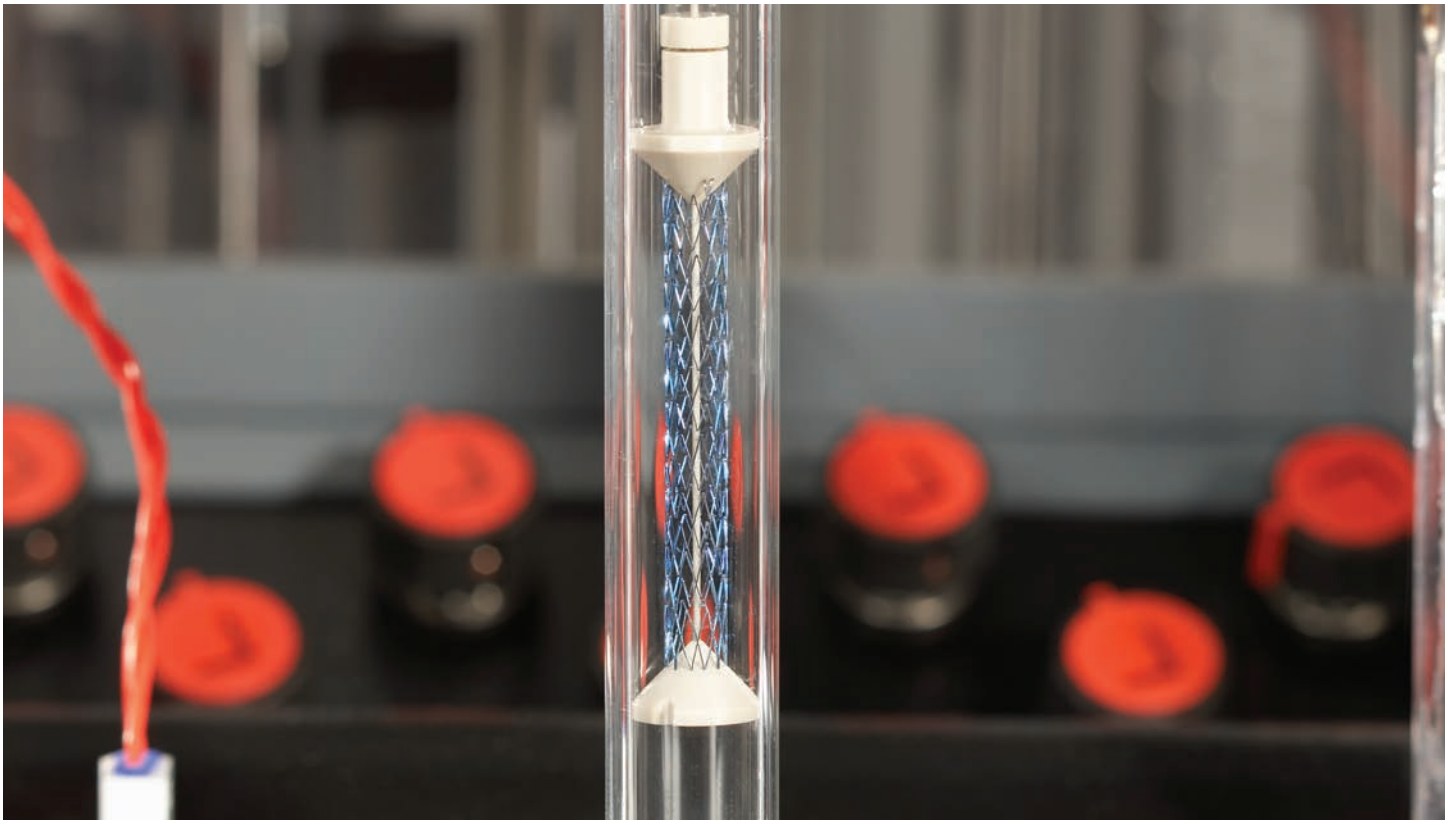
Agilent

Trusted Answers

Setting the Standard for Small-Volume Drug-Release Testing

Agilent 400-DS Apparatus 7



Bring Convenience, Throughput, and Efficiency to Your Quality Control and R&D Operations

The Agilent 400-DS Apparatus 7 reflects our commitment to innovative automation and integration. It's designed for small-volume dissolution testing of drug eluting stents (DES), as well as other novel dosage forms.

Several dissolution testing milestones are represented in the 400-DS. These advances include bathless heating, custom medical device holders, integrated autosampling, media replacement, and liquid handling. All are built into an easy-to-use dissolution apparatus with a small footprint.

What's more, you can independently control up to four 400-DS systems using 21 CFR Part 11 compliant software and one PC.

The First Compendial Small-Volume Apparatus for Testing Medical Devices

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

With virtually no evaporation, the 400-DS is suitable for dissolution tests lasting weeks, or even months. What's more, you can accelerate your workflow by running tests at up to 55 °C. You also have the choice between a 5 or 10 mL dissolution cell. With a 5 mL cell, as little as 3 mL may be used—providing significant gains in sample concentration for UV or LC analysis. This technique also virtually eliminates evaporation, even when used with some pure organic solvents.

In addition, media may be partially or completely replaced at each time point for each vessel using a built-in fluidics module. As many as five 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 giving 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 low-level release rates of APIs from medical devices.

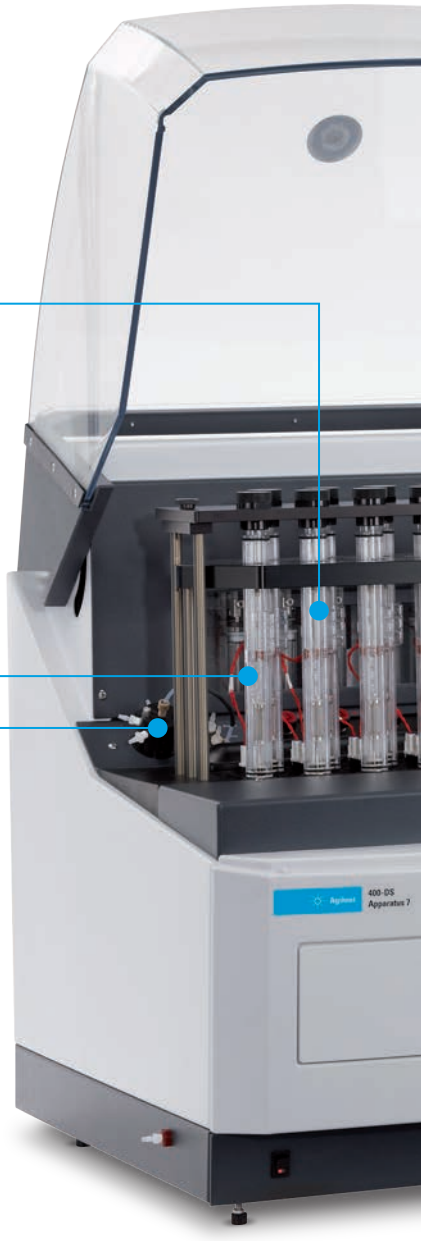
Streamline Your Small-Volume Dissolution Testing Workflow

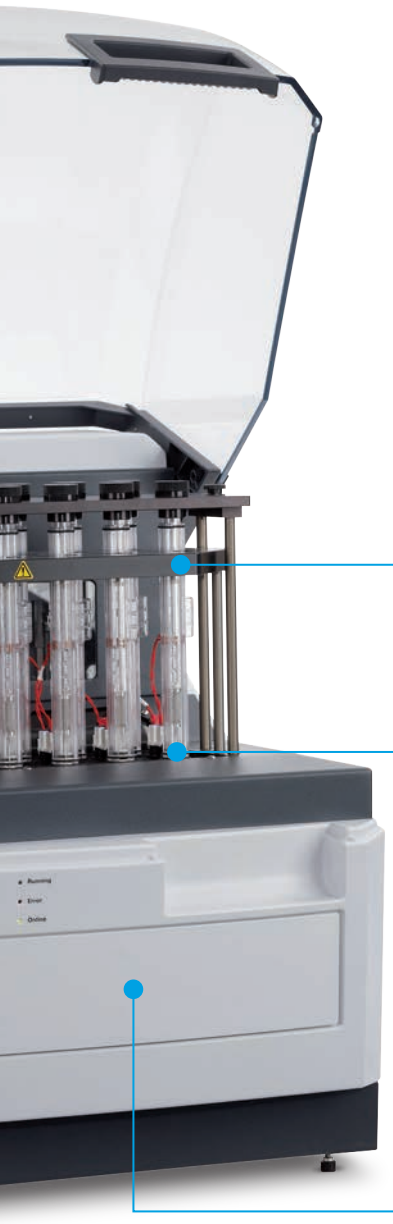
The 400-DS is an integrated USP Apparatus 7 with media replacement and autosampling functionalities built into its body.

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

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

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





Magnetically coupled agitators control holder reciprocation. They enable between 1 and 35 dips per minute (DPM) to best match your testing requirements.

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

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

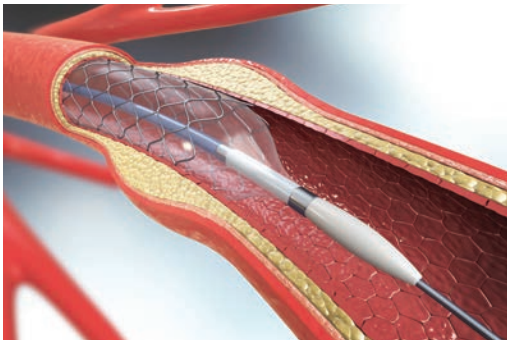
Media replacement

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.

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

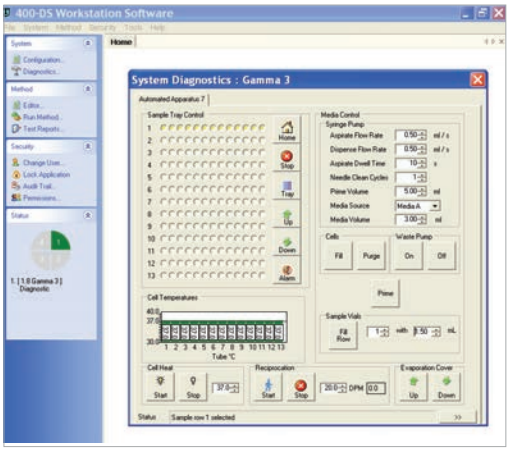
Dissolution cell design

- 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.



Control software

Windows-based PC software controls the 400-DS. The software can store the operating parameters and method data required for electronic records, 21 CFR Part 11 environment. A relational database is used for test result storage, archival, and retrieval.



Other 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 with the ability to export data from dissolution runs

Involved with dissolution testing?

Here's why you should join the Agilent Dissolution Community

Whether you own VanKel, Varian, Agilent, or another brand of dissolution apparatus, you can:

- Take advantage of product-specific content about apparatus, online analysis, and software.
- Review application notes, calculators, troubleshooting guides, and white papers available to community members.

Best of all, it's easy to join. Simply go to www.agilent.com, click "Resources," then "Agilent Community". The "Dissolution" section can be found here.

Learn more:
www.agilent.com/lifesciences/400-DS

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