified as HHH:MM:SS ± 2%
Number of Timepoints	Up to 36 (with tray change)
Input Voltage	115V / 230V AC; 50 / 60 Hz
Types of Media (per test)	Up to 5
Evaporation	0.2% or less over 24 hours

400-DS Dimensions

Height	Width	Depth	Weight
58.42 cm / 23 in.	53.34 cm / 21 in.	59.69 cm / 23.5 in.	58.97 kg / 130 lb.

400-DS sample tray

Dissolution Workstation Software

Complete, integrated control of multiple dissolution systems from a single computer

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

Method parameters, instrument and accessory information, and test data are captured and recorded with the software. View test status information in real time as the software progresses through the timepoints for each dissolution system. As part of 21 CFR Part 11 regulations, user changes to methods and system configurations can be easily tracked and documented.

Agilent's complete line of dissolution equipment is available for use with the Dissolution Workstation Software. This includes Apparatus 1, 2, 3, 5, 6 and 7 and the associated pumps and automated sampling equipment.

The Dissolution Workstation Software maintains a complete history for all executed tests, which can be digitally verified and electronically signed. Print, preview or export PDF-documented results generated by a dissolution run in the protected database created locally or on a network. The client-server architecture offers the potential to integrate or export the data to a laboratory information management system (LIMS).

Supported Apparatus

Agilent's complete line of dissolution equipment is available for use with Dissolution Workstation Software.

This includes:

- 708-DS, 709-DS as well as legacy models (USP Apparatus 1 and 2)
- BIO-DIS Reciprocating Cylinder and Reciprocating Holder (USP Apparatus 3 and 7)
- Legacy 806 Syringe Pump, 808 Filter Changer or 810 Peristaltic Pump
- 850-DS and legacy 8000 Dissolution Sampling Stations

Did You Know?

The latest version of Dissolution Workstation Software incorporates many features to enable compliance with enhanced Mechanical Qualification. These include:

- Electronic storage/linkage to Certificates of Conformance (COCs)
- Pre-test operational checks for verification for accessories
- Pre-test vessel table level verification
- Environmental vibration monitoring using the 280-DS Instrument Module

Dissolution Workstation Software

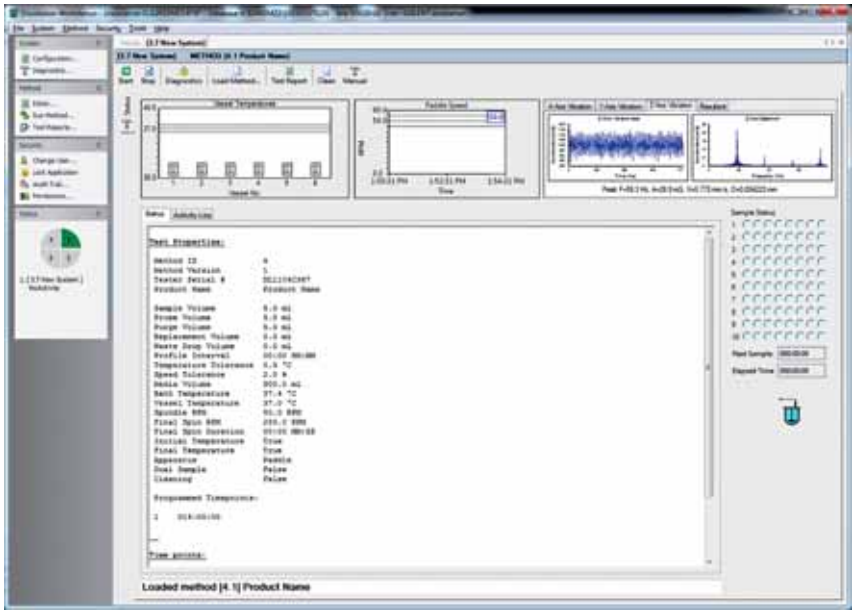
Description	Part Number
Dissolution Workstation Software (PC not included)	G4974AA
Dissolution Workstation SW Bundle (includes PC/Printer/Monitor)	G9264AA
280-DS Instrument Module Kit	12-0595

Did You Know?

The Instrument Module (IM) of the 280-DS MQS can be used with the Dissolution Workstation Software to monitor and record Vibration during your dissolution test. This feature allows the user to gather important data that can be used to track environmental conditions and help with failure investigations.

The Dissolution Workstation Software

- Contains several different user groups to assign proper rights and privileges to individual users
- Includes an audit trail feature that creates test reports highlighting differences between versions of methods or system configurations
- Can support dissolution methods that include a media change
- Does not have restrictions on the different combinations of equipment with any of four systems that may be configured
- Offers an ideal solution to eliminating manual transcription errors, and improving efficiency and data integrity



The Dissolution Workstation Software system status screen displays the activity of all systems in real time.

Agilent Dissolution Workstation Software Enhancements

- Consolidate and maintain data in one paperless location, with options of exporting information into your laboratory information management system (LIMS) or Microsoft® Excel®
- Add and document an automated system cleaning cycle to the end of each method, extending the life of your dissolution equipment. This auto-clean can even be an unattended operation when using the 850-DS Sampling Station.
- Comply with the latest enhanced mechanical qualification (MQ) guidelines, including verifying and documenting the condition of accessories prior to each test.
- Improve failure investigations related to environmental impacts by monitoring the dissolution apparatus and environment for vibration using the Instrument Module (IM) of the 280-DS Mechanical Qualification System.

When used with the Dissolution Workstation Software, the 280-DS Instrument Module provides valuable insight into real-time environmental test conditions.

Exclusive 280-DS Instrument Module (IM) monitoring provides important insights related to vibration

The importance of adding vibration and environmental impact monitoring to the Agilent Dissolution Workstation Software cannot be overstated as this feature provides the user with important information that is not available elsewhere. It has been known for many years that vibration can dramatically impact dissolution results. Regulatory bodies suggest companies monitor and control the level of vibration – you now have a tool to do just this. The lack of an industry-wide norm demonstrates how internal and external vibrations may affect each product and individual environments differently. With baseline values for vibration on the x-, y- and z-axes, dissolution systems as well as their environments can consistently be monitored in real time.

This added benefit may be used during early research to develop internal tolerances for specific methods, as part of a quality control initiative for well-established methods – or to watch for wear and tear to prevent instrument failure. If failure should occur, this feature speeds problem solving and helps to get instruments back online faster.

280-DS Mechanical Calibration System

Redefine dissolution qualification

Recalibration

Depending on usage conditions and frequency, the 280-DS should be periodically recalibrated. Agilent offers this service, which may be scheduled by visiting **www.agilent.com/lifesciences/dissolution3in1**

Easily perform measurements required for Mechanical Qualification (MQ) or the physical portion of the Performance Verification Test (PVT) in as little as 30 minutes for both paddles and baskets!

Agilent's 280-DS Mechanical Qualification System (MQS) allows you to measure all critical physical parameters of the dissolution apparatus with increased reliability and precision. The 280-DS works with any dissolution apparatus with an open-head design to obtain accurate, repeatable measurements virtually hands-free. Simply place either the Instrument or Vessel Modules to take measurements without the use of separate tools or added steps that increase time in the qualification process. Coupled with software ideal for a 21 CFR Part 11-compliant environment, the system has the ability to maximize analyst efficiency, reduce instrument downtime and improve dissolution failure investigations.

The Instrument Module (IM) and Vessel Module (VM) electronically capture all the necessary measurements for the 280-DS. These durable modules replace the need for individual measuring gauges with an all-in-one system that accurately verifies physical parameters without the guesswork associated with manual gauges.

Instrument Module measurements include:

- Vessel plate level
- Triaxal vibration
- Temperature

Vessel Module measurements include:

- Rotational speed (RPM)
- Shaft wobble
- Basket wobble
- Vessel centering
- Vessel verticality
- Shaft verticality
- Basket and paddle height

Agilent 280-DS Mechanical Qualification System and Workstation Software

Did You Know?

When using the 280-DS with an Agilent dissolution apparatus, the user achieves an additional advantage. A simple RS232 connection from the instrument to the PC allows the software to initiate spindle rotation when necessary. This is especially useful when measuring RPM, wobble and vibration, and provides even greater time savings and efficiency! This connectivity can be achieved by adding option #100 when ordering.

Reliable, Secure Data Recording and Storage

The 280-DS Workstation Software incorporates an intuitive, user-friendly interface built on a familiar and compliant software platform. It includes preloaded regulatory methods – such as ASTM E2503-07 – for quick setup and execution. Previously stored data files are categorized and easily retrieved from a secure database. The software also contains enhanced capabilities, such as data trending, that can improve failure investigations and increase apparatus integrity.

280-DS Mechanical Qualification System

Description	Part Number
280-DS Mechanical Qualification System, with 280-DS Workstation Software	G7980AA
Cable kit for Agilent/Varian/VanKel Dissolution Apparatus connection	G7980AA #100
HP ProBook laptop for use with 280-DS	G7980AA #650
280-DS Replacement Parts	
Magnetic Clip, RPM, 280-DS	K1005-02019

The 280-DS transforms the process of gathering mechanical qualification data.

Agilent 850-DS Dissolution Sampling Station with optional built-in filtration module.

850-DS Dissolution Sampling Station

Centralize Dissolution Workflow

Looking for the ideal autosampling solution for your laboratory? The 850-DS Dissolution Sampling Station, which replaces the well-known Agilent 8000 autosampler, can be seamlessly incorporated into your existing workflow to provide an unattended sampling and cleaning solution that increases productivity and eliminates variability. Supporting a range of dissolution methods, the 850-DS works with USP dissolution apparatus 1, 2, 3, 5, 6 and 7 for precise and repeatable results using conventional test tubes, HPLC vials and even 96-well plates.

- Create and store custom dissolution methods
- Control precise and repeatable sampling
- Document critical instrument data
- Prepare samples for subsequent UV-Vis or HPLC analysis

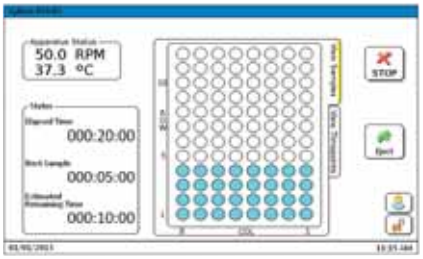
Legacy Instruments

The Agilent 850-DS with optional built-in filter changer module replaces the 8000 Dissolution Sampling Station, 806 Syringe Pump, 808 Filter Changer and 810 Peristaltic Pump. Each of these instruments will receive continued support for seven years for our existing customer installations. Parts and accessories for these instruments are available on page 138.

Built-in Syringe Pump and Optional Filter Changer Module

Conserve benchspace using the integrated syringe pump with variable speeds for shorter timepoint intervals. The 850-DS handles different types of media - including those containing surfactants - for superior autosampling performance. Media replacement is a standard feature and can be used with or without the optional filter module. Should you require filtration down to 0.2 or 0.45 micron, this is possible with the exclusive WhatmanTM 850-DS 8-channel filter plates from GE Healthcare that simplifies the need for replacement between timepoints. Visit **www.gelifesciences.com/distributors** for contact information regarding filter plate ordering.

The 850-DS optional filter module uses eight 25 mm filter membranes in a novel plate design.



The 850-DS firmware displays real-time status of method progression.

Firmware Capabilities

The 850-DS firmware supports eight languages including English, German, Hungarian, Japanese, Portuguese, Russian, Chinese and Spanish. Easily display real-time status of instrument conditions, including the sample tray format installed, as well as calculate time for minimum sampling interval during method setup, preventing timing errors.

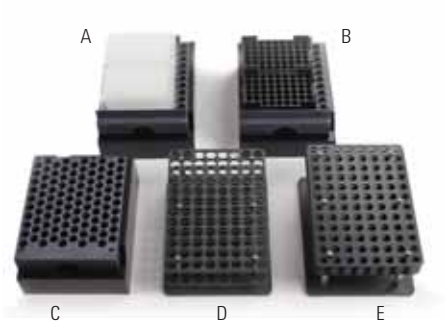
The firmware also:

- Differentiates between full and partial media change for accurate timing
- Can prevent unauthorized instrument and method changes
- Accepts methods with up to 36 timepoints
- Calculates minimum sampling intervals accounting for prime, sample and purge volumes
- Supports data export functionality via RS232, SD card, or optional built-in printer
- Synchronized start enables performance of two dissolution tests in parallel

Samples collected by the 850-DS into an Agilent HPLC sample tray can be placed directly into the HPLC autosampler, avoiding the need to manually transfer individual vials to a separate tray.

850-DS Dissolution Sampling Station

Description	Part Number
850-DS Dissolution Sampling Station	
850-DS Dissolution Sampling Station	G7930A
850-DS Dissolution Sampling Station Options	
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7930A #210
Sample tray kit, 108-position, 2 mL, includes tray and needle block assembly	G7930A #211
Sample tray kit, 100-position, 2 mL, includes tray and needle block assembly	G7930A #212
Sample tray kit, 96-well plate, includes tray and needle block assembly	G7930A #213
Add Dissolution Workstation software cable kit (software ordered separately)	G7930A #220
Add printer to 850-DS	G7930A #880
850-DS Filtration Module	G7931A
850-DS Dissolution Sampling Station Options and Replacement Parts	
Sample tray, 96-position, 12 x 8, 2 mL, for use with HPLC vials	K1005-05212
Sample tray kit, 108-position, 2 mL, requires needle block conversion	K1001-01202
Sample tray, 54-position, 9 x 6, for 2 mL vials, for use with K1001-01202	5022-6502
Sample tray kit, 100-position, 2 mL, requires needle block conversion	K1001-01203
Sample tray, 100-position, 10 x 10, for 2 mL vials, for use with K1001-01203	G1313-44510
Sample tray kit 96-well plate, requires needle block conversion	K1001-01204
Glass tubes, 16x100 mm, 250/pk	17-5001
Glass vials, 12x32 mm, w/ cap (PTFE/Silicon), 100/pk	17-5020



A (top left): 96-well plate sample tray – for use with two (2) 96-position well plates

B (top right): 108-position HPLC vial sample tray – for use with two (2) 54-position HPLC sample trays

C (bottom left): 100-position HPLC vial sample tray (zigzag) – for use with 100-position Agilent HPLC sample tray

D (bottom middle): 96-position test tube sample tray – for use with 16 x 100 mm test tubes

E (bottom right): 96-position HPLC vial sample tray – for use with 12 x 32 mm HPLC vials

The 850-DS Dissolution Sampling Station is also part of the following system bundles:

850-DS Dissolution System Bundles

Description	Part Number
850-DS Dissolution System Bundles	
708-DS Dissolution Apparatus and 850-DS Sampling Station	G7913A (see page 17)
709-DS Dissolution Apparatus and 850-DS Sampling Station	G7918A (see page 25)
Cary 60 Online UV Dissolution System – Multicell	G7926A (see page 118)
BIO-DIS Reciprocating Cylinder Apparatus and 850-DS Sampling Station	G7977A (see page 70)
Reciprocating Holder Apparatus 7 and 850-DS Sampling Station	G7978A (see page 76)

Note: Refer to the specific pages for more detailed information and available options.

850-DS Dissolution Sampling Station Dimensions and Specifications

Dimensions	
Height	40.0 cm
Height with filter module	60.0 cm
Width	39.0 cm
Width with filter waste bin	48.0 cm
Depth	60.0 cm
Weight	27.0 kg
Specifications	
Sampling accuracy	10 mL ± 2.5%
Sample volume per vial/tube	0.1-14 mL (up to 28 mL with dual sample)
Sample frequency	Method specific with minimum of 2 minutes
Number of samples per test	Up to 36 with manual tray exchange
Pump Speed	Variable (6-12)

Note: For the complete 850-DS specifications, visit **www.agilent.com/lifesciences/850-DS**

UV Dissolution Systems

Selecting a UV Dissolution System

Agilent offers UV Dissolution Systems with both the Cary 8454 UV-visible and the Cary 60 UV-visible Spectrophotometers. Whether you want an online or offline system, multicell based or in situ measurement via fiber optics, we have just the UV-visible system to suit your needs.

Online UV Dissolution System Configuration

1. Select the UV spectrophotometer that best suits your testing needs. Some important criteria to take into account:

Cary 8454 UV-visible Spectrophotometer

- The Cary 8454 is a diode array UV spectrophotometer that is ideal for use with single and select multicomponent products.
- The most economical configuration is equipped with a single flow cell. Samples are pumped to the flow cell by a peristaltic pump and read sequentially.
- When configured with a single apparatus, the eight-position multi-cell transport (MCT) option withdraws samples simultaneously, pumps the samples to the individual flow cells, reads and returns the samples to the vessels. For even greater flexibility, the MCT option can have up to four apparatus integrated with one UV spectrophotometer. Samples are withdrawn and read sequentially. After measurement, the sample is discarded as opposed to returned to the vessel.
- Updated software provides allows enhanced 21 CFR Part 11 security via OpenLab ECM.

Cary 8454 UV-visible Spectrophotometer

Cary 60 UV-visible Spectrophotometer

- Multicell UV Dissolution: Utilizes a multicell changer that allows for the integration of up to two dissolution apparatus with one UV spectrophotometer. In a single- or dual-apparatus configuration, each vessel has a dedicated flow cell. Samples are taken simultaneously and read sequentially. The Cary WinUV software also allows incorporation of the 850-DS Dissolution Sampling Station in line with the Cary 60, offering sample archival or offline collection for HPLC analysis.
- Fiber Optic UV Dissolution: May be configured for use with a fiber optic multiplexer, and integrated with either one or two apparatus. The fiber optic probes are mounted on the moveable manifold and are precisely positioned in the media only during measurements.

If you need assistance with selecting the system most suitable for your laboratory, please contact your Agilent representative.

2. Once you have determined the UV platform, you will need to determine which apparatus you would like to integrate. Both the 708-DS and 709-DS are fully compatible with these online UV systems. In addition, you can retrofit many older Varian and VanKel apparatus with either system.

Cary 60 UV-visible Spectrophotometer

UV Dissolution Selection Chart

Cary 8454 and Cary 60 UV-visible Spectrophotometers

General Information	Cary 8454	Cary 60
Software Package	ChemStation	Cary WinUV
Number of Apparatus	1 to 4 (Valve System)	1 to 2
Multicomponent Analysis	Yes (with select products)	No
Fiber Optic System Availability	No	Yes

Spectrophotometer Details	Cary 8454	Cary 60
Wavelength Range	190-1100 nm	190-1100 nm
Slit Width	1 nm	1.5 nm
Lamp Type	Tungsten and Deuterium	Xenon Flash
Instrument Design	Diode Array	Scanning
Wavelength Accuracy	< ± 0.5 nm	< ± 0.5 nm
Wavelength Reproducibility	< ± 0.02 nm	± 0.1 nm
Photometric Accuracy	< ± 0.005 Abs (NIST 930E)	± 0.005 Abs (NIST 930D)
Photometric Noise	< 0.0002 Abs	± 0.0001 Abs
Baseline Flatness	< 0.001 Abs	< 0.001 Abs
Stray Light	< 1.0% (198 nm) < 0.05% (220 nm) < 0.03% (340 nm)	< 1.0% (198 nm) < 0.05% (220 nm) ≤ 0.05% (370 nm)

Select from either of Agilent's UV-Vis Spectrophotometers for a complete online solution – Cary 8454 UV-Vis (left) or Cary 60 (right)

Online Sampling System Details	Cary 8454	Cary 60
Closed Loop Sampling	Yes (Multicell)	Yes (Multicell)
Path Lengths (mm)	1, 2, 5, 10 (Multicell)	0.2, 0.5, 1, 2, 5, 10 (Multicell) 1, 2, 5, 10, 20 (Fiber Optic)
Automated Dosage Delivery and Sampling	Yes	Yes
Temperature Monitoring	Yes	Yes
Simultaneous Sampling	Yes (Multicell)	Yes (Multicell)
Sequential Sampling	Yes (Valve Systems)	Yes (Fiber Optic)
Sample Filtration (minimum pore size µm)	5 µm	0.2 or 0.45 µm with 850-DS Dissolution Sampling Station and optional filter module
Sample Archival	No	Yes (Multicell with 850-DS Dissolution Sampling Station)

UV-visible Software Details	Cary 8454 (ChemStation)	Cary 60 (Cary Win UV)
Real-time Data Visible	Yes	Yes
Independent Methods	Yes	Yes
Offline Analysis	Yes	Yes
User-definable Dissolution Result Calculation	Yes	No
Tablet Weight Normalization	Yes	Yes
Medium Volume Changes	Yes	Yes
Customizable Reports	Yes	Yes
Apparatus Performance Tracking	Yes	No
21 CFR Part 11 Package	Yes	Yes
Electronic Signatures	Yes	Yes

Cary 8454 UV Dissolution Systems

Online UV Dissolution

Agilent, Varian and VanKel dissolution apparatus can be directly linked to the diode array Cary 8454 UV-visible spectrophotometer for automated test runs. The UV-visible ChemStation software integrates the apparatus, the spectrophotometer and the computer into a complete system supporting guided operation and unattended test runs with online test progress monitoring. The software supports test preparation, as well as post run activities. The software offers additional features by adding advanced capabilities for method development and validation, as well as a tool set for 21 CFR Part 11 compliance. The software can be operated in a workstation environment or within an OpenLab/ECM environment.

708-DS Dissolution Apparatus paired with the Cary 8454 UV-visible Spectrophotometer and UV-Chemstation Software

Online Sampling Systems

The ChemStation software controls the sampling and pumping systems, or you can choose to manually operate the systems. The pumps, with convenient cassette-mounted tubing, offer variable speeds for adjustable flow rates, which are reversible as well.

The online sampling systems support eight measurement channels depending on the hardware configuration. The measurement cycle at each timepoint is configurable with up to eight measurements consisting of a blank, standard and sample.

Disposable cannula filters prevent the transfer of non-dissolved particles into the flow cells. Reversal of the pump direction at the end of a transfer cycle flushes particles from the filters, avoiding clogging. Flow tests before and after completion of a run can be applied to ensure the equipment has performed reliably during the entire run.

A large variety of flow cells with different path lengths, from 1 to 10 mm, in combination with the variable pump times are ideal for aligning your target UV-visible analysis. You can adapt the various cell volumes, and measure the respective exchange pump time by the flow test included in the ChemStation software.

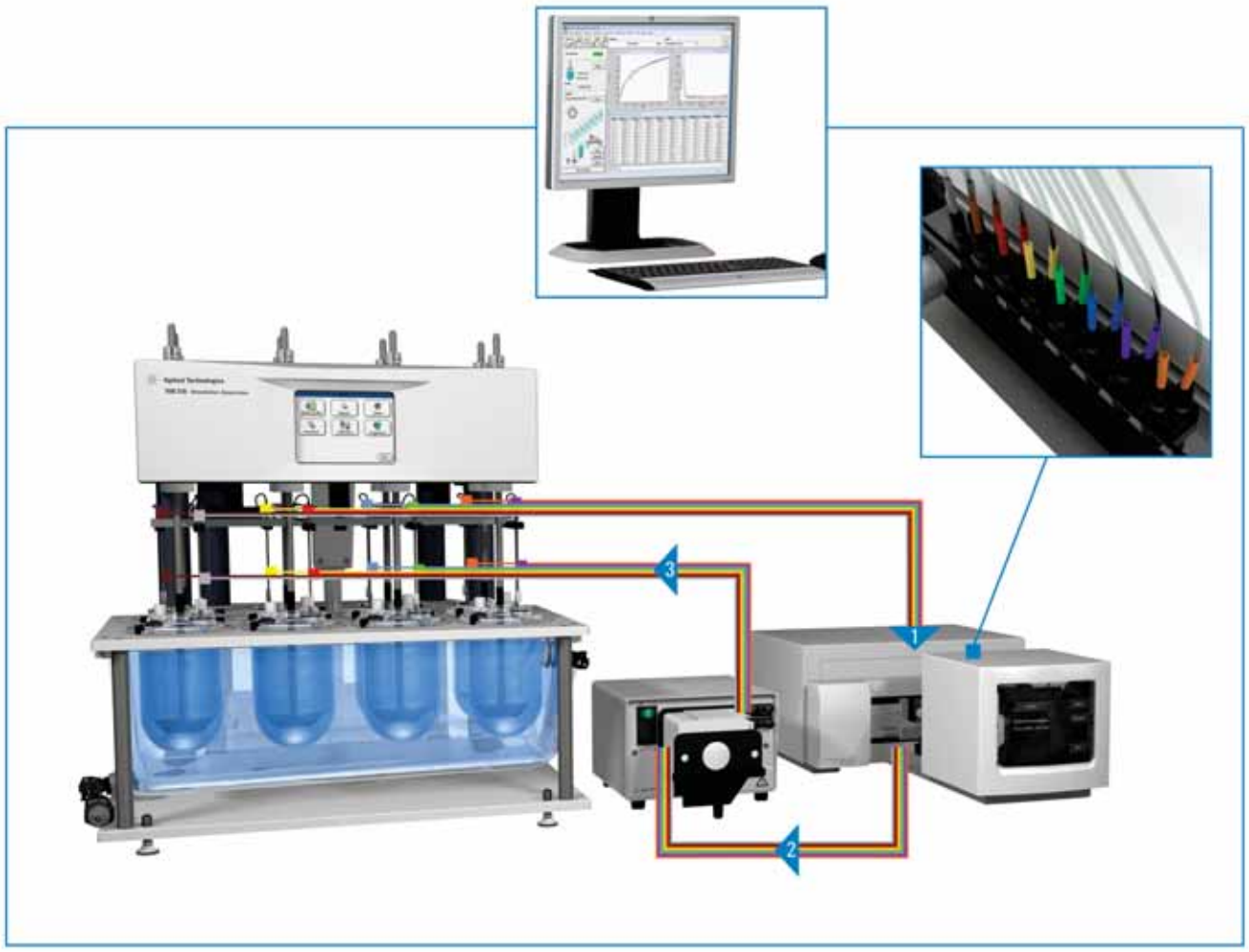
Services for complete qualification are available assuring the proper performance of the entire system.

Cary 8454 UV Dissolution System: Multicell-based Sampling

The multicell-based system is the most commonly used and versatile sampling system for single apparatus testing, and is ideally suited for QA testing and formulation development. The system uses a multicell transport with eight flow cells, one for the blank, up to six for the individual vessels and one for a standard, with a multi-channel pump to sample all vessels simultaneously. A minimum cycle time of two minutes is possible. The dissolution medium is returned to the vessel so that there is no change in medium volume during the test. The system is capable of taking a large number of data points, allowing for a well characterized dissolution profile.

Flow Configuration (as shown below)

1. The sampling manifold is lowered and the pump primes the lines.
2. The sample from each vessel is pulled into the flow cells of the Cary 8454 simultaneously. The manifold rises and the pump is stopped during measurement.
3. After measurement, the pump pushes the samples back to the return cannulas and into the vessels. All media is returned to the individual vessel from which it was drawn. No sample volume is lost in this-closed loop system.



Cary 8454 UV Dissolution System: Multicell-based Sampling

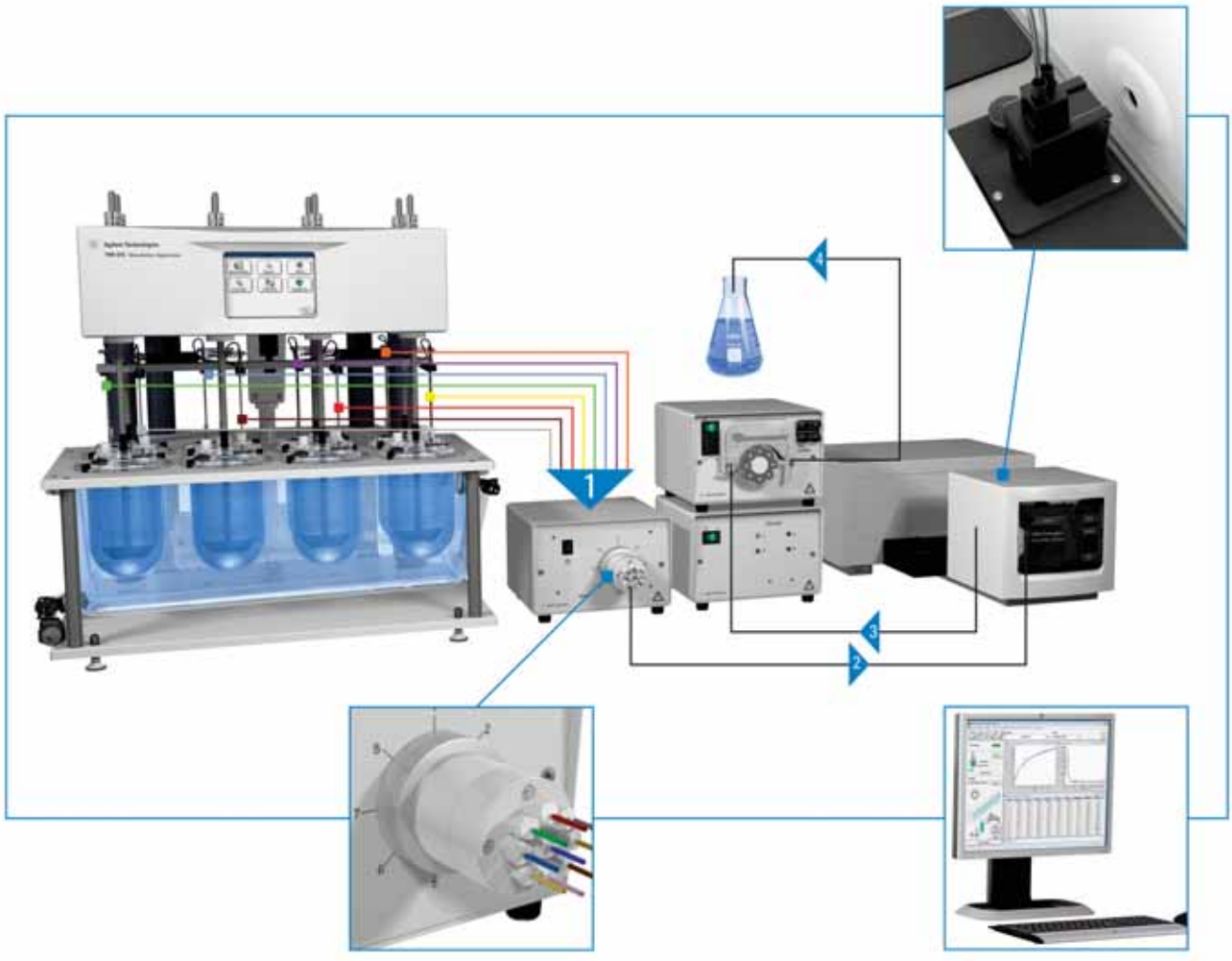
Cary 8454 UV Dissolution System: Valve-based Sampling

The valve-based system is the most cost-effective UV dissolution solution. The system uses an eight-port valve to switch between blank, control and the six dissolution vessels, with a single channel and flow cell. Because the sampling is sequential, the minimum cycle time is five minutes. The ChemStation software performs calculation correction for the approximate 4 mL waste volume during result processing.

Flow Configuration (as shown below)

1. The sampling manifold is lowered, the pump is activated and samples are pulled sequentially through the 8-port valve.
2. The samples are moved to a single flow cell on the Cary 8454 and individually read.
3. From the flow cell, the sample is pulled through the peristaltic pump.
4. Finally, the sample is discarded into a waste receptacle.

Once all vessel positions have been sampled and analyzed, the manifold rises until the next timepoint.



Cary 8454 UV Dissolution System: Valve-based Sampling

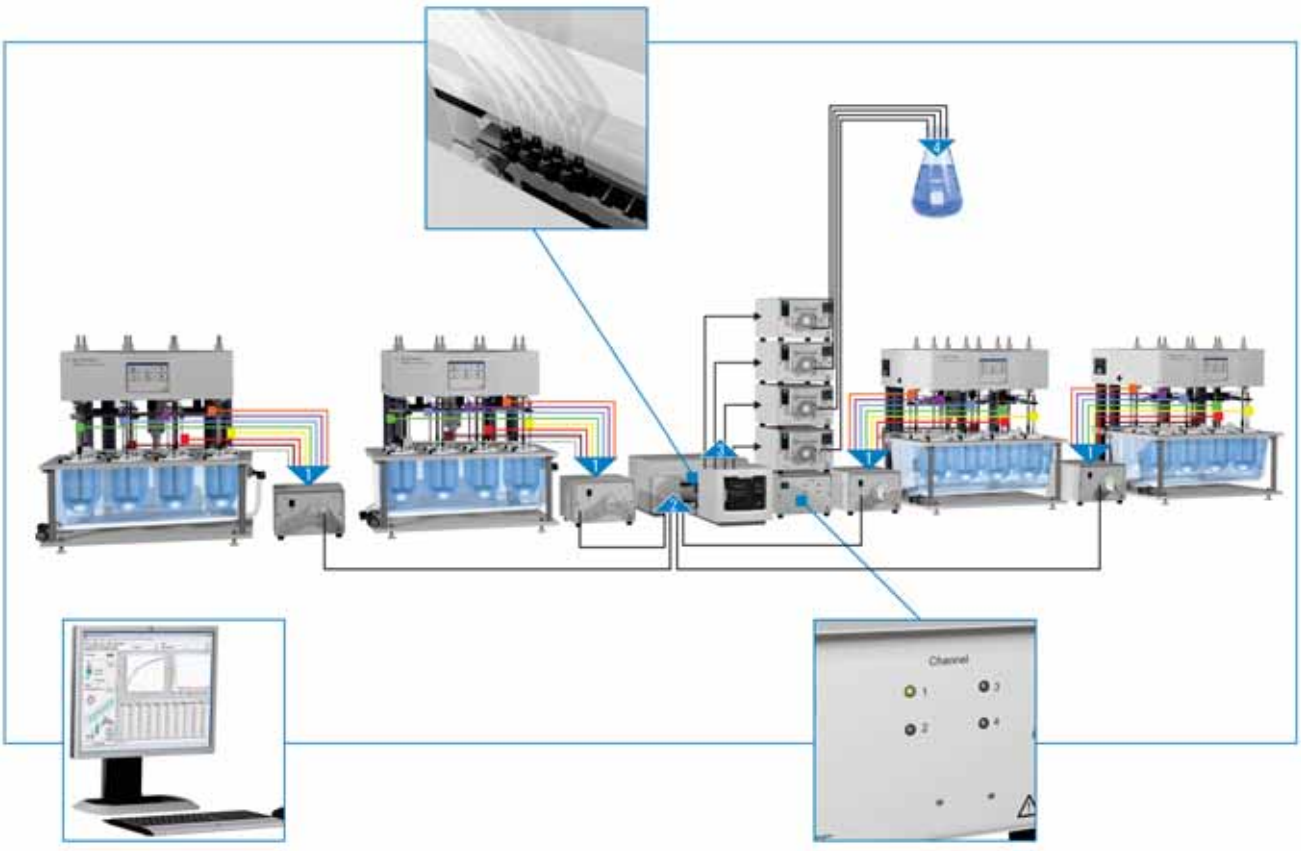
Cary 8454 UV Dissolution System: Multi-apparatus Sampling

The Cary 8454 UV dissolution testing system, in combination with the valve-based, multi-apparatus sampling capabilities, offers increased productivity when running a large number of samples. The system uses a single spectrophotometer to measure a blank, six vessels and a control in up to four apparatus all within five minutes, and each apparatus can run a different method, if needed. The methods and features are identical with the single-apparatus, valve-based system. In both systems the samples are read sequentially. Each apparatus has a dedicated flow cell.

Flow Configuration (as shown below)

1. At the appropriate timepoints, the sampling manifolds are lowered and the samples are moved individually to the 8-port valve.
2. One sample from each apparatus is pulled through the valve and placed into the flow cell assigned to that apparatus. The pump stops and the measurement is taken.
3. The samples are then pulled through the peristaltic pump.
4. Finally, the sample volume is discarded into waste.

This cycle is then repeated for the next vessel in each apparatus until all the samples have been measured. The sampling manifold is in the lowered position during the sampling process.



Cary 8454 UV Dissolution System: Multi-apparatus Sampling

Cary 8454 UV Dissolution Systems

Offline UV Dissolution

Sipper operation is easy with built-in measurement buttons.

In the offline approach of UV dissolution testing, the dissolution samples are collected independently of the Cary 8454 UV-visible spectrophotometer. For example, a number of dissolution apparatus can be used in conjunction with an automated sampling system. The samples are then manually transported to the Cary 8454 for analysis. Sample analysis and data evaluation are performed using the spectrophotometer and software, creating a flexible approach to evaluating dissolution results.

The offline analysis approach is scalable and applies to:

- Manual operation using standard UV cuvettes
- Sipper operation using a flow cell
- Autosampler that provides unattended sample introduction of up to 240 samples

Software support through UV-ChemStation software is used for introducing samples in the right sequence and is provided with your system. No change to a dissolution method is required, only the manner in which the sample is introduced.

In the combination with automated sampling, the use of the XY autosampler offers a significant automation and an optimum utilization of the spectrophotometer.

Cary 8454 UV-Visible Spectrophotometer Dimensions

Height	Width	Depth	Weight
18.5 cm / 7.3 in.	34.4 cm / 13.5 in.	56 cm / 22 in.	16.5 kg / 36.3 lbs.

UV-Vis ChemStation Software

Did You Know?

ChemStation's dissolution software supports full spectrum acquisition. During a dissolution run, corrections can be applied for capsule absorbance and background scattering. Multi-component analysis of formulations with multiple active ingredients can also be analyzed. Analytical methods can be optimized without repeating the test run simply by recalculation of the run data.

The UV-Visible ChemStation software belongs to Agilent's family of ChemStation software for analytical instruments, and its portfolio of features facilitates a strong learning and usability experience.

The application module for dissolution testing offers precise and accurate sample analysis combined with online and offline dissolution testing analysis and results evaluation. A ChemStation dissolution testing method is generated independent from the approach of sampling. This offers new opportunities in method transfer even if different approaches in the experimental setup and equipment are applied. A ChemStation dissolution method supports the dissolution workflow from test preparation to the final clean-up and results archival.

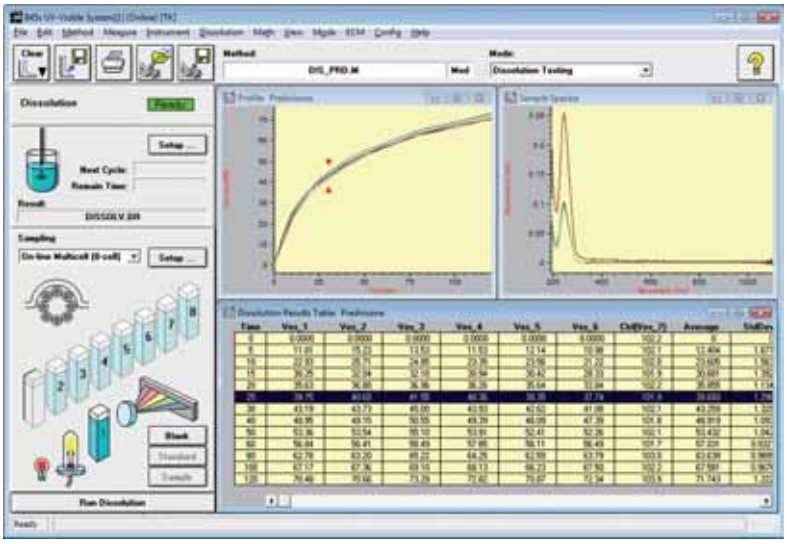
In its online configuration, the ChemStation dissolution software monitors and checks the apparatus performance during the dissolution test. The results file generated after test completion contains all information to verify, reprocess and document the dissolution experiment. ChemStation's Security Pack provides the necessary 21 CFR Part 11 requirement tools without the need of a database. Electronic signatures can be issued on a results file for various purposes. The UV-ChemStation software is OpenLab/ECM compatible.

Apparatus drivers, ChemStation software and the dissolution application module are required for complete control your Agilent, Varian or VanKel dissolution apparatus.

Agilent's OpenLAB Software Suite helps streamline data management for pharma regulatory compliance.

- Boost productivity by organizing the ever-increasing volume of data in your lab
- Used by 10 of the 11 top pharmaceutical companies for secure data storage
- Manage your lab's electronic content regardless of source

For more information, visit:
www.agilent.com/chem/openlabinfo



The run-time display shows profiles, actual values and the last spectra, as well as the status of instrument at a glance.

Cary 8454 UV Dissolution Systems

For the Cary 8454 UV Dissolution Systems, each bundle is fully inclusive of the apparatus, spectrophotometer and required accessories. The 708-DS Dissolution Apparatus is included as standard, but may be replaced by the 709-DS using the appropriate option.

The three bundles, which all offer automated runs analyzed by the Cary 8454 UV-visible Spectrophotometer, include:

Cary 8454 UV Dissolution System Bundles

Description	Part Number
Cary 8454 UV Dissolution System • 708-DS Dissolution Apparatus • Valve-based sampling system with Cary 8454 UV-visible Spectrophotometer • PC and printer • UV-visible ChemStation plus Security Pack software	**G7920A**
Multi-apparatus Cary 8454 UV Dissolution System • Two 708-DS Dissolution Apparatus • Multi-apparatus sampling system with Cary 8454 UV-visible Spectrophotometer • PC and printer • UV-visible ChemStation plus Security Pack software	**G7921A**
Multicell-based Cary 8454 Dissolution System • 708-DS Dissolution Apparatus • Multicell-based sampling system with Cary 8454 UV-visible Spectrophotometer • PC and printer • UV-visible ChemStation plus Security Pack software	**G7922A**
Cary 8454 UV Dissolution System Options	
Cary 8454 UV Dissolution System without printer	G792xA#890
Cary 8454 UV Dissolution System without PC and printer	G792xA#880
Cary 8454 UV Dissolution System without 708-DS Dissolution Apparatus	G792xA#900
Replace 708-DS with 709-DS Dissolution Apparatus	G792xA#910

Cary 8454 UV-Visible Spectrophotometer Systems and Accessories

Description	Part Number
Cary 8454 UV-visible System	
Cary 8454 UV-visible system	G1812AA
Cary 8454 UV-visible system with Security Pack	G1815AA
UV-visible ChemStation Dissolution Software	
Dissolution testing software	G1118AA
Agilent Dissolution apparatus driver software	G7900AA
Automated Sipper System for the Cary 8454 and 8453	89068D
Cary 8454 Sampling Systems	
XY Autosampler	G1811A
Multicell Transport Sampling System	G1127A
Valve Sampling System	G1128A
Multi-apparatus sampling system for two dissolution apparatus	G1129A
Additional sampling system for one dissolution apparatus	G1130A
Flow cell, for use with 8453/8454, 1 mm	5061-3396
Flow cell, for use with 8453/8454, 2 mm	5061-3397
Flow cell, for use with 8453/8454, 5 mm	5065-9918
Flow cell, for use with 8453/8454, 10 mm	5061-3398

The standard 708-DS Dissolution Apparatus includes:

- 8 testing positions
- Sampling manifold
- AutoTemp
- 7 1L clear glass vessels and one 200 mL conversion kit

The standard 709-DS is identically equipped to the 708-DS, except the 200 mL conversion kit is not available with the 709-DS. Eight 1L clear glass DVH vessels are included instead.

Should you require further customization (example: low actinic (red) vessels, 2L vessels, rotating cylinders, etc.), Agilent can easily custom configure your apparatus. Contact your Agilent representative for details.

Cary 60 UV Dissolution System

Online UV Dissolution – Multicell

Precise and accurate determination of dissolution concentrations is achieved with UV-Vis dissolution methods. These remain among one of the most common analytical techniques for dissolution sample analysis. Agilent's Online UV Dissolution System with the Cary 60 UV-visible Spectrophotometer integrates dissolution testing with online UV analysis to provide a single-source, automated performance testing solution.

Available in either single- or dual-apparatus configurations, the system supports individual flow cells for a range of path lengths from 0.2 to 10 mm. The multicell changer accommodates eight flow cells per dissolution apparatus, allowing for a blank, standard and six samples. The system can take both blank and standard readings during each timepoint. Additionally, each vessel position is configured with its own flow cell and tubing, eliminating cross-contamination.

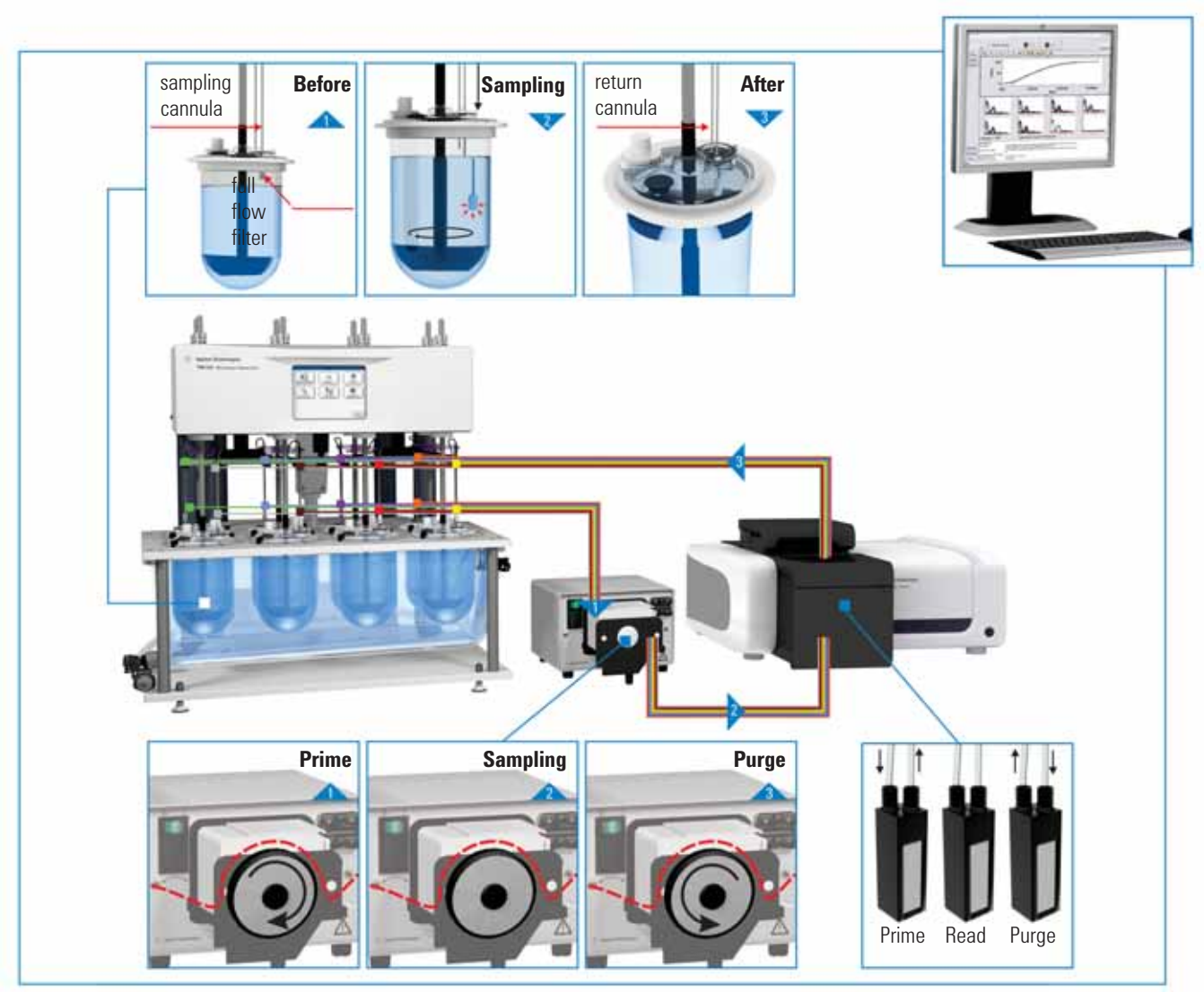
708-DS, 850-DS Dissolution Sampling Station and Cary 60 Multicell UV Dissolution System

Cary 60 UV Dissolution System:
Single Apparatus with 850-DS Dissolution Sampling Station and Peristaltic Pump

The Cary 60 can be configured with an 850-DS Dissolution Sampling Station or peristaltic pump to transfer the sample to the flow cell. Cells are analyzed and the sample is returned to the vessel maintaining vessel volume and eliminating the need for media replacement. Used with the spectrophotometer, the 850-DS can archive the sample for failure investigation if needed.

Flow Configuration (as shown below)

1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the peristaltic pump simultaneously.
2. The pump then moves the sample into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
3. After the samples are measured, the pump reverses flow and returns all sample volume to the dissolution vessels. No volume is lost in this closed-loop system. The sample lines are then purged and remain empty until the next timepoint.



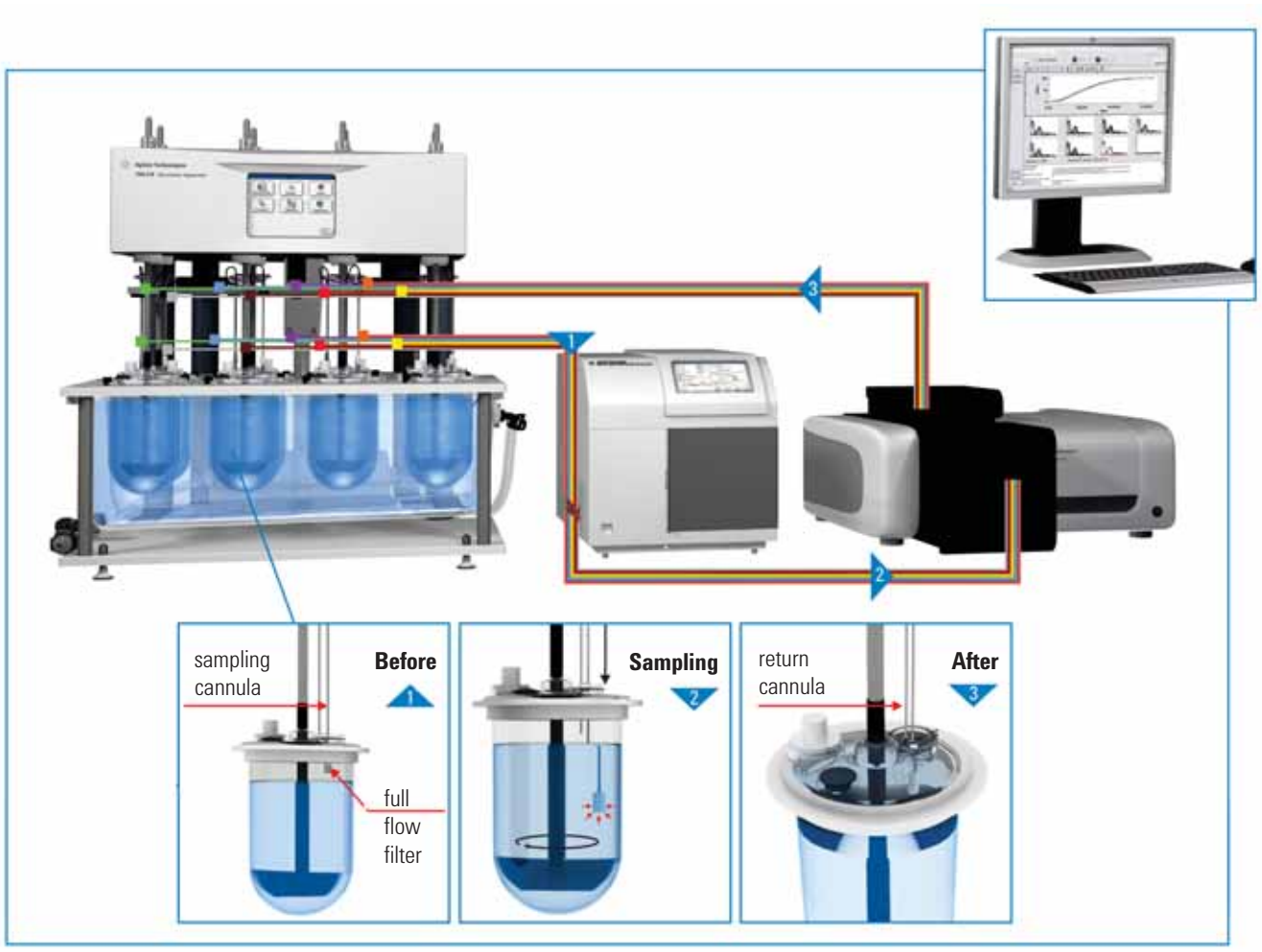
Cary 60 UV Dissolution System – Single Apparatus Setup with peristaltic pump

Cary 60 UV Dissolution System: Single Apparatus with 850-DS Sampling Station

The multicell system is ideal for providing repeatable results, especially when additional filtration or sample archival is required, via the 850-DS Dissolution Sampling Station with filter module. Integrating the 850-DS Dissolution Sampling Station with the Cary 60 allows you the flexibility of online UV analysis and offline collection for methods requiring an LC finish.

Flow Configuration (as shown below)

1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the builit-in 850-DS syringe pump simultaneously.
2. The 850-DS pumps and moves the samples through the filters on the integrated filter module.
3. Samples are then collected for archival in the 850-DS sample trays.
4. The volume continues on into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
5. After the samples are measured, the sample lines are purged with air and all volume is returned to the dissolution vessels. No volume is lost in this closed-loop system and the sample lines remain empty until the next timepoint.



Cary 60 UV Dissolution System – Single Apparatus Setup with 850-DS Dissolution Sampling Station

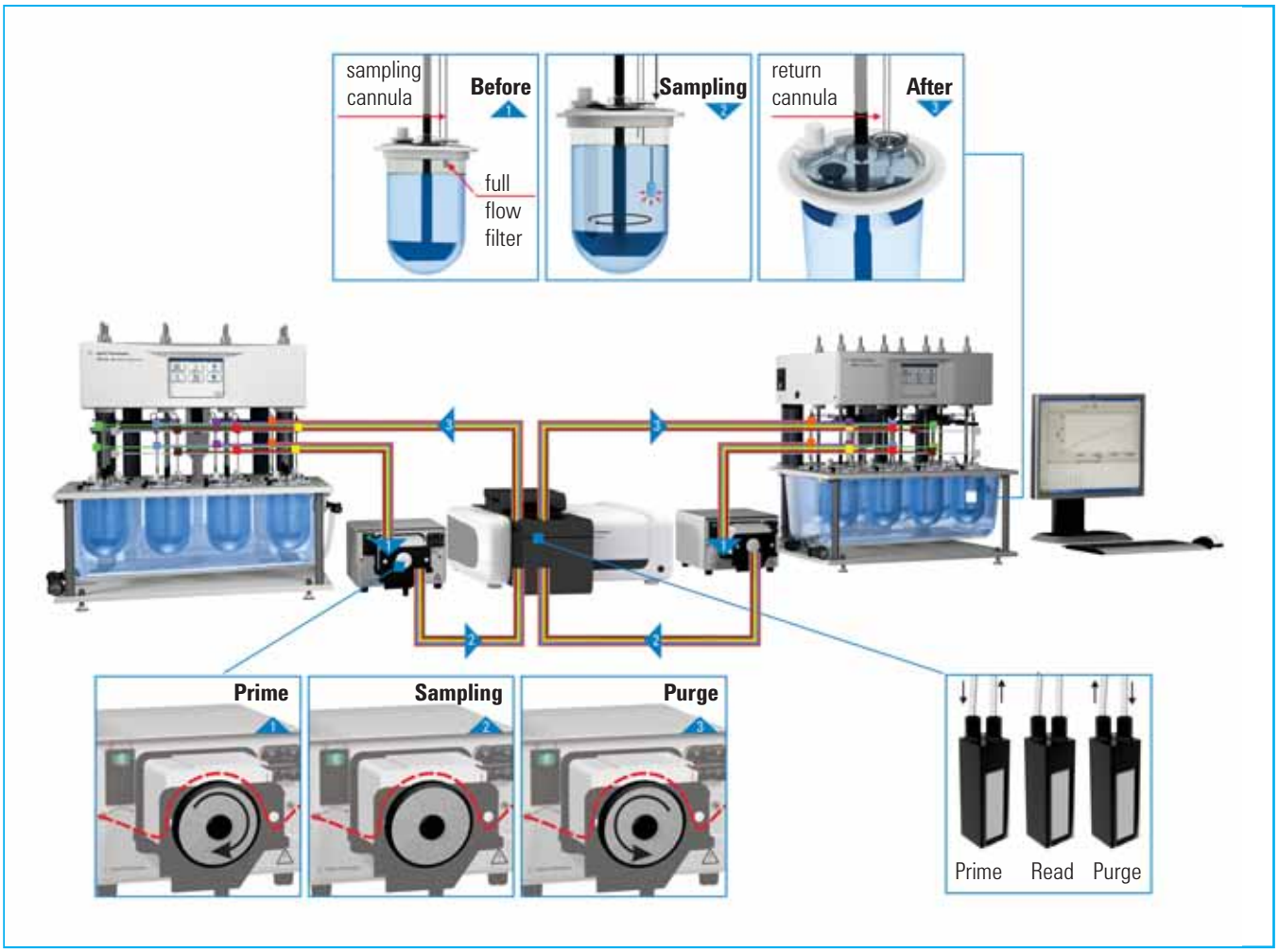
Cary 60 UV Dissolution System: Dual Apparatus with Peristaltic Pumps

For maximum efficiency, up to two dissolution apparatus can be used with a single Cary 60. A dual apparatus system will incorporate two peristaltic pumps or 850-DS Dissolution Sampling Stations to allow independent methods to be run on the two systems.

Flow Configuration (as shown below)

1. At each timepoint, the sampling manifold lowers and the blank, standard and samples are transferred to the respective peristaltic pumps simultaneously.
2. The pump then moves the sample into individual flow cells contained in the cell changer of the Cary 60. The manifold rises.
3. After the samples are measured, the pump reverses flow and returns all sample volume to the dissolution vessels. No volume is lost in this closed-loop system. The sample lines are then purged and remain empty until the next timepoint.

The flow configuration is identical for each apparatus in a dual-system setup. Independent methods can be executed concurrently. The cell changer of the Cary 60 supports two sets of dedicated flow cells, eliminating the chance of cross-contamination or carryover.



Cary 60 UV Dissolution System – Dual Apparatus Setup with Peristaltic Pumps

Cary 60 UV-Vis Spectrophotometer

Online UV Dissolution – Fiber Optic

Why Choose Fiber Optic UV Dissolution?

Save time with real-time sample analysis and reporting of dissolution data using in situ fiber optic probes. Also, no pumps or moving media/samples means no system flush is required. This greatly improves turnaround time and maximizes efficiency – simply rinse some key accessories and you're ready to begin the next test.

The Fiber Optic Online UV Dissolution System offers versatility and flexibility while delivering the highest level of automation and data integration for your UV dissolution needs. The Cary 60 UV-visible spectrophotometer offers excellent optical transmission and reproducibility capabilities, and the extended linear photometric range is ideally suited for superior fiber optic analysis.

The fiber optic multiplexer ensures precise and rapid position-to-position movement to decrease time needed between sample timepoints. The system's probes use silica fibers for optimal performance, and interchangeable tips make cleaning and replacement cost-efficient and easy. Tip pathlengths from 1 to 20 mm are available to accommodate a wide variety of sample concentrations.

Advantages of Fiber Optic UV Dissolution

- Ideal for rapid timepoint requirements with the ability to take readings as often as every 45 seconds
- Samples are read directly in the dissolution vessel, which eliminates contamination, carryover and dilution of samples
- Compensates for samples with excipient and background interferences
- Cleaning is simple, requiring only rinsing and wiping of the fiber optic probes and tips
- Fewer moving parts and consumables (e.g., filters, sample tubing) reduce cost of ownership

Cary 60 UV-visible Spectrophotometer with multiplexer for fiber optic UV dissolution

Cary 60 integrates easily with single- or dual-apparatus operation for increased throughput and automation

- Long-lasting, no warm-up time Xenon lamp flashes only when taking a measurement
- No degradation of photosensitive active drug components associated with continually burning lamps
- Virtual immunity to room light, reducing noise and allowing for a linear absorbance range up to 3.5 AU
- Configurable with Agilent 850-DS for collecting and archiving samples for LC analysis (multicell only)

The system is based on the Cary 60 UV-visible Spectrophotometer, with Xenon flash lamp technology for fiber optic utilization. Because the system is based on a standard spectrophotometer, parts and service are readily available worldwide.

The fiber optic system utilizes a 12-position multiplexer, to read samples sequentially. A single spectrophotometer can be used with two dissolution apparatus.

The fiber optic probes can be mounted on a movable manifold that lowers the probe to the correct sampling height in the vessel. The sample is read and the probe is raised either entirely out of the media or held in the upper level of the media to minimize bubble formation and prevent drying on the tip surface.

Cary 60 UV-Vis Spectrophotometer Dimensions

Height	Width	Depth	Weight
19.6 cm / 8 in.	47.7 cm / 19 in.	56.7 cm / 23 in.	18 kg / 40 lb

Cary 60 UV-Vis Spectrophotometer Specifications

Wavelength Range	Wavelength Accuracy	Wavelength Reproducibility	Photometric Range	UV-Vis limiting Resolution
190 - 1100 nm	± 0.5 at 541.94 nm	± 0.1 nm	± 3.5 Abs	≤ 1.5 nm

708-DS Dissolution Apparatus and Cary 60 Fiber Optic UV Dissolution System

Cary WinUV Dissolution Software

Testing in a Regulated Environment?

The Cary WinUV Dissolution Software includes an optional Compliance Manager package that allows your laboratory to install and configure proper 21 CFR Part 11 controls.

Did You Know?

When the Cary 60 is not being used for an online Dissolution test, there is an entire suite of applications available in the Cary WinUV software to maximize its value as a standalone spectrophotometer. These include Advanced Reads, Scan, Concentration, Kinetics, and more.

The Cary WinUV Dissolution Software supports both Agilent's Multicell and Fiber Optic Online UV Dissolution Systems. The software generates accurate and robust data and accommodates a wide variety of dissolution samples and methods. Analysts can easily customize final reports with a complete summary of the data acquisition using comparison and statistical evaluation tools, data tables and dissolution profiles.

Agilent Cary 60 UV-Vis Spectrophotometer

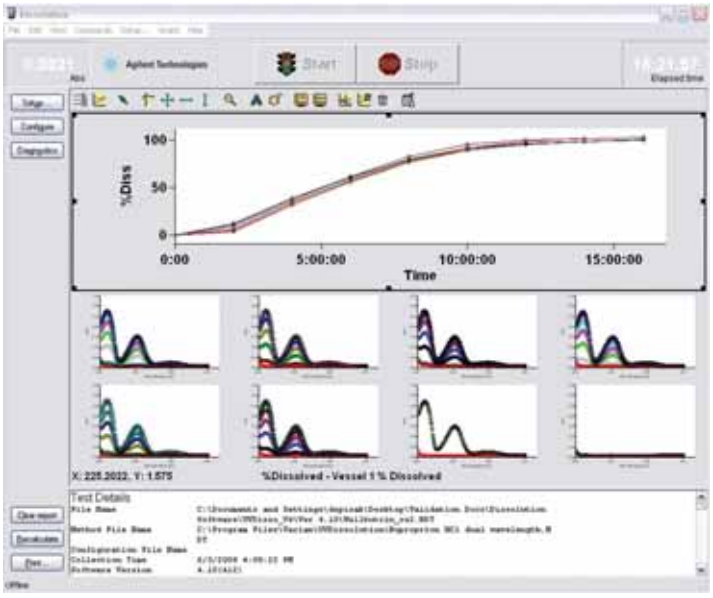
The Cary 60 utilizes a Xenon flash lamp that only turns on when acquiring a data point, minimizing photo-bleaching of samples. The Cary 60 acquires data at a rate of 80 Hz with a maximum scan rate of 24,000 nm/min applying a dual-detector approach to measure sample and source simultaneously.

This rugged instrument is easy to operate and economical to own. Because the lamp only illuminates when taking a reading, not only do you save energy, but there are significant lamp savings versus conventional deuterium lamp systems.

Cary 60 UV Spectrophotometer with 18-cell changer

Cary WinUV Dissolution Software

- Can integrate a peristaltic pump or 850-DS Dissolution Sampling Station with optional filter module for accurate preparation of samples and archival
- Controls apparatus features such as dosage delivery, automated sampling and vessel temperature monitoring
- Creates data processing and reports for samples taken offline using the UV dissolution manual application
- Accommodates media change methods, capsule shell corrections and infinity spins required for various methods
- Includes advanced UV capabilities, such as second derivative analysis, baseline correction and more, to work with challenging spectra
- Meets requirements for 21 CFR Part 11 compliance



Progression of a UV Dissolution profile as data is acquired

Flexible Standard Measurement and Calculation Options

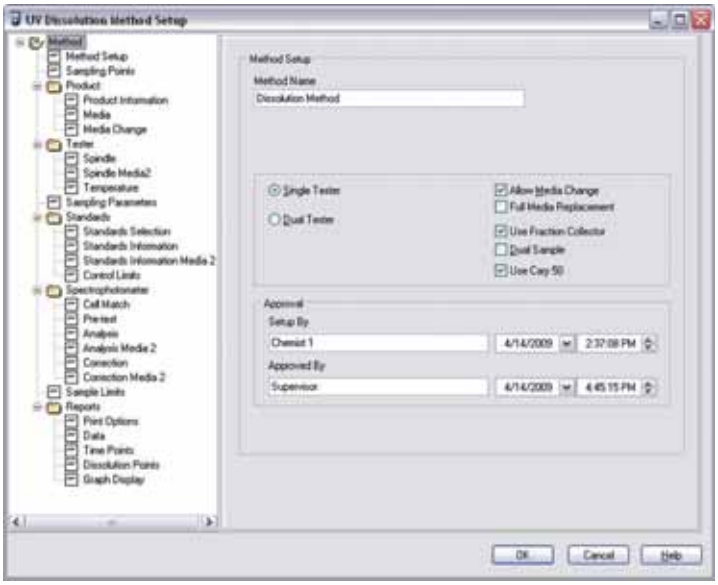
The UV Dissolution application incorporates several online standard options including Post Cycle Standard (for bracketed analysis), Bridged Mean, and Running Mean. Each method stores how results are calculated depending on your specific preferences.

Superior Linear Range (> 3 Abs) of the Agilent Cary 60 UV-visible Spectrophotometer

The linear range of a spectrophotometer defines the absorbance range in which measurements are accurate. The linear range of the Cary 60 permits the analysis of a wide range of sample concentrations, reduces the need for dilution or smaller path length cells, and measures highly turbid solutions (for fiber optics).

Key Software Functionalities

- Advanced UV-Vis analysis options include single wavelength, scan, and single and scan options
- Allows two independent methods to be run simultaneously when using a dual-apparatus configuration
- Online or offline testing of standards for percentage (%) and milligrams (mg) dissolved calculations
- Built-in PreTest Scan feature to confirm analysis wavelength prior to dosage introduction
- Immediate notification of out-of-specification results
- Supports media change or media addition methods
- Hardware configuration files and method files stored separately for quick retrieval and reduced turnaround times
- Dissolution profiles and customizable reports are visible in real time
- Manual data entry and recalculation provides flexibility by allowing you to obtain validated calculations and reports for samples taken on other offline systems
- Diagnostics module allows for easy troubleshooting and cleaning



A comprehensive Method Setup utility is at the core of Cary WinUV Dissolution Software

Dual-cell Tubing Kit

The Cary 60 makes it easy to interconnect two different cells within the multicell transport. This allows you to switch between two sets of cells, typically with different path lengths, with no disassembling or reassembling of the tubing lines. Switching between methods requiring cells of different path lengths is as easy as selecting the cells to be read using the Cary WinUV Dissolution Software. Only one dissolution apparatus can be used when the dual cell tubing is in place (P/N 11-1320).

Agilent's UV dissolution systems are scalable to your needs. In the ordering tables, you will find all components forming a complete dissolution testing system with UV-Visible analysis.

Automated UV Systems – Cary 60 Dissolution Software and Accessories

Description	Part Number
Cary 60 Software – UV Dissolution Multicell Packages	
Cary 60 Online UV Dissolution System – Multicell	G7926A
Note: Software and PC ordered separately (P/N G4971AA or G9261AA)	
Options for G7926A	
Add AutoTemp, for 708-DS	G7926A #105
Add low actinic - red accessories	G7926A #110
Delete basket shafts and baskets	G7926A #120
Delete paddles	G7926A #125
PTFE-coated paddles	G7926A #126
PEEK paddles	G7926A #127
Note: Only one selection may be chosen from options 125-127 for G7926A (not required).	
2L 708-DS Dissolution Apparatus	G7926A #140
Verified accessories	G7926A #145
Peristaltic pump	G7926A #200
Add 850-DS Dissolution Sampling Station, with built-in syringe pump	G7926A #205
Sample tray, 96-position, 2 mL, for HPLC vials (no conversion required)	G7926A #210
Sample kit, 108-position, 2 mL, includes tray and needle block assembly	G7926A #211
Sample kit, 100-position, 2 mL, includes tray and needle block assembly	G7926A #212
Sample kit, 96-well plate, includes tray and needle block assembly	G7926A #213
Cary 50/60 flow cell, 0.2 mm, 8/pkg.	G7926A #300
Cary 50/60 flow cell, 0.5 mm, 8/pkg.	G7926A #301
Cary 50/60 flow cell, 1 mm, 8/pkg.	G7926A #302
Cary 50/60 flow cell, 2 mm, 8/pkg.	G7926A #303
Cary 50/60 flow cell, 5 mm, 8/pkg.	G7926A #304
Cary 50/60 flow cell, 10 mm, 8/pkg.	G7926A #305
One (1) selection is required from options 300-305 for G7926A	

(Continued)

Automated UV Systems – Cary 60 Dissolution Software and Accessories

Options for G7926A	
Add printer, for 708/709-DS	G7926A #880
Add printer to 850-DS	G7926A #881
Delete 708-DS Dissolution Apparatus	G7926A #900
Replace 708-DS with 709-DS Dissolution Apparatus	G7926A #910
Dual system 708-DS	G7926A #920
Dual system 709-DS (option #910 also required)	G7926A #921
UV Dissolution Software	
UV Dissolution Software, multicell (PC not included)	G4971AA
UV Dissolution Software bundle, multicell, with PC, printer, monitor	G9261AA
Cary WinUV Software – UV Dissolution Multicell Accessories	
Benchtop table for UV dissolution system, with keyboard tray	11-1125
Flow cell for use with Cary 50/60, 10 mm	11-1300
Flow cell for use with Cary 50/60, 0.2 mm	11-1301
Flow cell for use with Cary 50/60, 0.5 mm	11-1302
Flow cell for use with Cary 50/60, 5 mm	11-1305
Flow cell for use with Cary 50/60, 2 mm	11-1310
Flow cell for use with Cary 50/60, 1 mm	11-1315
Cary 50 extended sample compartment	210163190
Cary 50 tubing coupler	210163390
Cary 50/60 18-cell holder	G6867A
Tubing kit, dual path length, for Cary UV Dissolution System	11-1320
Flowcell tubing replacement kit, for Cary UV Dissolution System	11-1226

Upgrade Your Cary 50/60

Increase productivity as laboratory needs change by using your dissolution apparatus and spectrophotometer into an online UV dissolution system. Add the necessary software, cell changer or multiplexer, and other accessories to maximize the efficiency of your instrumentation and streamline analysis.. Fiber optic probes/tips and flow cells must be ordered separately depending on the desired pathlength.

Cary WinUV Software – UV Dissolution Fiber Optic Packages and Software

Description	Part Number
708/709-DS and Cary 60 Fiber Optic Online UV Dissolution System	G7927A
Note: Software and PC ordered separately (G4972AA or G9262AA)	
Options for G7927A	
Add AutoTemp, for 708-DS	G7927A #105
Add low actinic - red, accessories	G7927A #110
Delete basket shafts and baskets	G7927A #120
Delete paddles	G7927A #125
PTFE-coated paddles	G7927A #126
PEEK paddles	G7927A #127
2-Liter 708-DS Dissolution Apparatus	G7927A #140
Verified accessories	G7927A #145
Fiber optic removable tip, 1 mm, 6/pkg.	G7927A #300
Fiber optic removable tip, 2 mm, 6/pkg.	G7927A #301
Fiber optic removable tip, 5 mm, 6/pkg.	G7927A #302
Fiber optic removable tip, 10 mm, 6/pkg.	G7927A #303
Fiber optic removable tip, 20 mm, 6/pkg.	G7927A #304
Note: One (1) selection is required from options 300-304 for G7927A.	
Add printer, for 708/709-DS	G7927A #880
Delete 708-DS Dissolution Apparatus	G7927A #900
Replace 708-DS with 709-DS Dissolution Apparatus	G7927A #910
Dual system 708-DS	G7927A #920
Dual system 709-DS	G7927A #921
UV Dissolution Software, fiber optic, without PC	G4972AA
UV Dissolution Software Bundle, fiber optic, with PC, printer, monitor	G9262AA

Cary WinUV Software – UV Dissolution Fiber Optic Accessories

Description	Part Number
Benchtop table for UV dissolution system, with keyboard tray	11-1125
4-port USB-to-serial converter	11-1011
External cuvette holder, 1 cm, for FO	11-1012
External cuvette holder cover, 1 cm	11-1014
Fiber optic patchcord, 20 in.	11-1424
Fiber optic probe, 2 m, no tip, for 7000, 7010, 708-DS, 709-DS	11-1425
Fiber optic probe, 2 m, no tip, 7025/7030	11-1426
Fiber optic removable tip, 1 mm	11-1429
Fiber optic removable tip, 2 mm	11-1430
Fiber optic removable tip, 5 mm	11-1435
Fiber optic removable tip, 10 mm	11-1440
Fiber optic removable tip, 20 mm	11-1445
Fiber optic probe holder, for Distek evaporation cover	12-0592
Cary 50/60 Upgrade Options	
Cary 60 fiber optic upgrade, includes Cary WinUV software for fiber optic UV dissolution and multiplexer, for 708-DS (probes/tips ordered separately)	11-1141

Content Uniformity

Content uniformity (CU) is a quality control processes for studying the individual content of the active ingredients of solid dosage forms, such as capsules and tablets. Multiple solid dosage forms are randomly selected and the content is analyzed to test the uniformity, using the general process of sample preparation—extraction and dilution—and then analysis by HPLC/UPLC-UV or UV.

The solid dosage form is within specification if:

- One or no individual content is outside the 85 to 115% limit of the average content, and
- No content is outside the limits of 75% to 125% of the average content

The preparation fails to comply with the CU test if:

- More than three individual contents are outside the 85 to 115% limit of the average content, or
- If one or more individual contents are outside the 75 to 125% limit of the average content

To achieve a reliable and accurate process for CU testing, it is essential to remove variables of the preparation and analysis technique being used. An automated solution introduces a high level of repeatability, removes analysts variability and can be consistently applied across different departments and facilities. With a robust and repeatable approach to CU testing, variation in CU data can be attributed to the solid dosage form and not put into question the actual process of preparing the samples ready for analysis.

CambTEK Rapid Extraction System (RES)

Rapid Extraction System

The CambTEK Rapid Extraction System (RES), in association with Agilent, provides an ideal platform for laboratories to automate and standardize their solid dosage form sample preparation for content uniformity testing. It was designed to improve laboratory productivity and to provide reliable, consistent results from minimal user touch-time, within development, quality assurance, and manufacturing environments.

Flexibility and Ease of Use

The unique design of the RES allows for sample preparation of a vast range of solid dosage forms, including standard and extended release tablets, capsules, powders, gels, pastes, swabs, stents, beads, intermediate granulation, pellets, solid and semi-solid matrices, and suppositories.

Using an intuitive barcode driven workflow, the RES allows users to automate sample preparation in six steps. The sample is first placed into the consumable flow cell and the barcode is scanned. Information about the sample is then entered, which becomes associated with that set of consumables, providing a chain of custody for the sample. The operator then simply places the sample onto the RES and presses the play button.

With solvent working volumes between 50 and 500 mL, the sample is quickly eroded and dissolved, using turbulent fluidic flow with optional ultrasonic energy. Multiple solvents and extraction events can be created in the method, giving complete flexibility of the extraction step. Pump speed is adjustable from 70 mL to 1L/min to give full control over the extraction process.

These features allow the RES to perform a wide range of functions, including:

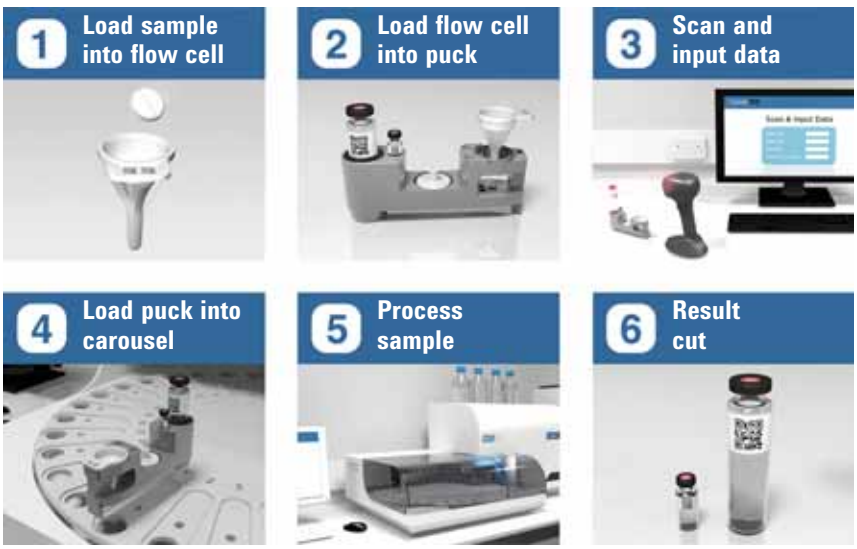
- Content uniformity testing
- Impurity testing
- Composite and bulk assay testing
- ICH stability assay testing
- Blend and granulation uniformity testing

After extraction, the solution is filtered and delivered to a 20 mL septa sealed vial, ready for accurate dilution (Class A equivalence) and/or dispensing to an HPLC vial for analysis. All dispense and dilution steps are checked gravimetrically to ensure high accuracy and repeatability, and all metadata is captured for quality assurance and complete audit trail.

The sanitary system design allows for thorough cleaning with <0.05% carryover easily obtainable and drying between samples, which facilitates the processing of non-consecutive samples on the 30-sample carousel, as well as quick batch processing.

Other features include:

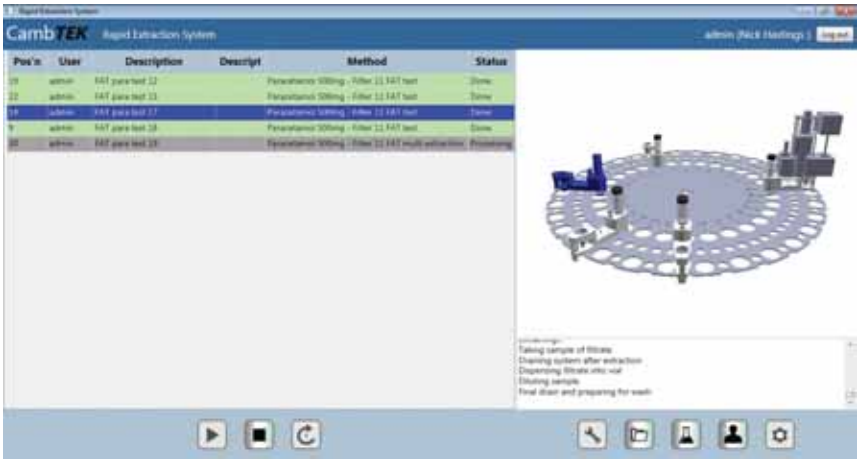
- 5-channel solvent selection allows for complex extraction profiles
- Off-line and adaptable on-line with HPLC or UV/MS analysis
- Powerful extraction of compounds with or without ultrasonics.
- Robustness testing/design space of analytical test methods to investigate sensitivity of extraction and dilution process.
- Highly variable working sequence giving random access workflow, or batch processing.
- Powerful and ease of use RES Command software gives full control over extraction parameters.
- Fast setup and operation keeps instrument touch time to a minimum, allowing for high productivity.



RES Workflow

Quality of Data

- Designed to highest standards to ensure regulatory and quality compliance of data integrity, validity and repeatability.
- Sanitary design of fluidic path minimizes cross contamination and carryover studies with difficult to clean compounds show <0.1% carryover is achievable with minimal wash steps.
- Developed to exceed Class A volumetric requirements with sophisticated gravimetric feedback for closed loop confirmation of dispensing processes.
- Eliminates potential variability due to analyst technique or human error.
- Sample barcode tracking provides chain of custody and improved GMP compliance.
- User control and implementable solutions for 21 CFR Part 11 compliance.
- Metadata for in-process checking and conformity, answering queries of who, when, and what.
- Comprehensive post-extraction report allows for detailed data collection of sample preparations performed and facilitates Out Of Specification (OOS) investigations.
- Optional on-line video monitoring assists method development and atypical OOS investigations.
- Capped and septa sealed vials maintain sample integrity.
- Enclosed system for additional safety and sample integrity.



RES data collection

Standardization and Compliance

The RES is a platform technology for site- and user-independent standardization of results, from R&D through to manufacturing.

- Supports R&D laboratories performing DoE, and new product developments, supporting Quality by Design (ICH Q8)
- Robust design and simplistic operation, the RES is ideal for screening and QA within in manufacturing facilities.
- Pressure monitoring allows end-point confirmation utilizing PAT concepts, thereby increasing test process understanding
- Fluidics and sonication provide good equivalency to manual methods, minimizing re-validation from manual processes to automation
- Comprehensive encrypted and secure documentation and user login protocols comply with 21 CFR Part 11
- User access rights control method approval and status

For more information on the Rapid Extraction System, including technical specifications, ordering and consumables, visit **www.cambtek.com**.

RES sample carousel

Uniformity of Dosage Units

Dose uniformity testing is performed on each batch of dosage forms to verify that the amount of API contained within the dosage forms is consistent throughout the batch. Tablets, capsules and other solid dosage forms are sampled from across the batch and are randomly selected for testing by the either the content uniformity method or the weight variation method. These procedures are harmonized between the USP, EP and JP and the method of uniformity testing is based on the amount or ratio of API to the weight of each dose.

For CU determinations, ten dosage units are individually prepared in volumetric solutions designed to completely extract and dissolve the API usually assisted with hydro-organic solvents and aggressive mixing. Test results should indicate that all ten units are less than or equal to the Level 1 % (L1%) limit, typically 15% unless otherwise specified. If not, twenty additional tablets are tested and the thirty total results must be less than the L1 % limit to conform.

Samples are generally analyzed by HPLC or UV depending on the number of active components or other components of the dosage form. The testing is usually conducted using a large amount of laboratory space due to the amount of volumetric glassware required, as well as shaking and ultrasonication equipment used to dissolve the samples. Group testing is often employed where several batches of ten tablets are prepared and run consecutively in HPLC systems.

For more information on Agilent UV-Vis Spectrophotometers see pages 96-121.
Information on the Agilent 1200 Series HPLC instruments can be found on page 121.

Agilent HPLC Solutions

A complete portfolio of scalable HPLC and UHPLC solutions for dissolution analysis.

For utmost flexibility Agilent has created a continuum of products – from compact instruments for routine LC to ultrahigh performance LC/MS systems. Choose the best configuration to optimize every part of your laboratory operations and be assured that each system can be enhanced as required to meet future challenges.

Regardless of your workflow, we have a solution to your method. We offer offline analysis through a segmented collection and filtration (down to 0.2 or 0.45 µm), as well as online analysis with the collection and filtration followed by direct injection. Additionally, our systems provide archival of samples in the event a failure investigation is required.

Agilent 1290 Infinity LC System

Agilent 1290 Infinity LC System

Infinitely more powerful

The Agilent 1290 Infinity LC is the last word in chromatographic performance providing highest speed, resolution and sensitivity.

- Wide power range up to 1200 bar – deploy any particle type, any column dimensions, or any mobile and stationary phases
- For seamless instrument-to-instrument method transfer, simply emulate other LC systems with Agilent's new ISET – Intelligent System Emulation Technology
- Lower total cost of ownership – get UHPLC productivity at service costs comparable to HPLC equipment quality

Agilent 1260 Infinity LC System

Agilent 1260 Infinity LC System

Infinitely more confident

The Agilent 1260 Infinity LC raises the standard in HPLC – without raising the price. It offers new levels of productivity, data quality and robustness to give you highest confidence in your investment.

- 600 bar standard pump pressure, 80 Hz standard detector speed and up to 10 times higher UV detection sensitivity – be prepared for today's and tomorrow's challenges
- 100% compatible with all your HPLC methods – ensuring riskless replacement of existing equipment
- Priced similar to earlier 1200 Series HPLC and markedly below 1200 Series RRLC systems – get enhanced UHPLC capability for HPLC price
- Available for isocratic, binary or quaternary solvent delivery – configure a system that exactly matches your needs for chromatographic performance and flexibility

Agilent 1220 Infinity LC System

Agilent 1220 Infinity LC System

Infinitely more affordable

The Agilent 1220 Infinity LC is a high quality, integrated system for routine HPLC and advanced UHPLC analysis, for maximum return on investment.

- 600 bar power range up to 5 mL/min and 80 Hz detector speed – prepare your lab to take advantage of latest advances in LC column technology
- Full compatibility with all other detectors within the 1200 Infinity Series and with 6100 Series Quadrupole MS – run any existing HPLC or UHPLC method
- Uses same technology and parts as 1260 and 1290 Infinity LC systems

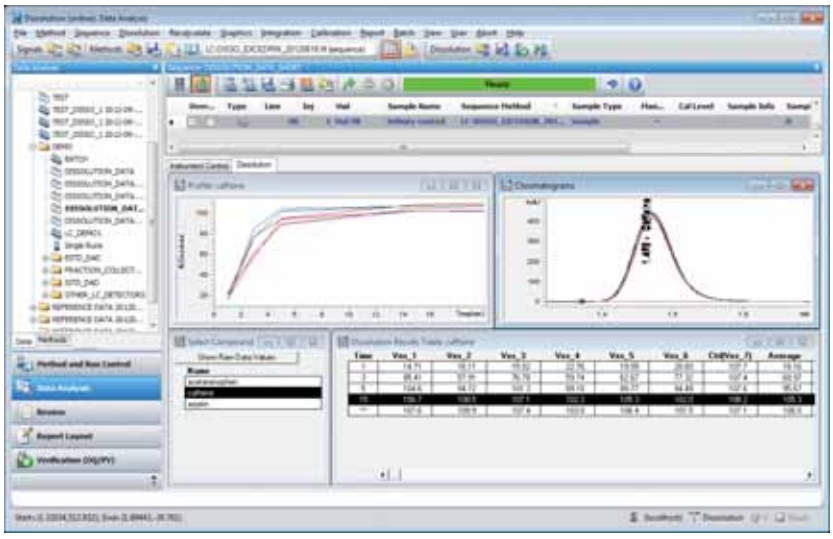
Integrating Dissolution and HPLC

Of course our first priority is integrating Agilent dissolution apparatus with Agilent analytical instruments and software. Having one source of dissolution equipment, analytical instrumentation and software ensures you receive the best service and support. We also realize that there are many other brands of equipment, so Agilent offers solutions to give you the choice of which tools work best for you.

Agilent dissolution equipment has many features not found on other dissolution equipment. UV-ChemStation and Cary WinUV software take full advantage of these productivity enhancing tools. However, this does not limit you to using other analytical systems with our dissolution apparatus.

If you are interested in integrating an existing HPLC system to an Agilent dissolution apparatus, this can be accomplished.

For more information on the integration of Agilent dissolution equipment with other analytical instruments, contact your Agilent representative.

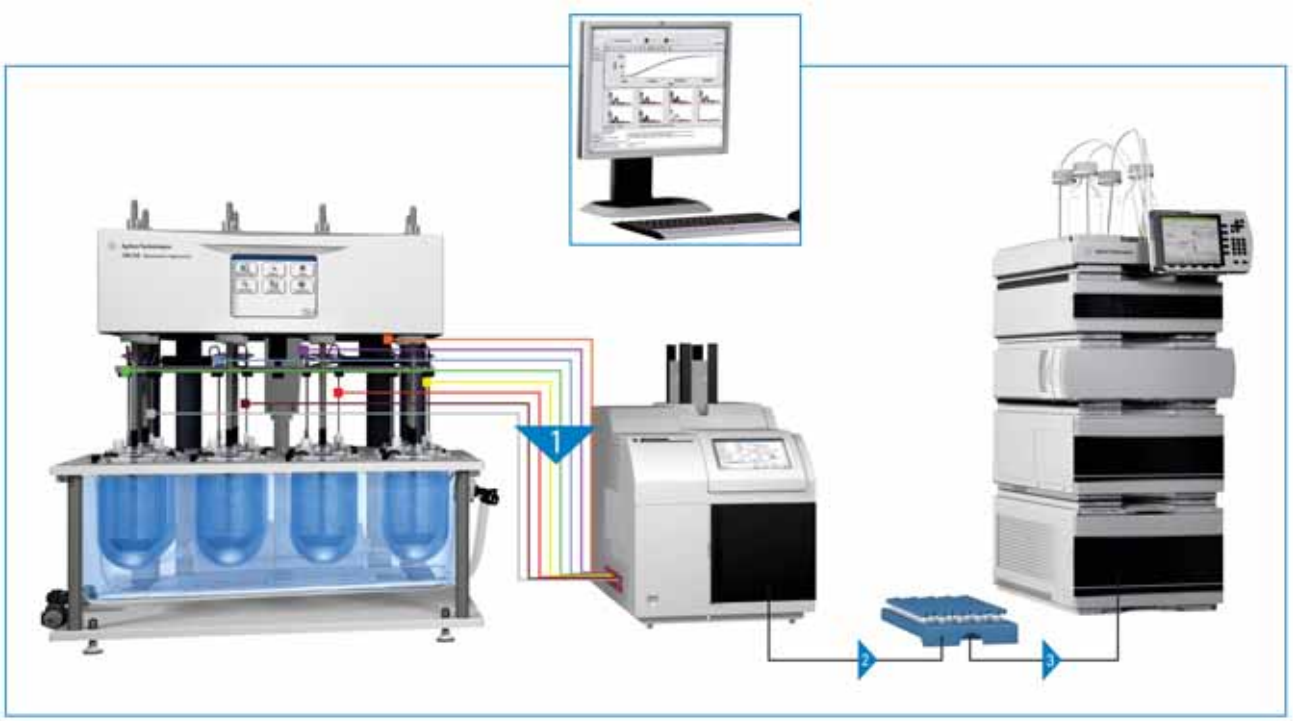


Agilent's integrated software solution simplifies dissolution data capture and analysis.

OpenLAB CDS ChemStation LC Dissolution Software

Streamline LC dissolution analysis

Agilent's LC Dissolution Software is an add-on module for use with the ChemStation Edition of Agilent OpenLAB Chromatography Data System (CDS). This software module simplifies the quantification and reporting of dissolution samples analyzed by HPLC, thus maximizing the investment of dissolution apparatus, LC instruments and informatics. Once dissolution samples have been collected, the samples are then loaded into the LC instrument and analyzed. The software module automates the setup of the LC instrument, incorporates the dissolution methodology, performs the sample analysis, and generates the final reports. Real-time views of the dissolution profile of all active ingredients are available as the analysis progresses.



The LC Dissolution Software creates an streamlined workflow by incorporating the dissolution methodology and HPLC data. Once samples have been collected, simply transfer the vials to the LC for analysis. The software add-on uses the dissolution parameters entered to perform all calculations and create a consolidated final report.

Maximize your laboratory workflow

- Integrate dissolution capabilities with your current LC analysis platform and eliminate manual data export
- Use existing chromatographic methods that easily integrate for automatic generation of analysis sequences, independent of hardware
- Ensure integrity and security of dissolution analysis data in a 21 CFR Part 11 environment.
- Integrating the Agilent LC Dissolution Software in your laboratory workflow helps you to capitalize on the investments you have made in dissolution apparatus and LC instrumentation and software.
- With separated dissolution and analysis functions, deploying the LC Dissolution Software ensures both sets of equipment can be fully utilized without having to wait for one of the two operations to finish.
- See your dissolution analysis progress by live updated views on dissolution tables and dissolution profiles for all active ingredients
- Get a quick overview based on a graphical presentation of the dissolution profiles, including quality limits
- Make use of OpenLAB's Intelligent Reporting capability based on report templates to support GLP-relevant information including: dissolution experiment information, reports on analytical method and calibration, summary reports on complete dissolution experiment and more. The Intelligent Reporting function within OpenLAB also allows highly customizeable reports.

OpenLAB CDS ChemStation LC Dissolution Software

Description	Part Number
OpenLAB CDS ChemStation LC Dissolution Software	M8365AA

Dissolution reports generated with Agilent's LC Dissolution Software

100 Automated Disintegration Apparatus

Integrated disintegration testing that conforms to harmonized regulatory requirements

An integral prerequisite for dissolution, dosage forms must be tested for disintegration to ensure maximum active pharmaceutical ingredient (API) contact with media and subsequent bioavailability. The disintegration test is an important quality control process that helps ensure the proper manufacturing controls are in place.

The fully programmable Agilent 100 Automated Disintegration Apparatus provides a reliable, compliant approach to disintegration testing. The reciprocating drive system, water bath, and heater/circulator are incorporated into a single instrument offering a compact design to save valuable bench space. The three-basket apparatus comes complete with accessories required to perform the standard USP disintegration test.

The easy-to-use numeric keypad includes program, temperature, and printer control options. Simply enter the time duration of the test and the baskets will be lifted from the beaker at the end of the run. The basket is held above the media until you return to inspect the results. Individual digital time displays for each basket, and tests can be run simultaneously or sequentially, maximizing laboratory efficiency. The optional printer can be added to document critical test information.

The standard 100 Automated Disintegration Apparatus comes with:

- Three (3) 6-tube basket(s), 10-mesh / 1905 µm (USP)
- Fluted disks – USP
- Three (3) disintegration beakers – USP
- Disintegration spacer gauge – 25 mm

Agilent 100 Automated Disintegration Apparatus

Verified Disintegration Accessories

Many standard disintegration accessories, such as the basket rack assemblies, can be ordered with individual certificates that verify conformance of critical dimensions. The certificates include the measurements, measuring device information, and its traceability. Any part number that ends in "V" indicates a Verified component.

Disintegration Testing

Description	Part Number
100 Automated Disintegration Apparatus, 3-basket	G7962A
6-tube, 10-mesh, 1905 µm, USP, verified	G7962A #110
6-tube, 20-mesh, 864 µm	G7962A #111
6-tube, 10-mesh, 1905 µm, nylon, with stainless screen	G7962A #112
3-tube, 10-mesh, 1905 µm, 38 mm, outer diameter	G7962A #113
3-tube, 10-mesh, 1905 µm, 38 mm, outer diameter, verified	G7962A #114
1-tube, 10-mesh, 1905 µm, 44 mm, outer diameter	G7962A #115
6-tube, 40-mesh, 381 µm, with screened cover	G7962A #116
Note: 110-116 Disintegration basket types - multiple selections possible, not required.	
Add printer	G7962A #880

100 Automated Disintegration Apparatus Baskets

Description	Part Number
Basket, 6-tube, 10-mesh, 1905 µm (USP)	37-3001
Basket, 6-tube, 10-mesh, 1905 µm (USP), verified with certificate	37-3001V
Basket, 6-tube, 20-mesh, 864 µm	37-3010
Basket, 6-tube, 10-mesh, 1905 µm, Nylon, stainless steel screen	37-3020
Basket, 3-tube, 10-mesh, 1905 µm, 38 mm outer dia.,	37-3030
Basket, 3-tube, 10-mesh, 1905 µm, 38 mm outer dia., verified with certificate	37-3030V
Basket, 1-tube, 10-mesh, 1905 µm, 44 mm outer dia.	37-3040
Basket, 6-tube, 40-mesh, 381 µm, with screened cover	37-3050

Agilent 100 accessories: (top row, left to right) 6-tube standard, 10-mesh basket; 3-tube, 10-mesh basket; 1-tube, 10-mesh basket; and 6-tube, 40-mesh basket;
(bottom row, left to right) standard screen with fluted disks; 3-basket screen with screws; plunger; and 6-tube screen

1L disintegration beaker

100 Automated Disintegration Apparatus Accessories

Description	Part Number
Suspension rod dia. for holding 1-basket rack	37-1040
Cover, for 6-tube, 10-mesh, 1905 µm basket	37-2100
Cover, for 3-tube, 10-mesh, 1905 µm basket	37-2105
Cover, for 6-tube, 40-mesh, 381 µm basket	37-2110
Screen, 10-mesh, 1905 µm, stainless steel, for 6-tube basket, set of 6	37-2200
Screen, 20-mesh, 864 µm, stainless steel, for 6-tube basket, set of 6	37-2205
Screen, 40-mesh, 381 µm, stainless steel, for 6-tube basket, set of 6	37-2210
6 USP fluted disks, for Agilent 100 and Standard Disintegration Apparatus	37-4000
6 USP fluted disks, for Agilent 100 and Standard Disintegration Apparatus, verified with certificate	37-4000V
3 Plastic disks, for Agilent 100 Disintegration Apparatus	37-4010
1 Plastic disk, for Agilent 100 Disintegration Apparatus	37-4020
6-tube plunger assembly	37-4100
3-tube plunger assembly	37-4110
6-tube plunger assembly, for use in Canada	37-4120
Replacement tubes, 6-tube basket, 25 mm, set of 6	37-5000
Replacement tubes, 6-tube basket, 25 mm, set of 6, verified with certificate	37-5000V
Replacement tubes, 3-tube basket, 38 mm, set of 3	37-5005
Replacement tube, 1-tube basket, 44 mm	37-5010
Disintegration beaker, for Standard Disintegration Apparatus	37-5200
Disintegration beaker, USP for Disintegration Apparatus	37-5305
Disintegration beaker, USP for Disintegration Apparatus, verified with certificate	37-5305V
Disintegration gauge, 2.5 cm, from vessel bottom	37-9000
Bath temperature probe	67-0300

Instant Status Reporting

By outfitting the 100 Automated Disintegration Apparatus with the optional printer, you have the ability to record instrument status at a predefined interval as well as at any time during the test by pressing Print on the instrument panel.

100 Automated Disintegration Printer Options

Description	Part Number
Printer option for Agilent 100, 115/230V	37-0200

100 Automated Disintegration Apparatus Dimensions

Height	Width	Depth	Weight
74.93 cm / 29.5 in.	55.88 cm / 22 in.	52.07 cm / 20.5 in.	29.7 kg / 65.5 lbs, dry with 3 baskets

100 Automated Disintegration Apparatus Specifications

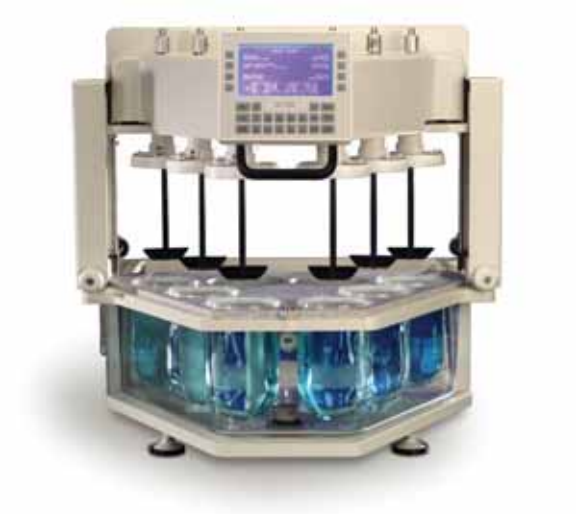
Dip Speed (DPM)	Stroke Length (cm)	Temperature Range (°C)	Temperature Accuracy (°C)	Test Duration (hh:mm:ss)
30 ± 1	5.5 ± 0.1	Ambient + 5 to 55	± 0.2	Up to 99:59:59

Accessories for Legacy Instruments

Agilent offers a complete line of dissolution and physical testing accessories to support legacy instruments that are still under service support.

Accessories for the following legacy instruments can be found in this section:

- 705-DS, 7000, 7010, 7025 V-Series and 7030 V-Series Dissolution Apparatus
- Calibration and Verification Tools
- QAII C Station and 5010 Calibration and Verification Tools
- 8000 Dissolution Sampling Station
- 806 Syringe Pump
- 810 Peristaltic Pump
- Rotating Bottle Apparatus
- 200 Tablet Hardness Tester
- 250 Friability Tester
- 350 Tapped Density Tester



Legacy 7025 V-Series Dissolution Apparatus

Accessories for Legacy Dissolution Apparatus

Ordering

Order Agilent parts and supplies for legacy instruments at **www.chem.agilent.com/store**

Basket Shafts / Assemblies

Description	Part Number
14.5 in. (37 cm) Basket Shafts for 7025/7030	
Basket shaft, USP, for 7025/7030	13-3615
Basket shaft, O-ring, for 7025/7030	13-3616
Basket shaft, USP, PTFE-coated, for 7025/7030	13-3617
Basket shaft, conical, for 7025/7030	13-3618
Mini basket shaft, O-ring, for 7025/7030	13-3619
21 - 24 in. (53 - 61 cm) Basket Shafts and Assemblies for 705-DS, 7000/7010E, 705/708/709-DS	
Basket shaft, USP 3-clip, 21 in.	13-3620
Basket shaft, O-ring, 21 in.	13-3621
Basket shaft, PTFE-coated, 21 in.	13-3622
Basket shaft, O-ring, Conical, 21 in.	13-3623
Basket shaft, 3-clip, Conical 21 in.	13-3624
Basket shaft, USP 3-clip, 24 in.	13-3629
Basket shaft, for bolus basket, 24 in.	13-3630

Electropolished stainless steel paddle

Paddle Shafts and Accessories

Description	Part Number
14.5 in. (37 cm) Paddle Shafts for 7025/7030	
Paddle, PTFE-coated, for 7025/7030	13-3589
Paddle, electropolished, for 7025/7030	13-3590
Paddle, PEEK, for 7025/7030	13-3591
Paddle, PTFE-coated, 200 mL, for 7025/7030	13-3592
Paddle, electropolished, 200 mL, for 7025/7030	13-3593
21 - 24 in. (53 - 61 cm) Paddle Shafts for use with 7000/7010E, 705/708/709-DS	
Paddle, PTFE-coated, 21 in.	13-3594
Paddle, PTFE-coated, 24 in.	13-3596
Paddle, electropolished, 21 in.	13-3595
Paddle, electropolished, 24 in.	13-3597
Paddle, PEEK, 24 in.	13-3598
Mini paddle, PTFE-coated, 24 in.	13-3599
Mini paddle, electropolished, 24 in.	13-3600
Mega paddle, electropolished stainless steel, 24 in.	13-3601
Shaft Accessories	
Collet, for 3/8 in. dia. shafts, for 7000/7010	12-1320
Collet, for 1/4 in. dia. shafts, for 7000/7010	12-1330
Shaft locking ring, for 705-DS, 708-DS, 709-DS, 7025/7030	12-2096

EaseAlign Vessels

EaseAlign vessels are designed to be used on the legacy 705-DS, 7000 and 7010 dissolution apparatus, and are compatible with many other manufacturer instruments as well. The EaseAlign vessel is held in place by a centering ring and is available in various types and sizes.

EaseAlign Vessels for 705-DS and 7000/7010 Dissolution Apparatus

Description	Part Number
EaseAlign vessel, 1L	12-5000
EaseAlign vessel, 1L, with certificate	12-5000V
EaseAlign vessel, low actinic - red, 1L	12-5010
EaseAlign vessel, low actinic - red, 1L, with certificate	12-5010V
EaseAlign vessel, 100 mL	12-5040
EaseAlign vessel, low actinic - red, 100 mL	12-5041
EaseAlign vessel, 200 mL	12-5050
EaseAlign vessel, low actinic - red, 200 mL	12-5051
EaseAlign vessel, flat bottom for Enhancer Cell, 200 mL	12-5055
EaseAlign vessel, 2L	12-5070
EaseAlign vessel, 2L, with certificate	12-5070V
EaseAlign vessel, low actinic - red, 2L	12-5075
EaseAlign vessel, clear plastic, 1L	12-5200
EaseAlign vessel, clear plastic, 1L, with certificate	12-5200V
EaseAlign Peak vessel, 1L	12-5500
EaseAlign Peak vessel, 1L, with certificate	12-5500V
EaseAlign Peak vessel, 2L	12-5510
EaseAlign Peak vessel, low actinic - red, 1L	12-5505
EaseAlign VF molded vessel, 1L	12-1502
EaseAlign VF molded vessel, 1L, with certificate	13-0020

1L EaseAlign vessel

TruCenter Vessels

Used with the 7025 and 7030 Dissolution Apparatus, TruCenter vessels offer superior centering and vessel verticality and are turned on a lathe during manufacture to find the exact center. The vessels incorporate a groove and synthetic flange with magnetic collar to align on the vessel plate. The magnetic closure on the vessel plate makes inserting or removing a vessel simple.

In addition to not floating when empty, an added benefit of the TruCenter vessel is the plastic collar that decreases the chance of breakage compared to traditional glass collared vessels.

Conversion kits are available to upgrade your 705-DS and 7000/7010 models to TruCenter vessels (see page 135).

TruCenter Vessels for 7025 and 7030 Dissolution Apparatus

Description	Part Number
TruCenter Vessels for 7025 Dissolution Apparatus	
TruCenter vessel, without adapter, 200 mL	12-5033
TruCenter vessel, with adapter, 200 mL	12-5034
TruCenter vessel, with collar, 1L	12-5035
TruCenter vessel, with collar, 1L, with certificate	12-5035V
TruCenter vessel, low actinic - red, with collar, 1L	12-5120
TruCenter vessel, low actinic - red, with collar, 1L, with certificate	12-5120V
TruCenter Peak vessel, with collar, 1L	12-5125
TruCenter Peak vessel, low actinic - red, with collar, 1L	12-5130
TruCenter VF molded vessel, 1L	12-1503
TruCenter VF molded vessel, 1L, with certificate	13-0030
TruCenter DVH Vessels for 7030 Dissolution Apparatus	
TruCenter DVH vessel, for 7030 only, 1L	12-5039
TruCenter DVH vessel, for 7030 only, 1L, with certificate	12-5039V

TruCenter Conversion

TruCenter vessels, standard on the 7025 Dissolution Apparatus, offer superior centering and vessel verticality compared to EaseAlign vessels. Conversion kits are available to upgrade your 705-DS and 7000/7010 models to TruCenter vessels. The TruCenter kit includes:

- 1L TruCenter vessel
- Adapter ring
- Evaporation cover

Vessel Conversion Kits and Accessories for 705-DS and 7000/7010 Dissolution Apparatus

Description	Part Number
1L Conversion Kits	
Conversion kit, TruCenter, with ground groove, 1L	12-6100
Conversion kit, TruCenter, with ground groove, 1L, with certificate	12-6100V
Conversion kit, TruCenter, with manual sampling evaporation cover, 1L	12-6101
100 mL Conversion Kits	
Conversion kit, EaseAlign, 100mL, without paddle	12-0310
200 mL Conversion Kits	
Conversion kit, EaseAlign, with 24 in. paddle, flat bottom vessel, 200 mL (for use with Enhancer Cells)	12-0301
Conversion kit, EaseAlign, 24 in. paddle, 200 mL vessel	12-0318
Conversion Kits Accessories	
Height spacer paddle, 100/200 mL, 15 mm, for 7000/7010	12-0320
Height spacer, 100/200 mL, 3.25 in., for 7000/7010	12-0321
Evaporation cover, EaseAlign, for use with 100/200 mL vessel	12-6315

Conversion Kits and Accessories for 7025 Dissolution Apparatus

Description	Part Number
100 mL Conversion Kit	
TruCenter conversion kit, with paddle, 100 mL	12-0308
TruCenter conversion kit, with paddle and temperature monitoring, 100 mL	12-0315
200 mL Conversion Kits	
TruCenter conversion kit, with paddle, 200 mL	12-0312
TruCenter conversion kit, with paddle and temperature monitoring, 200 mL	12-0314
Conversion Kits Accessories	
TruCenter vessel, with adapter, 200 mL	12-5034
TruCenter vessel, without adapter, 200 mL	12-5033

200 mL glass vessel used in conversion kits

Manual Sampling Accessories

Description	Part Number
Bent cannula with adjustable gauge, 4.75 in. (900 mL)	12-3215
Bent cannula with adjustable gauge, 7.75 in. (900 mL)	12-3216
Adjustable gauge kit (cannulas not included) (cannulas not included)	12-3217
Manual sampling bracket, manifold, 7000/7010	17-3150

Sampling Cannulas and Accessories

Description	Part Number
Sampling cannula, 4.5 in., 900 mL (for 7000/7010 manifold)	17-3300
Sampling cannula, 6.5 in., 500 mL, for 7000/7010 manifold	17-3305
Cannula extension kit, 500 mL (for use with one 4.5 in. cannula)	17-3306
Sampling cannula, 8.12 in., for 2 L vessel (for 7000/7010 manifold)	17-3307
Sampling cannula, 10 in., for 4 L vessel (for 7000/7010 manifold)	17-3309
Manual sampling cannula assembly, 500 mL	17-3311
Manual sampling cannula assembly, 900 mL	17-3312
Sampling cannula, for 7025/7030	17-3313
Return cannula, for 7025/7030	17-3314
Manual sampling cannula, for 7025/7030	17-3317
Return cannula, 2 1/4 in., for 7000/7010 manifold	17-3320

Replacement Sampling / Temperature Accessories for Legacy Dissolution Apparatus

Description	Part Number
Internal Motor Drive	
Internal motor drive, for 3x3 configuration	12-0200
Internal motor drive, for 4x2, 4x3, 4x4 configurations	12-0205
Sampling Manifold for 7000/7010	
Sampling manifold, for use with 3x3 configuration, 1L	17-3100
Sampling manifold, for use with 4x2 configuration, 1L	17-3102
Sampling manifold, for use with 4x4 configuration, 1L	17-3107
Sampling manifold, for use with 4x4 configuration, 200 mL	17-3116
Replacement Sample Manifold Tubing for 7000/7010	
Sample manifold tubing/cannulas, sampling, 1L, 3x3 configuration	1005-1687
Sample manifold tubing/cannulas, return, 1L, 3x3 configuration	1005-1688
Sample manifold tubing/cannulas, sampling, 2L, 3x3 configuration	1005-1782
Sample manifold tubing/cannulas, return, 2L, 3x3 configuration	1005-1783
Sample manifold tubing/cannulas, sampling, 1L, 4x2 configuration	1005-1692
Sample manifold tubing/cannulas, return, 1L, 4x2 configuration	1005-1693
Sample manifold tubing/cannulas, sampling, 2L, 4x2 configuration	1005-1778
Sample manifold tubing/cannulas, return, 2L, 4x2 configuration	1005-1779
Sample manifold tubing/cannulas, sampling, 1L, 4x4 configuration	1005-1670
Sample manifold tubing/cannulas, return, 1L, 4x4 configuration	1005-1671
Sample manifold tubing/cannulas, sampling, 2L, 4x4 configuration	1005-1780
Sample manifold tubing/cannulas, return, 2L, 4x4 configuration	1005-1784
Sample manifold tubing/cannulas, return, online UV, 4x4 configuration	1005-1785

(Continued)

Replacement Sampling / Temperature Accessories for Legacy Dissolution Apparatus

Description	Part Number
Replacement Sample Cannula Tubing for 7020/7025/7030	
Sample tubing/cannulas, sampling/return, 6-position, V-Series	1005-1787
Sample tubing/cannulas, sampling/return, 8-position, V-Series	1005-1786
Replacement Sample Tubing for 8000 Sampling Station and Pumps	
Sample tubing, syringe pump to filter changer, 6-position	1005-1722
Sample tubing, syringe pump to filter changer, 8-position	1005-1729
Sample tubing, syringe pump or filter changer to 8000, 6-position	1005-1696
Sample tubing, syringe pump or filter changer to 8000, 8-position	1005-1674
Sample tubing, from 8000 valves, 6-position	1005-1694
Sample tubing, from 8000 valves, 8-position	1005-1672
Sample tubing, to 8000 valves, 6-position	1005-1695
Sample tubing, to 8000 valves, 8-position	1005-1673
Tubing connector, barb fitting for peristaltic pump (female)	3090-0159
Tubing connector, union fitting (male)	3090-0160

Note: Motorized drives should be installed by a qualified Agilent service engineer.

Centering Rings and Accessories

Description	Part Number
Centering ring, EaseAlign, for 705-DS and 7000/7010	12-6050
Centering ring, EaseAlign, retrofit, 6-position, includes pins and evaporation covers	12-6060
Centering ring, EaseAlign, retrofit, 8-position, includes pins and evaporation covers	12-6062
Locating pins, EaseAlign, 12/pkg.	12-6065
Conversion kit, EaseAlign, for Hanson vessels, 6/pkg.	12-6070
Alignment plate, TruCenter	12-6115

Evaporation Covers and Accessories

Description	Part Number
Evaporation cover, low-loss split hinge design	12-6327
Evaporation cover, low-loss hinged, for EaseAlign centering rings	12-6328
Evaporation cover, low-loss hinged, for use with resident probes	12-6329
Evaporation cover, low actinic - red, with DDM opening, for EaseAlign centering rings	12-6311
Evaporation cover, for use with 4L vessels	12-6326
Evaporation cover, EaseAlign	12-6300
Evaporation cover, EaseAlign, PVC	12-6301
Evaporation cover, EaseAlign, for DDM	12-6310
Evaporation cover, EaseAlign, for use with 100/200 mL vessel	12-6315
Evaporation cover, EaseAlign, low actinic - red	12-6320
Evaporation cover, for use with EaseAlign, solid cover for non-vessel positions	12-6330
Evaporation cover, manual sampling, opening for Japanese sinkers, for 7025/7030	12-6352
Evaporation cover, dual sampling, for 7025/7030	12-6353
Evaporation cover, for three openings for basket and two sampling ports	12-0463
Evaporation cover, for single opening for basket and auto start	12-0464
Evaporation plugs, 36/pkg.	12-6350
Evaporation hole plug, for 7025/7030	12-6358

EaseAlign Centering Ring and Evaporation Covers

Rotating Cylinder and Accessories

Description	Part Number
Rotating Cylinder, 4.45 cm outside dia.	12-1360
Rotating Cylinder, 4.45 cm outside dia., with certificate	12-1360V
Rotating Cylinder, 25 mm outside dia.	12-1365
Rotating Cylinder, 4.45 cm outside dia., for 7025 only	12-1380
Rotating Cylinder, 25 mm outside dia., for 7025 only	12-1385

Intrinsic Dissolution Apparatus

Description	Part Number
Intrinsic Dissolution Apparatus, 0.5 cm^2 exposed surface area, with punch, shaft and holder, for 7000/7010*	12-4100
Intrinsic Dissolution Apparatus, 0.5 cm^2 exposed surface area, for use with 7025*	12-4105
Intrinsic Dissolution Apparatus, 0.125 cm^2 exposed surface area, for 7025*	12-4111

*Surface plate sold separately. Only one plate required for testing.

Water Baths

Description	Part Number
Water Baths and Replacement Parts	
Water bath, molded, for use with 4x4 configuration	60-1500
Water bath, for 7025 and 7030	60-2110
Water bath, for Rotating Bottle, 24x12x12 in.	60-2200

Calibration and Verification Tools

QAII C Mechanical Qualification Station Replacement Parts

Description	Part Number
Adapter, universal for QAII and QAII C	12-9005
Calibration shaft, with certification	12-9010
Reflective RPM sensor clip, black	12-9015
Reflective RPM sensor clip, white	12-9020
Magnetic RPM sensor clip, for 1/4 dia. shaft	12-9021
Magnetic RPM sensor clip, for 3/8 dia. shaft	12-9025
Printer paper, 10 rolls/pkg.	12-9995
Printer paper, 100 rolls/pkg.	12-9996
Ribbon cartridge, 5/pkg.	12-9997

QAII C Mechanical Qualification Station

Verification Tools

Description	Part Number
Height Spacers for USP Apparatus 1 and 2	
Height spacer, 100/200 mL, 3.25 in., for 7000/7010	12-0321
Height spacer, baskets, for 7000/7010	12-7210
Height spacer, paddles, for 7000/7010	12-7200
Height spacer paddle, 100/200 mL, 15 mm, for 7000/7010	12-0320
Height spacer, for Peak vessels	12-7220
Height spacer, paddles, ball without retrieval string, 25 mm	12-7240
Height spacer, paddles, ball with retrieval string, 25 mm	12-7250
Height spacer, paddles, ball with retrieval string, 25 mm, with certificate	12-7250V
Height spacer, intrinsic apparatus, ball with retrieval string, 38 mm	12-7260
Height spacer intrinsic apparatus, ball with retrieval string, 38 mm, with certificate	12-7260V
Height spacer, for attachment to paddles, 25 mm above bottom of vessel	12-7270
Height spacer, for attachment to paddles, 25 mm above bottom of vessel, with certificate	12-7270V
Height spacer, for attachment to basket shaft, 25 mm above bottom of vessel	12-7280
Height spacer, for attachment to basket shaft, 25 mm above bottom of vessel, with certificate	12-7280V
Height gauge, Rotating Cylinder, USP	12-7335

(Continued)

Verification Tools

Description	Part Number
Height and Centering Tools for USP Apparatus 1 and 2	
Vessel centering tool, pass/fail gauge, EaseAlign centering rings	12-7310
Vessel centering tool, pass/fail gauge, EaseAlign centering rings, with certificate	12-7310V
Height tool, stainless steel, sets height of basket and paddles, 25 mm	12-7300
Height tool, stainless steel, sets height of basket and paddles, 25 mm, with certificate	12-7300V
Height tool, stainless steel, sets height of basket and paddles, for 2L vessels, 25 mm	12-7301
Height tool, stainless steel, sets height of basket and paddles, for 2L vessels, 25 mm, with certificate	12-7301V
Height tool, stainless steel, sets height of basket and paddles, used for testing antibiotics, 45 mm	12-7330
Height tool, stainless steel, sets height of basket and paddles, used for testing antibiotics, 45 mm, with certificate	12-7330V
Height tool, stainless steel and Delrin, for Peak vessels	12-7230
Bubble level, for horizontal centering	12-7325

Sampling trays with HPLC septum-capped vials (top) and glass tubes (bottom)

Accessories for 8000 Dissolution Sampling Station

Description	Part Number
Accessories for 8000 Dissolution Sampling Station	
Media replacement option, internal (specify printer type)	17-0110
Media/rinse chamber	17-1200
Printer, retrofit kit	17-1400
Stacking rack, for 8000	17-1500
Autocalibration fixture	17-5100
810 Peristaltic Pump replacement cartridge	17-6020
Dual loop, 810 Peristaltic Pump kit with 6 cartridges	17-6021
Dual loop, 810 Peristaltic Pump kit with 8 cartridges	17-6022
Adapters, to connect PTFE to 810 Peristaltic Pump tubing, 24/pkg.	17-6050
Nut and ferrule, 1/4-28, for 1/16 in. inner dia. Tubing	17-6070
Trays for 8000 Dissolution Sampling Station	
Sampling tray, open tube, 16x100 mm	17-1000
Sampling tray, open tube, 15x100 mm	17-1010
Sampling tray, open tube, 15x85 mm	17-1015
Sampling tray, HPLC, 12x32 mm	17-1050
Sampling tray, HPLC, 15x45 mm	17-1065
Acrylic rinse tray, 6 vessels, 3x3, for 7000/7010	17-1300
Acrylic rinse tray, 7-8 vessels, for 7000/7010	17-1310
Acrylic rinse tray, for 708/709-DS	17-1351
Sample tubing rinse kit	17-1341

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Acrylic rinse trays

Accessories for 8000 Dissolution Sampling Station

Description	Part Number
Tubes, Vials and Needles for 8000 Dissolution Sampling Station	
Glass tubes, 16x100 mm, 250/pk	17-5001
Glass tubes, 15x85 mm, 1000/pkg.	17-5010
Glass vials, 12x32 mm, w/ cap (PTFE/Silicon), 100/pk	17-5020
Glass vial, clear, with PTFE/silicon cap, 15x45, 100/pkg.	17-5030
Glass vial, low actinic - red, with PTFE/silicon cap, 15x45, 100/pkg.	17-5035
Calibration tubes, 10 mL, 8/pkg.	17-5040
Replacement needle kit, 8/pkg. (4 long, 4 short)	K1002-00477
Replacement valve kit, long needle	17-6200
Replacement valve kit, short needle	17-6210
Replacement Tubing for 810 Peristaltic Pump	
Purple/white Marprene replacement tubing, 8/pkg.	17-6000
Purple/white Viton replacement tubing, 8/pkg.	17-6005
White silicone replacement tubing, 8/pkg.	17-6010

(Continued)

HPLC septum-capped vials (left) and glass tubes (right)

Accessories for 8000 Dissolution Sampling Station

Description	Part Number
Color-coded Clear Tubing for 8000 Dissolution Sampling Station	
Sample manifold tubing/cannulas, sampling, 1L, 4x4 configuration	1005-1670
Sample manifold tubing/cannulas, return, 1L, 4x4 configuration	1005-1671
Sample tubing, from 8000 valves, 8-position	1005-1672
Sample tubing, to 8000 valves, 8-position	1005-1673
Sample tubing, syringe pump or filter changer to 8000, 8-position	1005-1674
Sample manifold tubing/cannulas, sampling, 1L, 3x3 configuration	1005-1687
Sample manifold tubing/cannulas, return, 1L, 3x3 configuration	1005-1688
Sample manifold tubing/cannulas, sampling, 1L, 4x2 configuration	1005-1692
Sample manifold tubing/cannulas, return, 1L, 4x2 configuration	1005-1693
Sample tubing, from 8000 valves, 6-position	1005-1694
Sample tubing, to 8000 valves, 6-position	1005-1695
Sample tubing, syringe pump or filter changer to 8000, 6-position	1005-1696
Sample tubing, syringe pump to filter changer, 6-position	1005-1722
Sample tubing, syringe pump to filter changer, 8-position	1005-1729

(Continued)

Accessories for 8000 Dissolution Sampling Station

Description	Part Number
Color-coded Clear Tubing for 8000 Dissolution Sampling Station	
Sample manifold tubing/cannulas, sampling, 2L, 4x2 configuration	1005-1778
Sample manifold tubing/cannulas, return, 2L, 4x2 configuration	1005-1779
Sample manifold tubing/cannulas, sampling, 2L, 4x4 configuration	1005-1780
Tubing assembly, 2L, return cannula, 8-valve	1005-1781
Sample manifold tubing/cannulas, sampling, 2L, 3x3 configuration	1005-1782
Sample manifold tubing/cannulas, return, 2L, 3x3 configuration	1005-1783
Sample manifold tubing/cannulas, return, 2L, 4x4 configuration	1005-1784
Sample manifold tubing/cannulas, return, online UV, 4x4 configuration	1005-1785
Sample tubing/cannulas, sampling/return, 8-position, V-Series	1005-1786
Sample tubing/cannulas, sampling/return, 6-position, V-Series	1005-1787
Tubing assembly, return cannula, 12x12, for BIO-DIS	1005-1788
Tubing assembly, sampling cannula, 12x12, for BIO-DIS	1005-1789
Tubing assembly, male/female, 12x12, for BIO-DIS	1005-1790
Tubing assembly, male lure for 810 Peristaltic Pump, 12x12, for BIO-DIS	1005-1791
Tubing assembly, return valve, 12x12, for BIO-DIS	1005-1792
Tubing assembly, barbed fitting, 12x12, for BIO-DIS	1005-1793
Tubing assembly, sampling valve, 12x12, for BIO-DIS	1005-1794
Tubing assembly, 1L, sampling cannula, 6-valve, for 708-DS	1005-1881
Tubing assembly, 1L, return cannula, 6-valve, for 708-DS	1005-1882
Tubing assembly, 1L, sampling cannula, 8-valve, for 708-DS	1005-1883
Tubing assembly, 1L, return cannula, 8-valve, for 708-DS	1005-1884
Tubing assembly, 2L, sampling cannula, 6-valve, for 708-DS	1005-1885
Tubing assembly, 2L, return cannula, 6-valve, for 708-DS	1005-1886
Tubing assembly, 2L, sampling cannula, 8-valve, for 708-DS	1005-1887
Tubing assembly, 2L, return cannula, 8-valve, for 708-DS	1005-1888

(Continued)

Accessories for 8000 Dissolution Sampling Station

Description	Part Number
Color-coded Clear Tubing for 8000 Dissolution Sampling Station	
Tubing assembly, 8 flared, male to female, 72 in.	1005-1891
Tubing assembly, 6 flared, male to female, 72 in.	1005-1892
Tubing assembly, 8 double flared, male to male, 72 in.	1005-1893
Tubing assembly, 6 double flared, male to male, 72 in.	1005-1894
Tubing assembly, sampling cannula valve, 3x3, 200 mL	1005-1901
Tubing assembly, return cannula valve, 3x3, 200 mL	1005-1902
Tubing assembly, sampling cannula valve, 4x2, 200 mL	1005-1903
Tubing assembly, return cannula valve, 4x2, 200 mL	1005-1904
Tubing assembly, sampling cannula valve, 4x4, 100 mL	1005-1905
Tubing assembly, return cannula valve, 4x4, 100 mL	1005-1906
Tubing assembly, sampling cannula valve, 4x2, 100 mL	1005-1907
Tubing assembly, return cannula valve, 4x2, 100 mL	1005-1908
Tubing assembly, for 1L 708-DS, sample and return cannulas, 6-position	1005-1920
Tubing assembly, for 1L 708-DS, sample and return cannulas, 8-position	1005-1921
Tubing assembly, for 2L 708-DS, sample and return cannulas, 6-position	1005-1922
Tubing assembly, for 2L 708-DS, sample and return cannulas, 8-position	1005-1923
Tubing assembly, sampling cannula valve, 3x3, 100 mL	1005-1945
Tubing assembly, return cannula valve, 3x3, 100 mL	1005-1946
Tubing assembly, female/lure to sample cannula, 8-valve, for BIO-DIS	1005-1952
Tubing assembly, male/lure to male ¼-28, 8-valve, for BIO-DIS	1005-1953
Tubing assembly, female ¼-28 to return cannula, 8-valve, for BIO-DIS	1005-1954
Replacement Tubing Kit, BIO-DIS (all tubing, cannulas and fittings included)	27-0126

806 Syringe Pump Accessories

Description	Part Number
Replacement syringe, for 806 Syringe Pump	K1002-00437

810 Perisaltic Pump Accessories

Description	Part Number
Peristaltic Replacement Cartridge	
810 Peristaltic Pump replacement cartridge	17-6020
Peristaltic Replacement Tubing	
Purple/white Marprene replacement tubing, 8/pkg.	17-6000
Purple/white Viton replacement tubing, 8/pkg.	17-6005
White silicone replacement tubing, 8/pkg.	17-6010

Cartridges for 810 Peristaltic Pump

Rotating Bottle Apparatus

Rotating Bottle

Rotating Bottle Accessories

Description	Part Number
Conversion Kits	
Conversion kit, low actinic - red, 200 mL	32-0110
Conversion kit, 4 in. center shaft extensions, 16x100 mm tubes	32-0120
Bottle Caps	
Cap, with Viton liner, for 100 mL	32-1101
Cap, with Viton liner, for 200 mL	32-1105
Decanting cap, with 40-mesh screen, for 100 mL	32-1121
Decanting cap, with 40-mesh screen, for 200 mL	32-1125
Screens and Liners	
Viton liner, for 100 mL	32-1201
Viton liner, for 200 mL	32-1205
Replacement screen, for decanting cap, 40-mesh, for 100 mL	32-1221
Replacement screen, for decanting cap, 40-mesh, for 200 mL	32-1225
Clips	
Bottle clips, for 100 mL	32-1300
Bottle clips, for 16x100 mm tubes	32-1301
Bottle clips, for 28x98 mm (40 mL) tubes	32-1302
Bottle clips, for 200 mL	32-1305
Bottles	
Bottle, with cap, 100 mL	32-5001
Bottle, with cap, low actinic - red, 100 mL	32-5021
Bottle, with cap, low actinic - red, 200 mL	32-5030
Bottle only, low actinic - red, 100 mL	32-5521
Bottle only, 100 mL	32-5530

200 Hardness Tester

Agilent 200 Tablet Hardness Tester

200 Tablet Hardness Tester Calibration Tools

Description	Part Number
Calibration fixture	42-2000
Trim pot tool	42-2005
Hardness/calibration weight hanger	42-2020
Calibration weight, 200 gm, with certificate	42-1200
Calibration weight, 500 gm, with certificate	42-1205
Calibration weight, 1kg, with certificate	42-1210
Calibration weight, 2 kg, with certificate	42-1215
Calibration weight, 5 kg, with certificate	42-1220
Calibration weight, 10 kg, with certificate	42-1225
Calibration weight, 20 kg, with certificate	42-1230

200 Tablet Hardness Tester and Accessories

Description	Part Number
Hardness/fragment safety shield	42-2010
Hardness/fragment brush	42-2030
Tablet thickness gauge, handheld, dial gauge, 0-10 mm	42-6105
Tablet thickness gauge, handheld, digital gauge, 0-10 mm	42-6110
RS232 serial port, retrofit	42-0250
Thickness gauge option	42-0300
Thickness gauge retrofit option	42-0350
Battery for Mitutoyo gauge	42-0355
Printer, 115V/230V	42-0120

200 Tablet Hardness Tester Jaw Plates

Description	Part Number
Jaw plate, standard	42-1000
Jaw plate, shelf type	42-1005
Jaw plate, 1/8 x 60 degree	42-1010
Jaw plate, 1/16 radius	42-1015
Jaw plate, 1/4 radius	42-1020
Jaw plate, 1/8 radius	42-1025
Jaw plate, bolus type	42-1030
Jaw plate, 3/16 radius	42-1035
Jaw plate, flat face	42-1040
Jaw plate, adjustable	42-1050

Jaw plates (top row, L to R) standard, 1/8x60 degree, 1/8 radius, flat face
(bottom row, L to R) shelf, 1/16 radius, bolus, adjustable

250 Friability Tester

250 Friability Tester Accessories

Description	Part Number
Dual-chamber drum, clockwise rotation	47-1000
Dual-chamber drum, clockwise rotation, with certificate	47-1000V
Dual-chamber drum, counterclockwise rotation	47-1005
Dual-chamber drum, counterclockwise rotation, with certificate	47-1005V
Single-chamber drum, clockwise rotation	47-1010
Single-chamber drum, clockwise rotation, with certificate	47-1010V
Single-chamber drum, counterclockwise rotation	47-1015
Single-chamber drum, counterclockwise rotation, with certificate	47-1015V
Abrasion drum	47-1020
10-degree lift (wedge)	47-1030
Printer, 115V/230V, retrofit	47-0153

Agilent 250 Friability Tester with two dual-chamber drums

350 Tapped Density Tester

350 Tapped Density Tester, dual platform in the specially designed acoustic cabinet.

350 Tapped Density Tester Accessories

Description	Part Number
Tapped Density Tester Platforms	
Platform, 10 mL, 14 mm drop, USP	52-1000
Platform, 25 and 50 mL, 14 mm drop, USP	52-1010
Platform, 100 mL, 14 mm drop, USP	52-1020
Platform, 250 mL, 14 mm drop, USP	52-1030
Platform, 500 mL, 14 mm drop, USP	52-1040
Platform, 10 mL, 3 mm drop, USP or ASTM	52-1050
Platform, 25 and 50 mL, 3 mm drop, USP or ASTM	52-1060
Platform, 100 mL, 3 mm drop, USP or ASTM	52-1070
Platform, 250 mL, 3 mm drop, USP or ASTM	52-1080
Graduated Cylinders	
Graduated cylinder, funnel top, hexagonal base, 10 mL	52-5000
Graduated cylinder, funnel top, hexagonal base, 100 mL	52-5010
Graduated cylinder, funnel top, hexagonal base, 250 mL	52-5020
Graduated cylinder, standard top, hexagonal base, 25 mL	52-5040
Graduated cylinder, standard top, hexagonal base, 50 mL	52-5050
Graduated cylinder, standard top, hexagonal base, 500 mL	52-5060
Acoustic Cabinet	
Acoustic cabinet	52-2010
Printer	
Printer, retrofit, 115V/230V	52-0153

Service and Qualification

Agilent Services and Support: Your Laboratory Partner

Agilent offers you a variety of comprehensive qualification and service options for your dissolution apparatus and analytical instruments. Focus on what you do best and let Agilent provide you with installation and familiarization, hardware and software training, and complete qualification services.

Our service organization has the experience, education and training to ensure your dissolution equipment is properly installed and qualified, not only at the time of purchase, but throughout the life of the instrument. Our engineers and chemists are cGMP-trained and receive extensive ongoing training to ensure they have the requisite knowledge.

We can work with you to develop a service offering that meets your specific needs for:

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

We can help optimize your productivity by quickly resolving problems, maximizing your equipment uptime, adhering to agreed-upon service and qualification schedules, minimizing your compliance risk and reducing your administrative burdens.

Preventative Maintenance and Repair Service

Keeping your dissolution apparatus in top condition is critical to meeting current USP Performance Verification Test (PVT) requirements, as well as the recent enhanced Mechanical Qualification (MQ) specifications put forth by the FDA and ASTM. It is even more important that your apparatus are routinely serviced. We offer a number of repair contract options that cover maintenance, repair and qualification services. For Agilent's Service Center Repair information, visit **www.agilent.com/lifesciences/dissolutionrepair**

Qualification Documentation

Maintaining the proper instrument and qualification documentation is essential. To ensure you meet the cGMP requirements, Agilent provides qualification services and documentation for all our dissolution instrumentation. Our qualification protocols include installation qualification (IQ), operational qualification (OQ), and in the case of Apparatus 1 and 2, a performance qualification (PQ) based on the USP Performance Verification Test (PVT). A mechanical qualification (MQ) procedure is also available. Our PQ procedure contains current USP practices for qualification with current acceptance criteria. Similarly, the MQ protocol accurately reflects the current specifications and tolerances for physical parameters contained in the ASTM and FDA procedures. Our dedicated compliance group strives to ensure this documentation remains current according to the ever-changing industry regulations.

Compliance Services

Our laboratory services group provides a cost-effective alternative to performing these qualification services. You can be assured the job will be performed correctly. In fact, Agilent is ranked #1 in compliance by lab professionals worldwide.

Our service group is trained to perform the PQ for Apparatus 1 and 2. We offer these services for our own equipment, as well as for all other brands of dissolution apparatus. We will work with you or your metrology department to establish a schedule to ensure your equipment remains qualified. When performing a PQ, our services include a verification of the critical physical parameters and the chemical qualification using your USP prednisone tablets with either the single- or two-stage procedure for paddles and/or baskets.

For customers who choose to perform the MQ procedure, we provide this service as well. Our engineers are equipped with our electronic qualification tools to measure all the relevant physical parameters. Our protocols include the specifications as outlined in the USP, as well as the FDA and ASTM recommendations.

Training and Educational Services

Agilent offers training on the proper operation of all its equipment. This service can be ordered at the time of instrument purchase. We also offer a variety of other educational programs that can be delivered in a wide range of methods to best suit your needs.

Contact your Agilent representative for more information or to set up a time to discuss your specific requirements.

Did You Know?

A wide variety of preventive maintenance and service agreements are available for all of Agilent's dissolution and physical testing instruments. Contact your local Agilent representative to find the solution that best fits your laboratory's needs.

Enterprise Edition (EE) Compliance Services (IQ/OQ/PQ/MQ)

Description	Part Number
708/709-DS Dissolution Apparatus	
EE IQ Service for 708/709-DS	SYS-DI-708 R26N091
EE OQ Service for 708/709-DS	SYS-DI-708 R26J091
EE PQ Service for 708/709-DS	SYS-DI-708 R26P091
EE MQ Service for 708/709-DS	SYS-DI-708 R26M091
EE IQ/OQ Service for 708/709-DS	SYS-DI-708 R26H091
EE IQ/OQ/MQ Service for 708/709-DS	SYS-DI-708 R26T091
EE IQ/OQ/PQ Service for 708/709-DS	SYS-DI-708 R26U091
BIO-DIS Reciprocating Cylinder Apparatus	
EE IQ Service for BIO-DIS Apparatus 3 Reciprocating Cylinder	SYS-DI-BIO R26N091
EE OQ Service for Bio-Dis Apparatus 3 Reciprocating Cylinder	SYS-DI-BIO R26J091
Reciprocating Holder Apparatus 7	
EE IQ Service for Apparatus 7 Reciprocating Holder	SYS-DI-APP7 R26N091
EE OQ Service for Apparatus 7 Reciprocating Holder	SYS-DI-APP7 R26J091
400-DS Apparatus 7	
IQ Service for 400-DS (Small Volume Apparatus 7)	SYS-ZZ-OTHER2
OQ Service for 400-DS (Small Volume Apparatus 7)	SYS-ZZ-OTHER2
100 Automated Disintegration Apparatus	
IQ Service for 100 Automated Disintegration	SYS-ZZ-OTHER2
OQ Service for 100 Automated Disintegration	SYS-ZZ-OTHER2

(Continued)

Enterprise Edition (EE) Compliance Services (IQ/OQ/PQ/MQ)

Description	Part Number
850-DS Dissolution Sampling Station	
850-DS Dissolution Sampling Station IQ* (for use with 7000/7010,7025,705-DS,708-DS, Bio-Dis, App7)	Add "-E" to SYS-DI-XXX
850-DS Dissolution Sampling Station OQ* (for use with 7000/7010,7025,705-DS,708-DS, Bio-Dis, App7)	Add "-E" to SYS-DI-XXX
UV Dissolution Hardware and Software	
Cary 60 with UV-Vis Spectrophotometer, multicell or fiber optic, IQ	SYS-UV-60 R26N091
Cary 60 with UV-Vis Spectrophotometer, multicell or fiber optic, IQ/OQ	SYS-UV-60 R26J091
Cary 60 with UV-Vis Spectrophotometer, multicell or fiber optic, IQ/OQ	SYS-UV-60 R26H091
Cary 8454 UV-Vis Spectrophotometer, IQ	SYS-UV-VIS R26N091
Cary 8454 UV-Vis Spectrophotometer, OQ	SYS-UV-VIS R26J091
Cary 8454 UV-Vis Spectrophotometer, IQ/OQ	SYS-UV-VIS R26H091
UV Dissolution Software, Cary 60 or 8453/8454, IQ	SYS-SW-CS-E R26N091
UV Dissolution Software, Cary 60 or 8453/8454, OQ	SYS-SW-CS-E R26J091
UV Dissolution Software, Cary 60 or 8453/8454, IQ/OQ	SYS-SW-CS-E R26H091
Workstation Software	
IQ Service for Dissolution Workstation Software	SYS-SW-CS R26N091
OQ Service for Dissolution Workstation Software	SYS-SW-CS R26J091
280-DS Mechanical Qualification System	
IQ/OQ Service for 280-DS Mechanical Qualification System	SYS-ZZ-OTHER2

*Paper protocols (Classic) remain available for download via SubscribeNet. Certified Agilent Service Providers can still provide this method of qualification delivery upon request.

Dissolution Seminar Series

Agilent Dissolution Systems offers educational seminars that are specifically designed to provide the latest in theory, techniques and hands-on training for those involved with dissolution testing. Our instructors include Agilent employees, as well as prominent scientists from academia and the dissolution industry.

What makes these courses unique? The courses are not disguised sales presentations, with all course materials being vendor-neutral and designed to provide a solid base of knowledge. Also, course materials are relevant to a GMP environment. Our chemists understand the latest regulations and what it takes to comply.

These courses are offered at our Cary, NC training facility on a yearly schedule, or taught on-site, anywhere around the world. For a complete list of seminar dates and locations, please check our web site at **www.agilent.com**.

Fundamentals of Dissolution

This comprehensive two-day course is designed for new and emerging dissolution analysts. The course places emphasis on basic dissolution fundamentals and theory, along with focused discussions on current compendial dissolution testing apparatus, USP physical parameter requirements and the current USP calibration procedure. Hands-on workshops provide participants with experience preparing for and executing a dissolution test. This course will benefit novice, as well as experienced, dissolution analysts and those in quality control and assurance, calibration, and metrology. This course also serves as a refresher for those individuals with limited or intermediate dissolution experience. The hands-on workshops include dissolution apparatus familiarization, performing the dissolution test, and physical suitability testing.

Topics:

- Evolution of dissolution testing
- Dissolution fundamentals and theory
- Compendial dissolution testing
- Calibration of USP Apparatus 1 and 2
- Critical physical parameters
- Compendial and non-compendial drug release apparatus
- Methods of sample analysis
- Dissolution technique
- Regulatory issues

Upon successful completion of this course, the attendee should be able to:

- Describe basic principles of dissolution theory and compendial Apparatus 1 through 7
- Perform proper dissolution techniques to conform with USP guidelines
- List critical physical parameters associated with Apparatus 1 and 2
- Describe essentials in USP and enhanced mechanical qualification of Apparatus 1 and 2, as well as regulatory issues associated with dissolution and GMP guidelines

Dissolution Method Development and Validation

Designed for experienced R&D, method development, or QC chemists interested in the development and validation of discriminating in vitro dissolution methods, this highly intensive two-day course offers an interactive approach to the selection of a discriminating method, including discussion of biorelevant media and test conditions and an examination of appropriate testing equipment. New advancements in noncompendial apparatus and automated equipment (including fiber optics) in regards to innovative method development are also explored. The Biopharmaceutics Classification System will be an integral part of the method development aspects.

Accompanying these topics are presentations of regulatory guidelines for concise method validation and instructional exercises designed to enhance the student's learning experience. Participants will be encouraged to share their method development experiences and problems. This course is designed for individuals involved with research and development, quality control/quality assurance, and pharmacokinetics.

Topics:

- Overview of in vitro method dissolution
- Goals for dissolution method development
- Selection of test conditions
- Discrimination challenges
- Specification setting
- Test method generation
- Validation of the dissolution method
- Method transfer

Upon successful completion of this course the attendee should be able to:

- Develop a dissolution method according to current regulatory guidelines
- Assess the discriminatory power of your dissolution method
- Determine sources of error associated with the proposed method
- Perform thorough validation of all manual and automated methods
- Explore all aspects of method transfer

Correlating Dissolution and Bioavailability: Understanding IVIVC

This two-day course is designed for advanced dissolution analysts and individuals involved with analytical method development and validation, as well as quality control/assurance, formulations, stability, pharmacology, pharmacokinetics and regulatory affairs. In vitro dissolution tests seem to be the most reliable predictors of in vitro availability. While the bioavailability of drug substances and drug products in humans can provide evidence of a potential relationship between dissolution and physiological availability, it is often impractical to perform extensive and expensive human testing. The goal of the course is to learn how to assess and develop methods of correlating in vitro and in vivo performance parameters.

Topics:

- Fundamentals of correlation
- Bioavailability assessment
- Dissolution and bioavailability
- Basics of in vitro / in vivo correlation
- Characterization of dissolution data
- IVIVC parameters

Upon successful completion of this course the attendee should be able to:

- Discuss relevant aspects of dissolution and bioavailability
- Describe essentials of bioavailability assessment regarding various dosage forms
- Outline fundamentals of interpretation of dissolution profiling and data
- Explain regulatory perspective of IVIVC and SUPAC guidelines
- Characterize dissolution data
- Reduce, analyze, and interpret IVIVC data

In Vitro Dissolution of Ointments, Creams, and Transdermals

Designed for academic researchers and industry scientists with interests in evaluating drug release from topical preparations, the goal of the two-day course is for the participant to learn the application of current dissolution testing techniques and equipment in the evaluation of drug release from semisolids and transdermal drug delivery systems (both immediate and controlled release). Discussion includes the use of this technology in product development and quality control. This course is designed for individuals involved in the development, manufacturing, or quality control of topical products.

Topics:

- Compendial testing with Apparatus 5, 6, and 7
- New compendial chapters on diffusion cell technology
- Method validation
- Non-compendial testing
- Aspects of membrane selection
- Proposed calibration methodology
- SUPAC guidance
- Use of the Enhancer Cell and Franz Cell
- Method development
- World community regulatory requirements

The hands-on workshop includes:

- Use of the Enhancer Cell and Franz Cell
- Data analysis
- Method development
- Demonstration of Apparatus 5, 6, and 7

Upon successful completion of this course the attendee should be able to:

- Describe basics of compendial dissolution testing with USP Apparatus 5, 6, and 7
- Outline uses and restrictions of non-compendial testing and apparatus
- Explain uses of the Enhancer Cell and Franz Cell
- Describe ointment, cream, and transdermal method development and validation techniques
- Describe SUPAC guidelines for topicals
- Explain regulatory requirements with perspective on the world community

Dissolution and Bioequivalence of Generic Pharmaceuticals

This intensive two-day course is designed for the advanced dissolution analyst, as well as those involved in drug metabolism, drug disposition, generics, pharmacokinetics, and analytical methods development. Participants involved with research and development, quality control/quality assurance, and pharmacokinetics learn how to demonstrate bioavailability and bioequivalence of pharmaceutical formulations without designing and executing time consuming and expensive clinical trials in humans. Two pharmaceutical formulations are considered bioequilivent (BE) when their respective rate and extent of bioavailability (BA) following administration of a unit dose under standard clinical experimental conditions are substantially similar. In vitro testing is an ideal surrogate for predicting BA or BE of pharmaceutical formulations. This course presents the fundamental considerations necessary to understand BA or BE and the utility of in vitro dissolution testing in the prediction of BA or BE.

Topics:

- Biopharmaceutics Classification System (BCS)
- Dissolution method development for generic formulations
- Characterization/computation of dissolution parameters
- f_1 and f_2 equations
- IVIVC relevant to generics
- Computation of PK parameters for BA/BE
- Worldwide regulatory requirements for demonstration of BE, design of a clinical protocol

Upon successful completion of this course the attendee should be able to:

- Understand BCS and dissolution testing
- Develop dissolution test method development for generic formulations
- Use f_1 and f_2 expressions in generic drug development
- Comprehend IVIVC relevant to generic pharmaceuticals
- Compute PK parameters for BA and BE
- Design basic clinical protocol

Dissolution Seminar Series

For more information on dissolution seminars, visit
www.agilent.com/lifesciences/dissolutioncourses

For more information regarding on-site courses, contact your local Agilent representative.

Dissolution Exchange

Learn. Solve. Discuss.

The Agilent Dissolution Exchange, a free and interactive resource to learn about dissolution testing, solve laboratory testing challenges and discuss topics related to the dissolution industry. The exchange offers an expansive set of resources in the learn, solve and discuss areas of the program. These resources include:

- The Dissolution 1-on-1 self-paced dissolution tutorial developed by knowledgeable Agilent chemists
- Recorded webinars and presentations
- The Dissolution Discussion Group.
- White papers, posters, newsletters, etc.
- Contact resources for dissolution-related questions, including instrument selection, qualification, method development and more

For more information, visit **http://dissolution.chem.agilent.com**

Be a part of the Dissolution Exchange

Dissolution 1-on-1

Standardize your laboratory training with Agilent's self-paced course

To make it easier for analysts to get up-to-date dissolution training, Agilent recently launched a newly updated version of Dissolution 1-on-1, its industry-leading, self-paced training course on the Dissolution Exchange. This comprehensive online course is free and can serve as a training resource for new analysts or as a refresher for experienced dissolution chemists, technicians, reviewers, and metrologists.

Agilent has partnered with CoAcS, Ltd. to produce a comprehensive assessment package that you can purchase to test analysts on the course material. This testing package allows you to identify managers by site or department that can in turn identify those that need training and assessment. The training package offers up to three opportunities for successful completion, at which time the user and his manager receive confirmation of satisfactory completion. Training packages are managed and tracked online for your convenience.

Dissolution 1-on-1

Dissolution 1-on-1 includes the latest industry changes regarding dissolution apparatus qualification, plus an introduction to dissolution testing.

The course covers:

- The Dissolution Apparatus – Anatomy
- Critical Physical Parameters
- Performing the Dissolution Test
- Dissolution Apparatus Qualification
- Dissolution and Automation

Dissolution 1-on-1 Self-paced Training Course

Video Training

Labcast: Live from the Agilent Global Broadcast Studio

What is Labcast?

In simple terms, Labcast is a way for Agilent to communicate through video conferencing equipment with other capable sites around the world. Video broadcasting from our studios in Cary, NC allows instantaneous conferencing, training and services to all points around the globe. Agilent trainers can televisit you and your employees to explore the latest methods and techniques for effective dissolution testing. Keep your lab personnel updated on new practices with ongoing education programs and even link with other locations for standardized training sessions. All this without leaving home. Contact us to learn more!

Dissolution Apparatus Qualification; PVT versus MQ, What is Right For Your Laboratory

60-minute module

Agilent's Laboratory Services has prepared a one-hour seminar on the qualification of USP Apparatus 1 and 2. Significant changes have occurred in dissolution apparatus qualification during the last several years. The USP Performance Verification Test (PVT) migrated from a range test to a much more definitive test which focuses greatly on accuracy and variability of the dissolution apparatus through new acceptance criteria highlighting the geometric mean and %CV. Likewise, the alternative approach towards apparatus qualification, enhanced Mechanical Qualification (MQ) will also be highlighted and discussed in detail.

The module addresses the following topics:

- Overview of the Dissolution Performance Verification Test
- Background of Performance Qualification (PQ) and Analytical Instrument Qualification (AIQ)
- Dissolution Mechanical Qualification (MQ) standards, requirements, specifications and tolerances
- PVT and MQ: finding the right test for your laboratory
- Evaluation of why laboratories are using the MQ test

Dissolution Aberrant Data Investigation

60-minute module

Lack of proper failure investigation and documentation generally leads the list of problems in FDA observations of analytical laboratories. Many standard operating procedures for handling out-of-specification data do not properly deal with dissolution data. Join our chemists for a live seminar on the proper procedures for investigating and documenting out-of-specification dissolution test results in your lab.

The module addresses the following topics:

- Detailed procedures for properly investigating and documenting out-of-specification results
- Ideas about how rudimentary investigations may uncover calculation or standard preparation errors proceeding to additional testing
- Discussion on how proper investigation and reporting can limit the possibility that an analyst will repeat an error in a second test
- Review of actual FDA observations

Apparatus 3

60-minute module

The reciprocating cylinder, or Apparatus 3, became an official method in the USP XXII, Fifth Supplement. Given the increasing introduction of modified and extended release products, this valuable tool is growing in usage. This one-hour presentation covers the historical development as well as the principles of the operation and is designed for anyone interested in learning how the instrument operates.

The module addresses the following topics:

- Evolution of Apparatus 3 from previous dissolution apparatus
- Principles of operation
- Demonstration of Apparatus 3
- When to consider Apparatus 3 in method development
- Calibration requirements
- Automation of the sampling process
- Options / accessories for unique dosage forms

Dissolution Discussion Group

Tap into the knowledge-base from dissolution users around the world!

www.dissolution.com

The Agilent-sponsored DDG is a vendor-neutral online forum designed to host discussions on industry research, best practices, regulatory issues, R&D challenges and more, all in an open environment that is free from regulatory oversight. Discussions are anonymous and supported by fellow analysts and chemists in QC, R&D, stability and academia.

Practical Solutions Newsletter

You can have this dissolution-specific newsletter delivered right to your inbox! With the latest on our dissolution products, services and the ever-evolving regulatory environment, *Practical Solutions* is your resource to stay informed.

To receive your copy, register at
www.agilent.com/lifesciences/dissolution_registration.

Dissolution Hotline

Agilent's dissolution chemists are always available to assist with questions about finding the instrument that best supports your laboratory, method development and regulatory support. Contact our team at **dissolution.hotline@agilent.com**

Easy Ordering Terms and Conditions

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Many products and accessories in this catalog are shipped from stock, while others are built upon receipt of your order.

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We will be happy to supply a price quote via phone, email or fax if you need it in writing.

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UNLEASH DISSOLUTION CAPABILITIES

Agilent's new 850-DS Dissolution Sampling Station – think of it as the nucleus of the lab that can unleash the full capabilities of your dissolution sampling workflow.

Featuring integrated pumping and filtration, the 850-DS lets you manage the complete dissolution sample transfer, filtration, and collection workflow – all from a centralized interface. The 850-DS also automates the sample archiving for analysis, and integrates with UV and LC solutions.

Greater throughput, higher reproducibility, fewer instruments to qualify and maintain, and more analyst free time – the 850-DS Dissolution Sampling Station has the features to improve your dissolution sampling workflow. Learn more at **www.agilent.com/lifesciences/850-DS**

The Measure of Confidence

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