



Agilent Dissolution Portfolio

BETTER DESIGN, BETTER RESULTS. THE NEW STANDARD IN DISSOLUTION.

The Measure of Confidence



Agilent Technologies



AGILENT DISSOLUTION PORTFOLIO

QUALITY DISSOLUTION TECHNOLOGY PAIRED WITH INDUSTRY-LEADING ANALYTICAL INSTRUMENTS

The New Standard in Dissolution

Agilent now offers the market-leading family of dissolution apparatus and sampling systems that pair perfectly with our HPLC and UV systems. But we offer much more than just innovative products—we offer quality and value beyond the products themselves. Agilent's global presence ensures the same level of support around the world.

○ The Complete Solution

At Agilent, we do not stop with designing the best apparatus; we provide a comprehensive offering of services and support so you can be certain that your laboratory can get the answers you need. We provide comprehensive qualification services, training, SOP guidance and on-site support options, as well as educational seminars, hotline and technical support for equipment, methodology and regulatory compliance. We also sponsor the vendor-neutral online Dissolution Discussion Group (DDG) forum to enable industry knowledge-sharing and support. Plus Agilent's Analytical Instrument Qualification (AIQ) Services ensure proper installation and verification through installation, operation, performance and/or mechanical qualification documentation (IQ/OQ/PQ/MQ).

○ Dissolution Technology

Our design goal is to not just conform to the regulatory guidelines, but exceed the design criteria. Wherever feasible, we attempt to eliminate variables which can cause erroneous results. After all, dissolution data should reflect variation in the dosage form, not the dissolution apparatus. VanKel and Varian were early pioneers in automating the dissolution test to eliminate the human variability by providing precision and accuracy in sampling and filtration. We continue this approach in our current line of dissolution apparatus.

○ Analytical Finishes

Whether in R&D or QA/QC, when it comes to analyzing your samples, we offer industry-leading UV dissolution technology through the Cary 50 and Agilent 8453 UV-visible Spectrophotometers. Select either an offline or online system and we can help you automate your workflow. Should your methodology require HPLC analysis, Agilent's 1200 LC Series, with its flexible, modular design, ensures configurations ideally suited to meet your application requirements.

○ Regulatory Compliance

Dissolution apparatus are designed and manufactured to meet the strictest standards and regulatory requirements under current Good Manufacturing Practices (cGMPs). Our instruments meet the current harmonized standards for dissolution contained in the USP, EP and JP. For those laboratories that require qualification, our instruments are designed to meet the USP Performance Verification Test (PVT), as well as Enhanced Mechanical Qualification standards from the FDA and ASTM. Agilent has extensive qualification documentation and services that provide initial and ongoing verification that the apparatus conforms to these standards.

○ Applications and Testing Capabilities of Agilent Dissolution Apparatus

We provide the instruments and accessories to test essentially all types of dosage forms, from tablets, capsules, ointments, crèmes, gels, transdermal patches, microspheres, powders, implants, and more. Our dissolution and drug release apparatus are designed to accommodate immediate, modified, sustained or extended release products and

adhere to the compendial standards and regulatory guidance. We also offer proven non-compendial modifications for the testing of novel dosage forms when traditional pharmacopeial apparatus prove unsuitable for characterizing drug release profiles.

DISSOLUTION APPARATUS	DESCRIPTION	COMMON PRODUCTS TYPES	
Stirred Vessel Methods - The basket and paddle dissolution apparatus are the most common throughout the world. These methods traditionally require the placement of individual dosage forms into 1-Liter glass vessels containing a fixed volume of fluid referred to as dissolution medium.			
Agilent 708-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 Dissolution Apparatus for Rotating Paddle (USP Apparatus 2)	Paddle blade fixed to the bottom of a shaft fabricated from 316 stainless steel or Teflon 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 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 patch	
Agilent 708-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 patch	
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 typically reciprocate in 300 mL vessels and the holder apparatus in 50 mL vessels.			
Agilent BIO DIS Reciprocating Cylinder Apparatus (USP Apparatus 3)	Mimicking the pH changes of the GI tract, 300 mL glass cylinders containing the dosage form between capped screens of varying mesh sizes reciprocate 10 cm within media for a designated time period before the dosage form is transported to another row of media (six rows are available)	• Capsules • Beads • Enteric coated products	• Extended, modified or sustained release formulations
Agilent Reciprocating Holder Apparatus (USP Apparatus 7)	Holders designed for small sustained or extended release, including small-volume products, reciprocate through a distance of 2 cm within glass 50 mL vessels	• 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 Cell 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 • Transdermals
Agilent Peak Vessel	The Peak vessel contains an inverted peak in the base of the vessel to displace the unstirred zone, preventing cone formation.	• Beads	• Products exhibiting coning problems

For more information

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