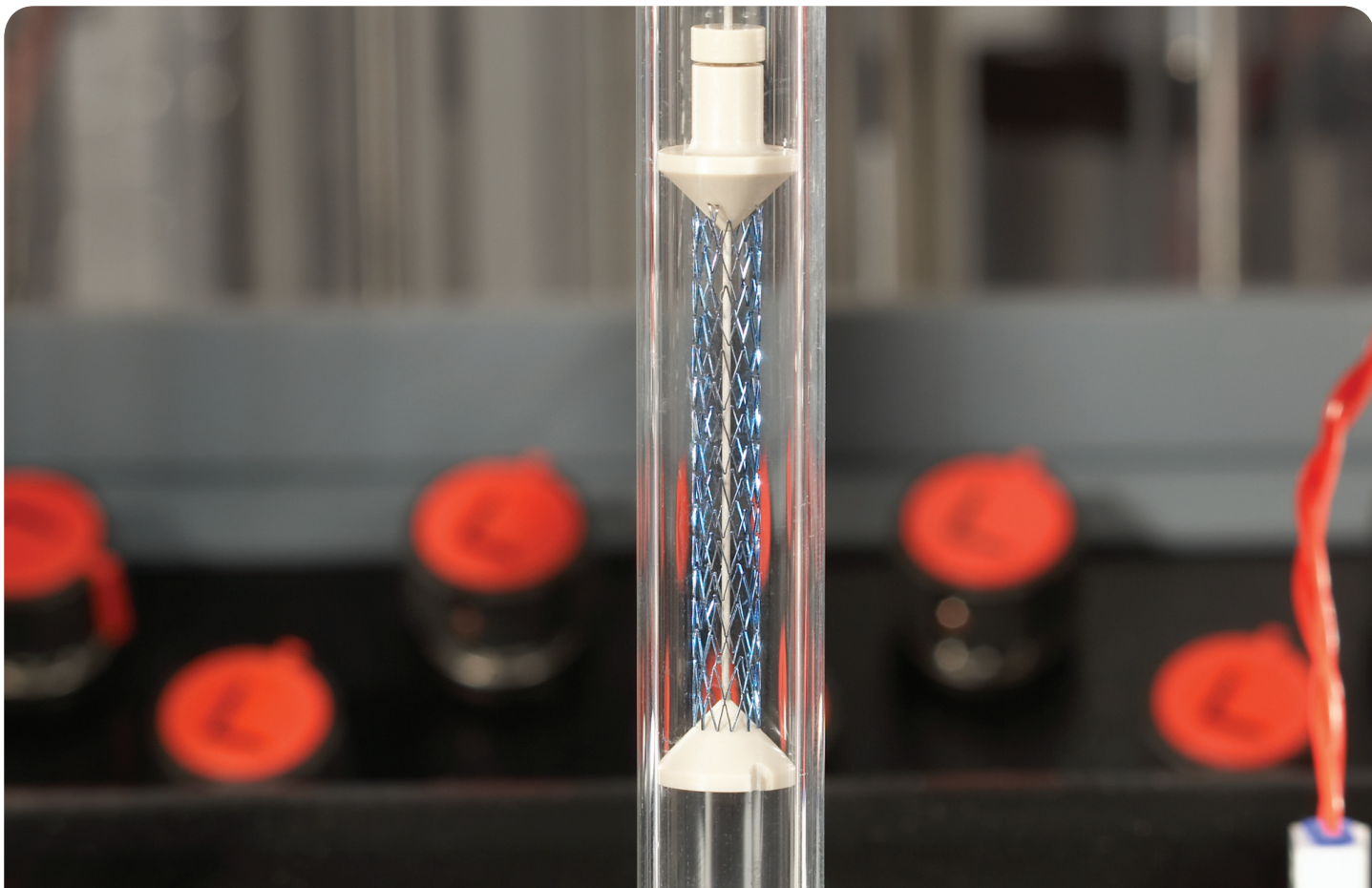


400-DS Dissolution Apparatus 7

The Measure of Confidence



Agilent Technologies



Unsurpassed Commitment to Innovation

The 400-DS Dissolution Apparatus 7 is the result of Agilent's strong commitment to innovation in the areas of automation and integration for dissolution testing.

The 400-DS is specially designed for small-volume dissolution testing of combinatorial drug products such as drug eluting stents (DES), extractables and leachables, and other extended-release pharmaceutical products.

The technological advances that Agilent has incorporated into the 400-DS represent several milestones in the field of small-volume dissolution testing — bathless heating, custom holders for a variety of medical devices, integrated autosampling, media replacement and liquid handling capabilities are all built into the body of this small-footprint, easy-to-use dissolution apparatus.

21 CFR Part 11 compliant software and one PC can independently control up to four 400-DS systems.



The first compendial small-volume apparatus for testing medical devices

Using simplified testing options, the 400-DS is ideal for small amounts of slowly releases active pharmaceutical ingredients (API). The 400-DS meets all compendial requirements of USP Apparatus 7 and operates at significantly lower volumes of media than are common in this type of product testing.

The small volume of the 5 and 10 mL dissolution cells, with the ability to handle media volumes as low as 3 mL , provides significant gains in sample concentration for UV or LC analysis while virtually eliminating evaporation even when used with organic solvents. Media may be partially or completely replaced at each timepoint for each vessel using a built-in fluidics module. As many as four different media may be used during a single method.

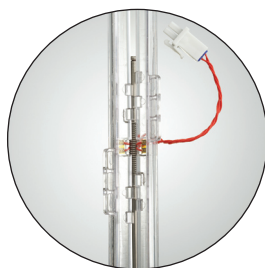
The 400-DS dissolution apparatus can simultaneously test up to 12 samples and a control or standard, while providing users direct visibility of each dissolution cell. Magnetically-coupled agitators provide the reciprocating motion from the exterior of the chamber.



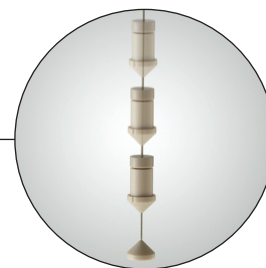
The Agilent 400-DS is an innovative, high-performance instrument for testing release rates of low levels of active pharmaceutical ingredient (API) from medical devices.

Product Highlights

The 400-DS is an integrated USP Dissolution Apparatus 7 with media replacement and autosampling functionalities built into the body of the apparatus.



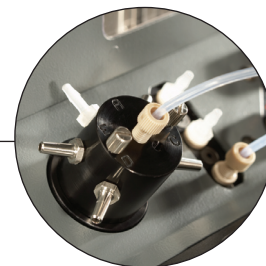
The heating jacket around the dissolution cell saves you time and maintenance; no water bath is required. Built-in temperature probes ensure reliable and accurate results.



A variety of custom reciprocating holders are available, allowing you the flexibility to test a range of combinatorial drug products.



Sampling ports at the base of the dissolution cell ensure reliable autosampling at the defined timepoints.



A multiport valve allows automated media replacement with up to four different media types.



The patent-pending magnetically-coupled agitators control holder reciprocation enabling between 1 and 35 dips per minute (DPM) to best match your requirements.



Our integrated autosampler saves bench space. It includes 13 individual racks containing either 2 or 4 mL HPLC sampling vials for up to 36 timepoints.

Media Replacement



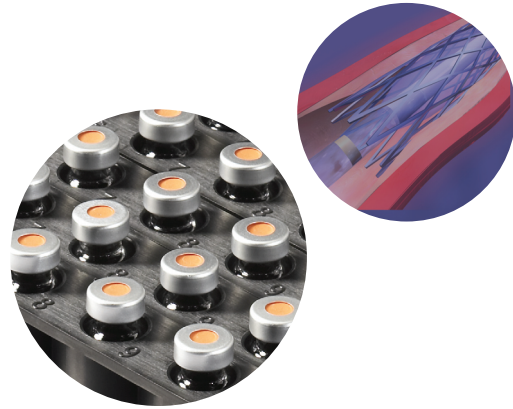
The integrated fluidics module of the 400-DS features a syringe pump system for reproducible sampling and supports automated partial or total media replacement capabilities.

Dissolution Cell Design

- A glass tube, open at both ends, is placed on top of the fluidics module.
- A heating jacket surrounds each tube (no water bath is required).
- The sample holder is inserted and the evaporation cover plate is placed in position on top of the dissolution cells.
- All sampling is done 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.



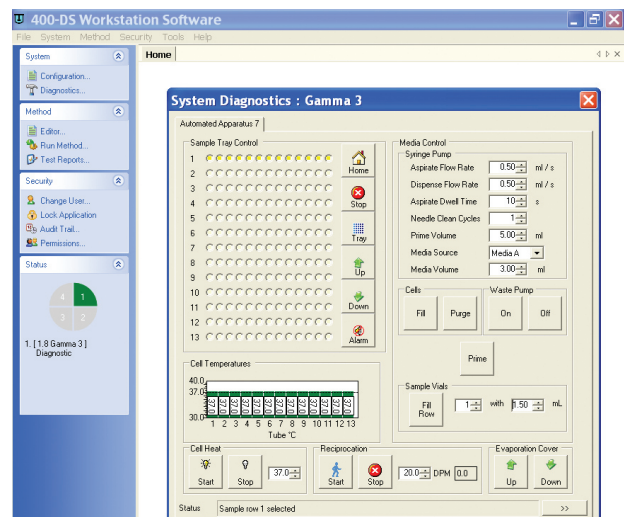
A set of 13 dissolution cells surrounded by heating jackets and situated on top of a sampling port provide a high level of automation, throughput and convenience.



400-DS Control Software

The 400-DS is controlled by Windows®-based PC software which is capable of storing the operating parameters and method data required for an electronic records, 21 CFR Part 11 environment.

A relational database is used for test result storage, archival and retrieval.



Additional system control functions include:

- Independent control of up to four dissolution apparatus
- Diagnostic utilities to verify system functionality
- Method data entry and the ability to store multiple methods
- System configuration and the facility to store multiple configurations
- Ability to execute any method on any system
- Live status feedback during the execution of a method
- Electronic signatures of collected test data
- Audit trail and user inactivity lockout
- Standard reporting capabilities with the ability to export data from dissolution runs

Agilent 400-DS Dissolution Apparatus 7

Agilent is known for developing state-of-the-art technology and exceptional products. With the 2010 addition of Varian Inc., we now offer an even greater range of instrumentation, as well as the most comprehensive columns and supplies portfolio in the market. Just as important are the best-in-class service and technical support teams with deep expertise focused on finding solutions for our customers.

Our customers are engaged in a broad range of endeavors, from performing routine tests to addressing complex scientific challenges that will impact the way we live. At Agilent, we understand that all scientists, regardless of their specific area of focus, share a common need for answers they can trust. This universal need is summed up in a word: Confidence.

Confidence means having tools that are precise, consistent, and utterly reliable. It means access to expert support to ensure that those tools run with optimal performance. Above all, this means knowing Agilent, now with the strength of the people and products from Varian, provides the technology—and the Measure of Confidence—you need to be successful.

For more information on the 400-DS please go to:
www.agilent.com/lifesciences/400-DS

This information is subject to change without notice.
© Agilent Technologies, Inc. 2011
Printed in U.S.A., July 25, 2011
5990-7387EN

The Measure of Confidence



Agilent Technologies