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400-DS Dissolution Apparatus



The Varian 400-DS Dissolution Apparatus sets the performance standard for drug-release testing of medical devices. It is the first dissolution apparatus built specifically for small-volume dissolution testing of combination drug products that meets all compendial requirements for USP Apparatus VII. The 400-DS provides compliance with 21 CFR Part 11 guidelines and brings an unprecedented level of convenience, throughput and efficiency to your quality control and R&D operations.

To provide greater convenience and save valuable laboratory bench space, the autosampler is integrated into the body of this small footprint dissolution apparatus.

Parameter	Specification	Tolerance
Sample reciprocation	20.0 mm (stent movement)	± 1.0 mm
Dip rate	Range 5-35 DPM	0.5% of rate
Temperature control	Range ambient +5 up to 50 °C; ambient = 25 °C	± 0.2 °C or better
Media volume	3-5 mL (5 mL cell) or 8-12 mL (10 mL cell)	1% of volume
Sample volume	2 mL vial tray or 4 mL vial tray	1% of volume
Sample timepoint	Timepoint specified as HHH:MM:SS	± 2% of timepoint
Test duration	1 hour to 28 days	N/A
Number of samples per test	Up to 36 timepoints (tray change required after each set of 12 timepoints)	N/A
Input voltage	115/230 V AC; 50/60 Hz	N/A
Number of refill media types	4 types	
Evaporation	0.2% or better of volume in 24 hours	N/A
Dimensions	21 in. (w) x 23 in. (h) x 23.5 in. (d); 130 lb 53.34 cm x 58.42 cm x 59.69 cm; 58.967 kg	
Safety and CE testing standards	EN 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use; Part1: General Requirements (EN61010-1:2001) European Standard EN 61326-1 "Electrical equipment for measurement, control and laboratory use EMC requirements"; Part 1: General Requirements (EN 61326-1:1998), Class B; for both immunity and emission	

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Ordering Information

Item Description	Part Number
<i>Apparatus Includes 13 reciprocating holders, dissolution cells, and heater elements</i>	
400-DS Dissolution Apparatus, 5 mL dissolution cell, with PC, printer, software	33-0105
400-DS Dissolution Apparatus, 5 mL dissolution cell (additional units, without PC, printer, software)	33-0106
400-DS Dissolution Apparatus, 10 mL dissolution cell with PC, printer, software	33-0505
400-DS Dissolution Apparatus, 10 mL dissolution cell (additional units, without PC, printer, software)	33-0506
400-DS control software (required for each additional PC)	11-0035
Replacement Parts	
Reciprocating holder for drug-eluting stent, 5 mL	33-9009
Dissolution cell, 5 mL	33-9005
Heater element, 5 mL	33-9006
Reciprocating holder for drug-eluting stent, 10 mL	33-9012
Dissolution cell, 10 mL	33-9000
Heater element, 10 mL	33-9001
Consumable Products	
Glass vials, 2 mL, 12 x 32 mm, pre-crimped, pack of 100	33-9010
Sample row for vial tray, 4 mL, (single)	33-9002
Glass vials, 4 mL with PTFE/Silicon cap, 15 x 45 mm, pack of 100	17-5030
Extraction tool	33-9007
Sample row for vial tray, 2 mL, (single)	33-9013
Services and Documentation	
IQ Service, 400-DS	69-3102
OQ Service, 400-DS	69-3105
IQ OQ Service, 400-DS	69-3100
IQ Qualification Guide, 400-DS	76-3020
OQ Qualification Guide, 400-DS	76-3021
IQ OQ Qualification Guide, 400-DS	76-3017
Preventative Maintenance, 400-DS (1 per year)	75-4900
Preventative Maintenance, 400-DS (2 per year)	75-4910
Service Agreement, 400-DS	75-4920
Extended Warranty, 400-DS (1 year)	75-4925

Varian, Inc.
 www.varianinc.com
 North America: 800.926.3000, 925.939.2400
 Europe The Netherlands: 31.118.67.1000
 Asia Pacific Australia: 613.9560.7133
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