

Flexible, Compliant, Compatible Dissolution

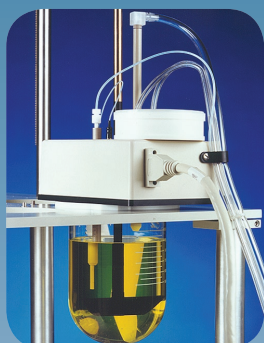
- ▶ The MultiDose G3 is a fully automated dissolution system compatible with standard accessories and compliant with FDA 21 CFR Part 11.

Fully Automated

- ▶ Combined with the versatile G3 controller - the MultiDose G3 gives you a highly compatible dissolution system that will enhance your laboratory's productivity.

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Automation Yields Results

Dissolution testing is a labor-intensive task. The MultiDose G3 creates an immediate increase in the testing capacity of your laboratory, providing users the opportunity to conduct other tests while the system is running.

- ▶ Link up to eight different basket or paddle methods with different requirements within each batch.
- ▶ MultiDose G3 savings in labor typically averages more than one full-time employee per system.
- ▶ Apply system tests to your standards and controls.
- ▶ Write methods, view results, create reports from your office.
- ▶ Compatible with Automation Certified filters.



MultiDose G3 for Method Developers

The tremendous flexibility of the MultiDose G3 software makes it the ideal tool for you to perform comparative studies for method development.

Independent vessel control allows you to vary parameters such as:

- ▶ Multiple dosage strengths
- ▶ Multiple media exchanges
- ▶ Multiple media volumes

Other features:

- ▶ Multiple component analysis (MCA)
- ▶ Background correction
- ▶ Export to Excel
- ▶ Optional long cannula for smaller volume dissolution (< 300 mL)

...and developed methods can be exported to systems in QA groups or shared from a central server.



MultiDose G3 for QA departments

Reliable, predictable throughput and ease of use, along with a strong service and support organization are some of the reasons many of the top pharmaceutical and generic manufacturing companies are among our customers.



Compliance

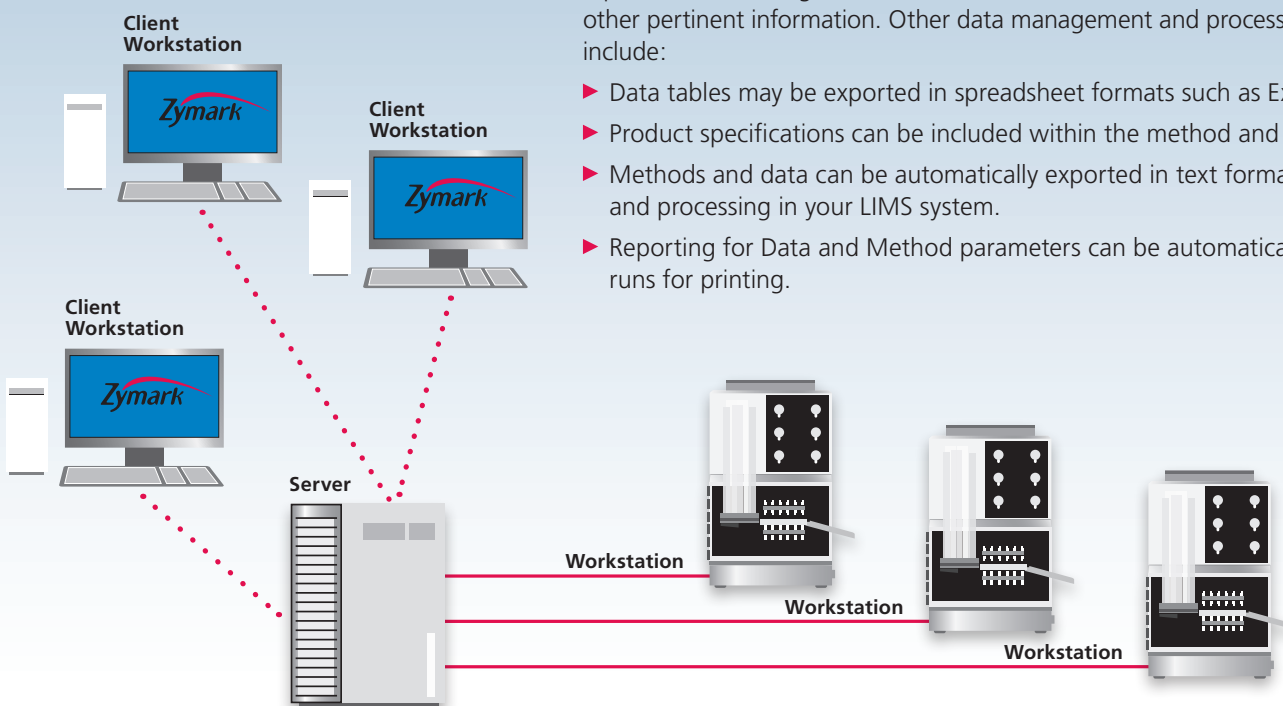
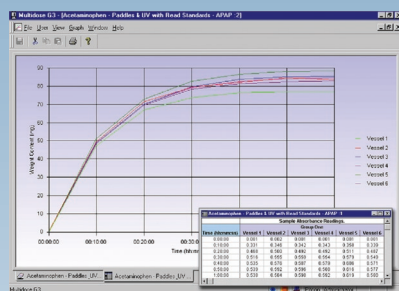
The flexible nature of the MultiDose G3 allows you to configure the system to meet your company's policies relative to 21 CFR Part 11. Utilizing encryption technology and individual access rights, its relational database assures the security of your information. It is also equipped with user configurable electronic signature capabilities. All of this is, of course, tracked by the MultiDose G3's searchable audit trail. Additional features include:

- ▶ Edited methods and post-edited data create new entries and do not overwrite original entries.
- ▶ Password settings such as expiry, password length, and log-on attempts can be configured to comply with your company.
- ▶ Access rights can be tailored for groups and individual users as well as subordinate administrators.
- ▶ Records for inactive users and groups are maintained by the software.

Data Processing and Management

The MultiDose G3 allows you to process and manage your data with greater speed and efficiency than ever before. You can process data from multiple components and analyze information from different vessels. Post run edits allow you to change parameters to recalculate results while maintaining the original record. Full spectral scans can be run with or without running dissolution analysis. The use of derivatives and multiple wavelength corrections are also possible. The software includes a single, centralized database that may be used by an unlimited number of workstations on a local area network. Network connections are fault correcting and divert data to the local workstation database in the event of a network failure. The query function makes it easy to find and retrieve methods, batches, data, and reports. Electronic signature status is indicated in the database along with other pertinent information. Other data management and processing features include:

- ▶ Data tables may be exported in spreadsheet formats such as Excel®.
- ▶ Product specifications can be included within the method and test data.
- ▶ Methods and data can be automatically exported in text format for storage and processing in your LIMS system.
- ▶ Reporting for Data and Method parameters can be automatically linked to runs for printing.



Easy as 1, 2 or 3

Selecting a system couldn't be easier. We offer 3 standard configurations to cover your dissolution needs:

- ▶ Collection
- ▶ Online UV
- ▶ Online UV + Collection

The development of custom configurations are also available upon request.



Specifications

Sample Capacity	Eight Independent and Unattended Dissolution Runs
Number of Media	1 Deionized Water and 1 Auxiliary Media (4 with Auxiliary Media Switching Valve)
Deionized Water Inlet	276 kPa (40 PSI) max, 1 L/min minimum flow rate
Vessel Wash	Hot Water, 552 kPa (80 PSI), 49°C (120°F) Max
Sparge Gas	Helium, 207 kPa (30 PSI) max
Vessel Fill Range	500 – 1000 mL
Vessel Fill Accuracy	Exceeds USP Specification
Media Tank Balance	+/- 1 g Accuracy
Bath	VK 7000
UV/VIS	Agilent 8453
Filtration	SOTAX and Zymark® certified Pall™ PSF filters and common brand 25 mm luer-lock filters
Sampling Flow Rate	5.0 mL/min to 12 mL/min
Fraction Collector	Zymark MultiFill
Fraction Collector Capacity	21 Fractions with 13 x 100 mm Test Tubes
	21 Fractions with 16 x 100 mm Test Tubes
	24 Fractions with 11 mm Vials
	24 Fractions with 4 mL WISP Vials
	All doubled with MultiFill Option
Operating System	PC that Supports Windows XP
Power	120 VAC at 10 Amps 220/240 VAC at 5 Amps
Baskets	USP standard
Wire Sinker	Magnetic sinkers required for automated retrieval.
Benchspace Requirement	83" Linear Array, 57" Non-linear Arrangement Plus Allowances for UV, MultiFill, Bath and other Accessories

Additional Benefits

- ▶ Sample frequencies can be run as fast as five minutes for conventional sampling and as fast as every two minutes for re-circulation.
- ▶ All vessels must meet temperature requirements specified by the method before runs are allowed to start.
- ▶ Media may be fully exchanged during the dissolution method.
- ▶ User defined sampling depth with different media volumes assures consistent sampling most closely matching manual testing approaches. Sampling depth is automatically determined based on vessel volume