Varian, Inc.

Quality, Convenience, Support: Varian, Inc. Provides it all.

For more than half a century, Varian has been at the forefront of scientific instrument innovation. Through the acquisition of VanKel Technology Group in 2000, Varian is the world leader in dissolution instrumentation. Varian's continuous innovation and commitment to quality assures you the very best in dissolution testing products. Varian is the only dissolution manufacturer that is part of an analytical instrument company. As a result, you get truly integrated products.

Quality

Varian provides the highest quality dissolution products and accessories available on the market. Our products are subject to an exhaustive array of stability, performance, and reproducibility testing to ensure that the products you order years in the future will perform the same or better than the ones you use today. Our dissolution products are designed and manufactured in Cary, NC an ISO 9001:2000 facility. We take pride in the quality of our products and we take pride in your success with our products.

Convenience

Enjoy the benefits of one-stop shopping with Varian's impressive line of dissolution and physical testing products. Whether you prefer to catalog shop or browse online at www.varianinc.com, you will be impressed not only with our product line but with our superior customer service.

Support, Education, and More

We realize quality equipment is just one component of your work. Assisting you with technical support via our free hotline (see page 128) is just another way we support your efforts. LabCast, Varian's live video exchange, offers opportunities for you to explore the latest news in dissolution testing. Keep your personnel abreast of new practices with these live broadcasts...straight from our lab to yours! Find out more about this cutting edge resource on page 135.



▲ Analytical Instruments Products and Dissolution Testing Center, Cary, NC, US



▲Mass Spectrometry Center, Walnut Creek, CA, US



▲ Optical Spectroscopy and Analytical HPLC Center, Mulgrave, Victoria, Australia



▲Consumable Products Center, Lake Forest, CA, US



▲ Consumable Products and Gas Chromatography Center, Middelburg, The Netherlands

Providing state-of-the-art equipment is just part of what we offer. We believe education is critical to ensuring correct results. For this reason, we offer numerous educational programs geared to various functions within a pharmaceutical lab. From Fundamentals of Dissolution to Understanding IVIVC, we offer a wide range of educational opportunities for dissolution scientists. Our seminar series is specifically designed to provide the very latest in theory, techniques, and hands-on experience. These are true knowledge-based programs and are continually updated to meet changing regulatory guidelines. These seminars are offered in selected cities or can be taught at your facility. Read more about our educational programs on page 131.

The DDG Dissolution Discussion Group[®] is a FREE online and independent forum providing unparalleled opportunities for you to anonymously discuss important dissolution issues. Want to tap into the knowledge of your peers? Learn more on page 138.

Varian's postinstallation services is another way in which we offer more support to our customers. From preventive maintenance contracts to full chemical calibrations to extended warranty contracts, we are at your service! Need application support or qualification services? Let our dissolution experts help you every step of the way. See page 130 for more details.

For all your dissolution needs...Varian is at your service.

Dissolution Testing	1
VK 7025 V-Series Dissolution Apparatus	3
VK 7000/7010 Dissolution Apparatus	8
Varian 708-DS Dissolution Apparatus	15
Varian 705-DS Dissolution Apparatus	
Vessel Conversion Kits	19
Vessels & Accessories	21
Basket Shafts	
USP Apparatus 1 — Rotating Basket & Special Baskets	
USP Apparatus 2 — Paddle & Accessories	
Intrinsic Dissolution Apparatus	
USP Apparatus 6 — Rotating Cylinder	
USP Apparatus 5 — Paddle Over Disk	
QAII C & Verification Tools	
Varian HPLC Columns for Dissolution Testing	
VK 8000 Dissolution Sampling Station for Apparatus 1 & 2	
VK 808 Filter Changer	62
VK 8020 Sample Collector & HPLC Auto-Injector	
Dissolution Workstation Software	
On-line Analysis: UV and LC	
Cross-platform Integration	87
Extended Release Testing	
USP Apparatus 3 — Reciprocating Cylinder — BIO-DIS III	91
USP Apparatus 7 — Reciprocating Holder	
USP Apparatus 7 — Reciprocating Holder — Varian 400-DS	
Rotating Bottle Apparatus	
Automated Sample Processing	
VK 8020 Sample Collector & HPLC Auto-Injector	
VK 8000 Dissolution Sampling Station for Apparatus 3 & 7	
VK 808 Filter Changer	104
Disintegration Testing	
VK 100 Disintegration Apparatus	111
the stage of the s	
Hardness Testing	
VK 200 Hardness Tester	117
Friability Testing	120
Tapped Density Testing	122
Water Baths	124
Heaters & Circulators	
	120
Services	
Hotline	
Laboratory Services	
Educational Services	
Labcast	
Dissolution 1-on-1	137
DDG Dissolution Discussion Group	400
יייים ווסופרוס ווסופרוס ווסופרוס המח	139



To Place an Order

You can order more than 75,000 products on-line at www.varianinc.com - shop Varian, including many of the products in this catalog, 24 hours a day, 7 days a week, 52 weeks a year. You can shop at your convenience, save your shopping cart items for 6 months or until you delete them, and reorder from previously ordered carts. We hope you enjoy this convenient way to find and order products.

Please include the following information with all Phone, Fax and e-mail orders:

- Purchase order number
- Telephone, fax, and e-mail
- Shipping address

- Company name and contact person
- Billing address
- Item numbers, description, and quantities

In the U.S.:



🕋 Call toll-free 800.229.1108 between 8:00 a.m. and 5:00 p.m. Eastern time, Monday through Friday, except on business holidays



Fax orders to 919.677.1138, attn. Customer Service



E-mail orders to dissolution.sales@varianinc.com



Mail hardcopy orders to: Customer Service, Varian, Inc., 13000 Weston Parkway, Cary, NC 27513-2250 U.S.

Outside the U.S.:



For international calls: 919.677.1108

Contact Varian Customer Service or your local Varian representative to confirm pricing at the time the order is placed. Each order is subject to a \$50 minimum. Please note that prices are subject to change without notice.

Delivery

We attempt to keep standard accessory items in stock. If delivery is urgently required, please inform Customer Service at the time of your order.

Net 30 days with prior credit approval.

Returns

For all returns, please contact Varian Customer Service toll-free at 800.229.1108 (U.S.) or 919.677.1108 for shipping instructions and a return authorization number (RAN). Items returned for damage or defect will be credited upon receipt of merchandise and inspection. All other authorized returns are subject to a 15% restocking fee plus shipping and handling charges. All returned items must include a packing slip, contact person, as well as telephone and fax numbers. All items must be properly packaged to prevent damage during shipping.

Service and Warranty Information

Varian offers a one-year warranty on parts and a one-year warranty on labor (with some exclusions, see below). Varian will, at its option, either repair or replace any mechanical and electrical components in your instrument which prove to be defective. During the first year of warranty coverage, there will be no charge for the labor to repair your unit. Varian will determine the best site to repair the unit, either onsite or returned to Varian. Onsite warranty services are provided at the initial installation point. Installation and onsite warranty services are available only in Varian service travel areas.

Exclusions and Limitations

Excluded from this warranty are expendable or consumable items such as, but not limited to, paddles, baskets, vessels, and acrylic water baths. Heater/ circulators are warranted separately. Also excluded is damage from improper or inadequate maintenance by the customer, user-induced chemical action or contamination, unauthorized modification or misuse, and improper site preparation and maintenance.

Obtaining Warranty Service

To obtain warranty service in the U.S., contact our Service Department at 800.229.1108 or fax to 919.677.1138 to obtain authorization to return units for repair. To obtain warranty information outside the U.S., contact your authorized Varian representative. At the option of the customer, onsite warranty service is available, but travel charges may be incurred. The customer must prepay all shipping charges for products returned to Varian (unless otherwise authorized), and Varian will pay all charges for return to the customer.

Service

Note that all items sent in for service or calibration require the following:

- If not covered under warranty, the item must be secured with a purchase order number before service work is performed. Estimates for service are available upon request.
- Include a written request for service explaining problems with the instrument or calibration, serial number, a billing and shipping address, a contact person, and telephone and fax numbers with all items shipped to the attention of our Service Department.
- All items must be properly packaged to prevent damage during shipping. The customer is responsible for repackaging charges for return shipping if
 incoming packaging is deemed insufficient.
- Prior to shipping, contact Varian's Service Department at toll-free 800.229.1108 (U.S.) or 919.677.1108 to obtain shipping instructions and a return authorization number (RAN).

Varian's Commitment to Quality

Varian is proud of our commitment to quality. Of the quality standards after which companies can model their quality system, Varian complies with the most comprehensive standard, ISO 9001:2000. This standard is a model for use by both manufacturing and service organizations to certify their quality system from initial design and development of a desired product or service through production, installation, and servicing.





Dissolution Apparatus Overview

Dissolution Apparatus Overview

Varian manufactures United States Pharmacopeia (USP) dissolution apparatus 1, 2, 3, 5, 6, and 7. We also manufacture many unique accessories that are outside of USP specifications but solve many challenging release rate problems. Many of these items are displayed throughout this catalog. Please let us know how we can be of assistance with any of your specialized requirements.

USP APPARATUS 1: Rotating Basket

- Standard 40 mesh basket
- Other mesh size baskets are available
- Special baskets of various design and sizes are available
- Volume ranges from 100 mL to 4L
- A variety of vessel sizes are available
- See pages 3, 8 and 16 for Apparatus 1, and pages 30 33 for basket options

USP APPARATUS 2: Paddle

- Standard stainless steel paddle or Teflon-coated stainless steel paddle
- Dura-Tef (Teflon) and PEEK paddles are available
- Volume ranges from 100 mL to 4L
- A variety of vessel sizes are available
- See pages 3, 8 and 16 for Apparatus 2, and pages 34 36 for paddle options

USP APPARATUS 3: Reciprocating Cylinder

- Sequential operation for pH profiling
- Volume ranges from 100 mL to 1L
- 300 mL outer media tubes are standard
- See page 90 for Apparatus 3

USP APPARATUS 5: Paddle Over Disk

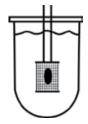
- Standard stainless steel paddle with stainless steel screens
- Used for transdermal patches in a standard for round-bottom vessel
- Accessories are used with the Varian 705-DS[™], VK 7000, VK 7010, VK 7025 and 708-DS
- Volume 900 mL
- A variety of screen sizes are available. Custom screen sizes can be manufactured.
- See pages 3, 8 and 16 for Apparatus 5, and page 44 for Apparatus 5 accessories

USP APPARATUS 6: Rotating Cylinder

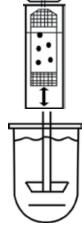
- Two-piece assembly for testing transdermal patches using a standard dissolution instrument
- Accessories are used with the Varian 705-DS[™], VK 7000, VK 7010, VK 7025 and 708-DS
- Volume 900 mL
- See pages 3, 8 and 16 for Apparatus 6, and page 43 for Apparatus 6 accessories

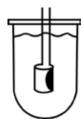
USP APPARATUS 7: Reciprocating Holder

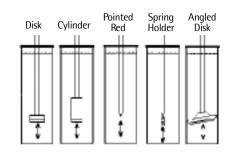
- · Utilizes sequential operation and a variety of dosage holders
- Volume ranges from 20 to 275 mL
- Useful for transdermal patches and osmotic pump delivery systems as well as other nondisintegrating dosage forms
- Modified version for small volumes (such as stents) are available
- See pages 94-95 for Apparatus 7













Interchangeable Paddle/Basket Shaft System

All Varian dissolution apparatus come standard with Interchangeable Paddle/Basket Shaft Systems. The system allows the operator to switch between paddles and basket shafts without height readjustment. The system is a two-piece assembly engineered to easily set the shaft length to maintain consistent clearance from the bottom of the vessel. Carryover concerns, typically associated with two-part shafts, are eliminated in the Varian design by having the junction above the liquid level. So when switching between paddle and basket methods, no height readjustments are required.



Interchangeable Paddle/Basket Shaft System

V-Series Dissolution Apparatus

VK 7025 Standard Features

- Innovative V-shaped design offers a direct frontal view of the six sample vessels
- Optional control of individual spindles is ideal for automated methods
- Standard Dosage Delivery Module (DDM) can be programmed for simultaneous or sequential dosage delivery
- Standard AutoTemp in-vessel temperature monitoring system automatically measures and records individual vessel
- temperatures
- Motorized drive for easy automation
- TruCenter vessels simplify vessel centering
- Removable vessel plate for easy cleaning
- Low-profile design reduces the overhead clearance required
- Apparatus 1, 2, 5, 6 and Intrinsic

The V-Series utilizes a high throughput, low vibration circulator. The circulator is designed to fit behind the water bath, saving valuable space Truly an industry revolution, these apparatus offer enhanced performance unlike any other-the design substantially minimizes external influences so the resulting release rate is a function of the dosage form.

A Clear Choice

A difference you can see! The innovative V-Series is an excellent example of the products we create to address the critical challenges faced by dissolution scientists. Featuring a unique V-shape, this sophisticated series of apparatus offers enhanced visibility allowing you to see the six sample vessels at all times from the front of the apparatus while taking up minimal bench space.

Easy Cleaning

Cleaning the water bath has never been easier. The VK 7025 models feature a unique, removable vessel support plate and a built-in drain hose that greatly simplify cleaning the water bath. With the enhanced design and state-ofthe-art technology of the V-Series, you'll never look at dissolution the same way again.

Dosage Delivery Module

The VK 7025 retains many of the features Varian built into other instruments for ease-of-use. Standard on these units, the Dosage Delivery Module (DDM) can be programmed to automatically deliver dosages into vessels (simultaneously or sequentially) with instant or delayed starts. This feature replaces the need for manual dropping, saving analysts' time by allowing for unattended test starts. Also standard on these units is the AutoTemp in-vessel temperature monitoring system that automatically measures and records individual vessel temperatures.

Individually Driven Cannulas

Perform staggered drops (with the DDM feature) and sequential sampling, with individually driven cannulas, without disturbing vessel hydrodynamics or causing the negative effect associated with resident dwelling probes. Cannulas are individually controllable to ensure accurate sampling position based on the specified volume of media used. This feature is ideal for use with the VK 8000 or other automated online systems.

Motorized Drive Unit

Varian pioneered the use of a motorized drive unit. With the touch of a button, the motorized drive unit on the VK 7025 lowers to the proper position with no sudden shocks to the system. When the drive unit is down, a touch of a button automatically raises the drive unit. The motorized drive unit ensures smooth operation and facilitates use in an automated system. Once raised, the drive unit can be moved back for unobstructed access to the vessels.

Spindle Assembly

This system offers the flexibility of using basket shafts, mini paddles, and baskets for low-volume dissolution testing

Our spindle assembly utilizes several O-rings to secure the shaft. We utilize a locking collar to set the height. Shafts can easily be raised through the spindle assembly during changeover. We also offer two-piece interchangeable shaft assemblies for even easier changeover between basket and paddle assemblies.

O-ring Assembly

Our unique O-ring design assures the shaft is held in the precise location. Once the height is set and locked in place with the use of a locking ring, there is no need to worry about a change in alignment. Raising the paddle or basket is easily done by sliding the shaft upwards. For staggered starts, simply pull the shaft up so it is no longer in the media.

> Would you like to see the V-Series Dissolution Apparatus in action? Request an electronic product profile CD for an interactive demonstration of the V-Series' unique capabilities.



V-Series Dissolution Apparatus

TruCenter™ Vessels

All dissolution vessels have inconsistencies in the glass thickness. Consequently, centering from the outside of the vessel is time consuming and requires verification. Varian's innovative TruCenter design has eliminated these problems by aligning from the internal vessel diameter. There is a Delrin flange or centering collar attached to the ground ring around the outside of the vessel wall.

The vessel is precisely aligned and locked in place by magnets imbedded in the vessel support plate and vessel centering collar. The precision machined flange assures the vessel sits flat and parallel to the axis of the shaft and reduces the chance of breakage.



TruCenter vessels - perfect centering every time, The unique Delrin flange helps prevent vessels from chipping. Open design makes vessel removal and replacement easy!

Display Information

The V-Series has a large front panel display that offers two character sizes: standard for programming and larger for across-the-room visibility during instrument operation. These models feature large buttons on the alphanumeric keypad and a display that is easy to read when the drive unit is in the up or down position. The display shows full information on spindle speed, elapsed time, temperature, and more.

Built-in Alarms

The V-Series has a variety of built-in alarm features. You are warned of any temperature deviations from the set parameters, power outages as well as the upcoming calibration date.

Parameter Programming

A simple menu allows you to easily program your parameters including:

- Delayed start
- RPM (10 250 RPM)
- Length of test
- Temperature
- Infinity spin

Timed Wake-up (VK 7025 only)

This unique feature automatically turns on the dissolution apparatus and heater/circulator at a predetermined time. This ensures your water bath is at the proper temperature when ready to begin testing without operating the heater/circulator continuously.

Spindle Motor Monitor

These apparatus report the number of spindle motor hours that the instrument has been in use. This on-screen record allows you to schedule preventive maintenance on actual operating hours rather than arbitrary time periods.

Printer

Our built-in dot matrix printers produce documents that can be directly inserted into your laboratory notebooks documenting time of day, start and stopping times, elapsed time, RPM, and water bath temperatures. Every V-Series unit includes a built-in Report Center II Printer.

VK 7025C

The VK 7025C instruments are identical to the VK 7025, but they incorporate AutoSpindle Control (ASC). See the following page for a complete description of ASC.

V-Series Dissolution Apparatus

AutoSpindle Control

Two models of the V-Series apparatus feature AutoSpindle Control (ASC). ASC allows each spindle to be operated independently via electronic control. This is important because of USP recommendations that dissolution media is nonrotating when dosage forms are delivered into the vessel. The USP requires that the dosage form drop to the bottom of the vessel before rotation begins. This feature is most useful in automated systems that can take advantage of ASC and the dosage delivery capabilities of the VK 7025 and VK 7030. The systems include the Varian UV Dissolution System as well as the Agilent UV System. The Varian V-Series dissolution apparatus with the ASC option makes it possible to meet USP standards by controlling each spindle individually. Rotation of each paddle begins only after the dosage form for that particular vessel is introduced, thus making automated staggered starts possible. In addition, V-Series apparatus incorporate individually controlled sampling cannula so that the unit can be programmed to lower all sampling cannulas simultaneously or sequentially.

Molded Water Bath

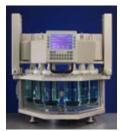
This seamless water bath was designed to warm all vessels evenly by stabilizing the temperature gradient. This design assures uniform temperature control and makes cleaning easy. The seamless water bath is molded from clear PETG, a high-performance polymer with more heat and chemical stability than acrylic. The clear water bath allows you to see the vessels through the water bath. To ensure the water bath contains the appropriate amount of liquid, there is a fill line for baths with or without vessels in place. The easy access water bath drain spout allows for quick and simple routine cleaning.



V-Series System Configurations

VK 7025

• Apparatus 1, 2, 5, 6 and Intrinsic







VK 7025 with Drive Unit Up



VK 7025 with Drive Unit

VK 7025

Dimensions and Weight						
Size:	Height		Width		Depth	30 in.
		68.58 cm		67.31. cm		76.2 cm
Weight:	185 lb/	83.9 kg				

VK 7025

Instruments are shipped with standard features including AutoSampling, AutoTemp, and built-in Report Center II Printer.

Item Description	Part Number
VK 7025 6-position, 115V	11-6004
VK 7025 6-position, 230V	11-6005
VK 7025 6-position, clutch, 115V	11-6006
VK 7025 6-position, clutch, 230V	11-6007
VK 7025 8-position, 115V	11-7004
VK 7025 8-position, 230V	11-7005
VK 7025 8-position, clutch, 115V	11-7006
VK 7025 8-position, clutch, 230V	11-7007

VK 7025 Accessory Kits

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 6 or 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

Item Description	Part Number
Accessory kit, 6-position, Teflon paddle	1001-1027
Accessory kit, 6-position, stainless steel paddle	1001-1028
Accessory kit, 6-position, stainless steel basket, standard clip	1001-1029
Accessory kit, 6-position, stainless steel basket, 0-ring	1001-1030
Accessory kit, 8-position, Teflon paddle	1001-1122
Accessory kit, 8-position, stainless steel paddle	1001-1123
Accessory kit, 8-position, stainless steel basket, standard clip	1001-1124
Accessory kit, 8-position, stainless steel basket, O-ring	1001-1125

VK 7030 Accessory Kits

Contact your Varian representative for questions about the VK 7030 and 7030C Dissoluton Apparatus.

Conversion Kit Accessories for VK 7030

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

ItemDescription	Part Number
Accessory kit, Teflon paddle	1001-1031
Accessory kit, stainless steel paddle	1001-1032
Accessory kit, stainless steel basket, standard clip	1001-1033
Accessory kit, stainless steel basket, O-ring	1001-1034

Conversion Kit for VK 7025

Item Description	Part Number	
Conversion Kit for VK 7025, 200 mL	12-0314	

Conversion Kit Accessories for V-Series

The following items are for use with either the 100 mL Conversion Kit or the 200 mL Conversion Kit unless otherwise indicated.

Item Description	Part Number
Vessel for V-Series, 200 mL, adapter included	12-5034
Vessel for V-Series, 200 mL, adapter not included	12-5033

If you intend to automate your VK 7025 with an on-line UV system, and it is important to keep your standard solution under the same conditions as your sample, then select one of the following accessories to add to your order:

Item Description	Part Number
Conversion kit for 100 mL, VK 7025, per vessel location	12-0315
Conversion kit for 200 mL, VK 7025, per vessel location	12-0314

^{*} The conversion kit includes: one vessel (100 mL or 200 mL, as appropriate), one mini paddle, one paddle locking ring, one centering ring, and one evaporation cover with mounted AutoTemp and cannula.

Cannula Accessories for V-Series

Item Description	Part Number
Sampling Cannula for V-Series	17-3313
Return Cannula for V-Series	17-3314
Manual Sampling Cannula for Sampling through the drive unit	17-3315
Bushing for Manual Sampling Cannula (replacement)	12-0316
Cleaning Reservoir, includes 8 reservoirs for cleaning sampling lines	12-1320
Cleaning Reservoir with Cover	17-1321
Protective Drip Tray for V-Series	17-1330

Apparatus Accessories for V-Series

Apparatus Accessories for V-Series	
Item Description	Part Number
Paddle, Teflon-coated, for V-Series	12-1005
Paddle, Teflon-coated, for V-Series with certificate	12-1005V
Paddle, electropolished, for V-Series	12-1035
Paddle, electropolished, for V-Series with certificate	12-1035V
Paddle, PEEK, for V-Series	12-1205
Paddle, 200 mL, Teflon-coated, for V-Series	12-1228
Paddle, 200 mL, Teflon-coated, for V-Series with certificate	12-1228V
Paddle, 200 mL, electropolished, for V-Series	12-1229
Basket Drive Shaft, USP, Teflon-coated, for V-Series	12-2041
Basket Drive Shaft, USP, Teflon-coated, for V-Series with certificate	12-2041V
Basket Drive Shaft, Conical, Teflon-coated, for V-Series	12-2042
Basket Drive Shaft, DuraFit, Teflon-coated, for V-Series	12-2043
Basket Drive Shaft, DuraFit, Conical, Teflon-coated, for V-Series	12-2044
DuraFit Basket Shaft for V-Series	12-2045
Basket Drive Shaft, DuraFit, Conical, for V-Series	12-2053
Basket Drive Shaft for Mini Basket, DuraFit for V-Series (shaft only)	12-2079
Wood Intrinsic Dissolution Apparatus for V-Series (for VK 7025 only)	12-4105
Shaft Locking Ring for V-Series	12-2096

Vessels for V-Series

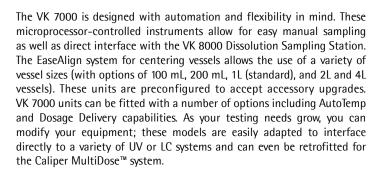
Item Description	Part Number
Vessel, TruCenter, USP, 1000 mL, collar included	12-5035
Vessel, TruCenter, USP, 1000 mL, collar included, verified	12-5035V
Vessel, TruCenter, USP, 500 mL, collar included	12-5037
Vessel, TruCenter, 1000 mL, collar included, amber	12-5120
Vessel, TruCenter, 1000 mL, collar included, peak	12-5125
Vessel, TruCenter, 1000 mL, collar included, amber, peak	12-5130
Vessel, TruCenter, 1000 mL, collar included, Teflon-coated	12-5140
Vessel, TruCenter DVH (for VK 7030) with ground groove, USP, 1000 mL	12-5039
Cover for Vessel Opening for V-Series	12-6358



VK 7000/7010 Dissolution Apparatus

VK 7000/7010 **Standard Features**

- Motorized drive unit for easy automation
- Unique time-saving features including automatic start, EaseAlign centering rings, and individual clutch control
- Large volume conversion option accommodates 1L, 2L, and 4L vessels meeting all USP, JP, and EP requirements
- Small volume conversion kits accommodate 100 VK 7000 Dissolution mL and 200 mL vessels meeting all USP, JP, and EP Apparatus requirements
- Apparatus 1, 2, 5, 6 and Intrinsic



Motorized Drive Unit

Varian pioneered the use of a motorized drive unit. With the touch of a button, the motorized drive unit on the VK 7000/7010 lowers to the proper position with no sudden shocks to the system. When the drive unit is down, a touch of a button automatically raises the drive unit. The motorized drive ensures smooth operation and facilitates use in an automated system.

Spindle Assembly

This system offers the flexibility of using basket shafts, mini paddles, and baskets for low-volume dissolution testing.

Our spindle assembly utilizes several O-rings to secure the shaft. Once the height is set and locked in place with the use of a locking ring, there is no need to worry about a change in alignment. Raising the paddle or basket is easily done by sliding the shaft upwards. For staggered starts, simply pull the shaft up so it is no longer in the media. We also offer two-piece interchangeable shaft assemblies for even easier changeover between basket and paddle assemblies.



EaseAlign Centering Rings

The patented EaseAlign rings center and align vessels accurately by using the inside diameter of the vessel. Inconsistencies inherent in glass wall thickness make attempting to align vessels by the outside diameter less accurate. EaseAlign centering rings allow simple, accurate vessel alignment.

Display Information

The 4-line, 40-character LCD operational monitor allows for a simple, easy-



to-read display. During operation the display includes time, date, elapsed time, start time, set and actual RPM, set and actual water bath temperature, and printer status.

Built-in Alarms

The VK 7000/7010 has a variety of built-in alarm features. You are warned of any temperature deviations from the set parameters and power outages as well as an upcoming calibration date.

Parameter Programming

A simple menu allows you to easily program your parameters including:

- Delayed start
- RPM (10 250 RPM)
- Length of test
- Temperature
- Infinity spin

Timed Wake-up

This unique feature automatically turns on the dissolution apparatus and heater/circulator at a predetermined time. This ensures your water bath is at the proper temperature when ready to begin testing without operating the heater/circulator continuously.

Spindle Motor Monitor

These apparatus report the number of spindle motor hours that the instrument has been in use. This on-screen record allows you to schedule preventive maintenance on actual operating hours rather than arbitrary time periods.

Printer

Our built-in dot matrix printers produce documents that can be directly inserted into your laboratory notebooks documenting time of day, start and stopping times, elapsed time, RPM, and water bath temperatures. Every VK 7000/7010 includes a built-in Report Center II Printer.

Molded Water Bath

This seamless water bath was designed to warm all vessels evenly by stabilizing the temperature gradient. This design assures uniform temperature control and makes cleaning easy.

The water bath is molded from clear PETG, a high-performance polymer with more heat and chemical stability than acrylic. Because the water bath is seamless, cleaning is easy. The clear water bath also allows you to see the vessels.

To ensure the water bath contains the appropriate amount of liquid, there is a fill line for water baths with or without vessels in place.

Easy Drain

The easy access water bath drain spout allows for quick and simple routine cleaning.

Standard Features for the VK 7010/ Optional Features for the VK 7000

This cost-effective dissolution apparatus will not restrict future productivity enhancements. With the appropriate accessories and options it can be upgraded to an online UV, LC, or fully automated system.

The following options are standard on the VK 7010:

- Dosage Delivery Module (DDM)—The DDM can be programmed to drop tablets into nonrotating media simultaneously when using paddles. Sequential starts can also be programmed but require that you manually lower the shafts should you wish to drop the tablets into nonrotating media.
- AutoTemp In-vessel Temperature Sensing System—AutoTemp measures and records in-vessel temperature at designated timepoints. It can also be used to initiate a run when the vessel temperatures have stabilized. See page 42 for details.
- Motorized Sampling Manifold—There are two methods for pulling samples using the motorized Sampling Manifold. The manual sampling bracket in conjunction with the motorized manifold facilitates the raising and lowering of the sampling cannula to ensure the correct USP sampling location. The automatic sampling manifold used in conjunction with the VK 8000 and other online systems allows the entire sampling process to be performed automatically. At programmed intervals or by manual control, the motorized sampling manifold lowers to provide properly timed and precisely positioned sampling. The USP recommends caution when using a resident dwelling probe which may create hydrodynamic disturbance. The resident probe effect has been shown to cause up to a 5% difference in dissolution results for certain products. Contact your Varian representative for Application Notes on this subject.
- DDM, AutoTemp and the Motorized Sampling Manifold can all be easily added to a VK 7000.

Complete System, No After Purchase Add-ons

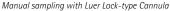
When you purchase a Varian dissolution apparatus, Varian provides you with an all-inclusive price quote. This quote includes the price of all equipment necessary to properly operate the instrument. You receive your choice of baskets or paddles, glass or plastic vessels, as well as evaporation covers and all tubing and connectors.

Manual Sampling or Automated Systems

When sampling manually, the VK 7000/7010 can be used with longer shafts and additional spacers. This allows more working room between the base plate and the drive unit for easy access to all vessels.

When used in an automated fashion, shorter shafts are used and the drive unit is closer to the vessel plate. We also offer the ability to pull samples manually using the motorized drive. Simply lower the sampling manifold and pull samples from the sampling bracket. See page 42 for details.







Motorized Sampling Manifold

VK 7000, 1L, 6- or 8-position



This model provides "easy access" to the active vessels. All active spindle locations are on the front and sides of the table, facilitating manual sample collection.

VK 7000

VK 7000, 6- or 8-position

Dimensions and Weight						
Size:	Height	37 in.	Width	26 in.	Depth	22 in.
		94 cm		66 cm		56 cm
Weight:	155 lb/:	70.3 kg				

VK 7000

Item Description	Part Number
VK 7000, 1L, 6-position, 115V	10-1200E
VK 7000, 1L, 6-position, 230V	10-1300E
VK 7000, 1L, 8-position, 115V	10-1600E
VK 7000, 1L, 8-position, 230V	10-1700E

VK 7000, 1L Accessory Kits

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 6 or 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

Item Description	Part Number
Accessory kit, 1L, 6-position, stainless steel, 21 in. paddle	1001-1001
Accessory kit, 1L, 6-position, Teflon, 21 in. paddle	1001-1002
Accessory kit, 1L, 6-position, stainless steel basket, standard clip, 21 in. shaft	1001-1003
Accessory kit, 1L, 6-position, stainless steel basket, 0-ring, 21 in. shaft	1001-1004
Accessory kit, 1L, 8-position, stainless steel, 21 in. paddle	1001-1102
Accessory kit, 1L, 8-position, Teflon, 21 in. paddle	1001-1103
Accessory kit, 1L, 8-position, stainless steel basket, standard clip, 21 in. shaft	1001-1104
Accessory kit, 1L, 8-position, stainless steel basket, 0-ring, 21 in. shaft	1001-1105

VK 7000 Configurations

VK 7000, 2L, 6- or 8-position

VK 7000 2L models are available in both 6 -and 8-positions. The base plate layout is the same as the 1L units. This unit is equipped with a deeper water bath positioned under an elevated vessel table. The VK 7000 2L system can be used with conventional 1L vessels or 2L vessels for maximum flexibility.



VK 7000 2L

VK 7000, 2L, 6- or 8-position

Dimensions and Weight						
Size:	Height		Width		Depth	22 in.
		117 cm		66 cm		56 cm

VK 7000 Equipped With A 2L Water Bath

Item Description	Part Number
VK 7000, 2L, 6-position, 115V	10-1800E
VK 7000, 2L, 6-position, 230V	10-1900E
VK 7000, 2L, 8-position, 115V	10-1920E
VK 7000, 2L, 8-position, 230V	10-1930E

VK 7000, 2L Accessory Kits

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 6 or 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

Item Description	Part Number
Accessory kit, 2L, 6-position, stainless steel, 24 in. paddle	1001-1009
Accessory kit, 2L, 6-position, Teflon, 24 in. paddle	1001-1010
Accessory kit, 2L, 6-position, stainless steel basket, standard clip, 24 in. shaft	1001-1011
Accessory kit, 2L, 6-position, stainless steel basket, 0-ring, 24 in. shaft	1001-1012
Accessory kit, 2L, 8-position, stainless steel, 24 in. paddle	1001-1110
Accessory kit, 2L, 8-position, Teflon, 24 in. paddle	1001-1111
Accessory kit, 2L, 8-position, stainless steel basket, standard clip, 24 in. shaft	1001-1112
Accessory kit, 2L, 8-position, stainless steel basket, 0-ring, 24 in. shaft	1001-1113

Do you know "sink conditions" is defined as maintaining a volume of dissolution media that is at least three times greater than the volume at the saturation point of the drug?



VK 7000 Small Volume Apparatus

VK 7000 Small Volume Apparatus

- Use with mini paddles and mini baskets
- Designed for use with the Enhancer Cell™ for topicals, creams, and ointments
- Requires few accessories to operate
- Not offered in a CE-approved version

This specially configured VK 7000 accepts 12 vessels (either 100 or 200 mL) along with Varian's mini paddle or mini basket shafts. You get all the same programming features of the VK 7000.

Although designed for use with Enhancer Cells, this system is also used when special, smaller volumes are required. Flat- or round-bottom vessels are available. Additionally, both mini paddles and mini baskets are designed for this system. See page 45 for more information on the Enhancer Cell.

Drug Release Testing for Topical Treatments

The VK 7000 small volume system solves the dissolution testing dilemma associated with creams, ointments, or other topical treatments. This systems uses the tested Paddle over Enhancer Cell Apparatus.

Simplified Enhancer Cell Centering

Our specially designed 200 mL flat-bottom, self-aligning glass vessels perfectly align your Enhancer Cell in the vessel. Consistent placement of the Enhancer Cell provides you with reliable and reproducible results.

Run Multiple Lots Simultaneously

The 12-spindle, 12-position configuration allows you to operate two 6-sample tests simultaneously. Each test is conducted under the same method, instrumentation, and physical environment.

Can Also be Used with Mini Baskets

A specially designed mini basket fits on a DuraFit basket shaft. See page 32 for more information.

Easy-to-Automate Sampling

This system connects easily to the 12-position VK 8000 Dissolution Sampling Station (see page 54).



Vessel, Mini Paddle, and Enhancer Cell



Mini Basket and DuraFit Basket Shaft



Dissolution Calculation Spreadsheets and Formulas in Excel Format

- The Single Point Dissolution Calculation Spreadsheet calculates milligrams dissolved and percent dissolved per dose for dissolution tests with a single timepoint.
- The Replacement Media Dissolution Calculation Spreadsheet calculates milligrams dissolved and percent dissolved per dose and corrects for analyte removed for up to 12 timepoints.
- The Nonreplacement Media Dissolution Calculation Spreadsheet calculates milligrams dissolved and percent dissolved per dose correcting for nonreplacement media and analyte removed at up to 12 timepoints.

Use these spreadsheets to quickly and easily perform calculations and reduce mathematical errors in your analysis. As with any outside program, you should validate this spreadsheet prior to implementing at your facility.

Yours free – just visit our Web site at www.varianinc.com, go to the Dissolution section, and click on Laboratory Services.

VK 7010 Configurations

VK 7010 System Configurations



VK 7010

The VK 7010 model is an enhanced version of the VK 7000. The two additional standard features of the VK 7010 are:

- The motorized manifold equipped with AutoTemp and sampling cannulas
- The Dosage Delivery Module (DDM) to automatically drop tablets at the precise time (this feature is especially useful for simultaneous or sequential dropping of tablets when running the system as Apparatus 2)

Each configuration includes your choice of glass or plastic vessels and paddles or baskets and basket shafts. EaseAlign centering rings and evaporation covers are included. Control of the high throughput heater/circulator is integrated into the VK 7010.

VK 7010, 1L

Dimensions and Weight						
Size:	Height	37 in. 94 cm	Width	26 in. 66 cm	Depth	22 in. 56 cm
Weight:	155 lb/7	0.3 kg				

VK 7010, 1L

Item Description	Part Number
VK 7010, 1L, 6-position, 115V	10-0300E
VK 7010, 1L, 6-position, 230V	10-0400E
VK 7010, 1L, 8-position, 115V	10-0700E
VK 7010, 1L, 8-position, 230V	10-0800E

VK 7010, 1L Accessory Kits

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 6 or 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

Item Description	Part Number
Accessory kit, 1L, 6-position, stainless steel, 21 in. paddle	1001-1005
Accessory kit, 1L, 6-position, Teflon, 21 in. paddle	1001-1006
Accessory kit, 1L, 6-position, stainless steel basket, standard clip, 21 in. shaft	1001-1007
Accessory kit, 1L, 6-position, stainless steel basket, 0-ring, 21 in. shaft	1001-1008
Accessory kit, 1L, 8-position, stainless steel, 21 in. paddle	1001-1106
Accessory kit, 1L, 8-position, Teflon, 21 in. paddle	1001-1107
Accessory kit, 1L, 8-position, stainless steel basket, standard clip, 21 in. shaft	1001-1108
Accessory kit, 1L, 8-position, stainless steel basket, 0-ring, 21 in. shaft	1001-1109



VK 7010 Configurations/Accessories

VK 7010, 8-position, 2L

The VK 7010 2L model is configured the same as the 1L units except with a deeper water bath positioned under an elevated base plate. The VK 7010 2L system can be used with conventional 1L vessels or 2L vessels for maximum flexibility.

System includes:

- 2L vessels
- 19-inch paddles or rotating baskets and shafts

This unit is intended to be used as a 2L system. 1L vessels are provided for USP calibration only. The AutoTemp manifold is designed to monitor the temperature in 2L vessels only.

VK 7010, 2L

Dimensions and Weight						
Size:	Height	46.06 in. 117 cm	Width	25.98 in. 66 cm	Depth	22.05 in. 56 cm
Weight	160 lb/72.6 kg					

VK 7010, 2L

Item Description	Part Number
VK 7010, 2L, 6-position, 115V	10-1935E
VK 7010, 2L, 6-position, 230V	10-1955E
VK 7010, 2L, 8-position, 115V	10-1940E
VK 7010, 2L, 8-position, 230V	10-1950E

VK 7010, 2L Accessory Kits

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 6 or 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

Item Description	Part Number
Accessory kit, 2L, 6-position, stainless steel, 24 in. paddle	1001-1013
Accessory kit, 2L, 6-position, Teflon, 24 in. paddle	1001-1014
Accessory kit, 2L, 6-position, stainless steel basket, standard clip, 24 in. shaft	1001-1015
Accessory kit, 2L, 6-position, stainless steel basket, 0-ring, 24 in. shaft	1001-1016
Accessory kit, 2L, 8-position, stainless steel, 24 in. paddle	1001-1114
Accessory kit, 2L, 8-position, Teflon, 24 in. paddle	1001-1115
Accessory kit, 2L, 8-position, stainless steel basket, standard clip, 24 in. shaft	1001-1116
Accessory kit, 2L, 8-position, stainless steel basket, 0-ring, 24 in. shaft	1001-1117

Internal Dosage Delivery Module Retrofit

- Saves time
- Easy and precise way to drop tablets for automatic (simultaneous or sequential) delivery of dosage forms to vessels with instant or delayed start through keypad or computer control
- Eliminates errors when manually dropping tablets or capsules
- For the VK 7000 Dissolution Apparatus

This option replaces the existing top cover of the dissolution apparatus with a new one containing motors, staging platforms, and Dosage Delivery Module tubes. This retrofit requires a service technician to install.

Dosage Delivery Module

Item Description	Part Number
Dosage Delivery Module for 6-position Easy Access, 4+2	12-0104
Dosage Delivery Module for 7-position Easy Access, 4+3	12-0111
Dosage Delivery Module for 8-position Easy Access, 4+4	12-0106

Replacement Delivery Tubes



Replacement Delivery Tubes

The dosage form drops into the vessel through internal delivery tubes. The replacement tubes are sold in sets of eight and have a threaded end (except P/N 12-0115) for easy replacement.

Replacement Delivery Tubes

Item Description	Part Number
DDM Tubes (internal) for use with VK 7000 and VK 7010 (set of 8)	12-0120
DDM Tubes (bottom extension) for use with VK 7000 and VK 7010 (set of 8)	12-0121
DDM Tubes for use with V-Series apparatus (set of 6)	12-0122
DDM Tubes for VK 7000/7010 in on-line UV system (set of 8)	12-0119

Varian 708-DS Dissolution Apparatus

708-DS

The 708-DS dissolution apparatus is Varian's next generation dissolution apparatus designed for testing tablets, capsules and other dosage forms. The 708-DS supports a broad set of applications ranging from manual dissolution testing to automated, high-throughput analysis. It provides extensive flexibility to match the needs of individual laboratories, whether in research or testing.

The 708-DS, available with either a manual or motorized lift mechanism, is available in 6- and 8-position configuration and can be configured for 100mL, 200mL, 500mL, 1L or 2L TruAlign™ vessel volumes. The instrument, supports several innovative automation options, including automated media temperature sensing, dosage delivery and sampling. You can decide which automation options make sense for your laboratory.

A quiet and compact heater/circulator is integrated into the back of the apparatus in order to save valuable bench space. The angled acrylic water bath makes draining and cleaning quick and easy. And the intuitive user interface is operated through a color touch screen, operable in English, Spanish, Japanese and Chinese. The apparatus voltage ranges from 90 to 250V AC, 50 or 60 Hz.

For more information on the new 708-DS Dissolution Apparatus, contact your Varian representative or visit www.varianinc.com/dissolution/.



708-DS Dissolution Apparatus



Varian 705-DS Dissolution Apparatus

The Varian 705-DS Difference

As the world's leading manufacturer of dissolution testing instrumentation, Varian, Inc. has developed the new Varian 705–DS Dissolution Apparatus for laboratories seeking state-of-the-art technology in an economical, easy-to-use instrument. With interchangeable paddle/basket shaft assemblies, chemical-resistant touchscreen technology, and robust design, the Varian 705–DS offers unrivaled cost-of-ownership advantages to our customers.

Varian 705-DS Standard Features

- Integrated temperature probe to verify vessel temperatures before, during, and after a run
- Records spindle hours for easy preventive maintenance (PM) scheduling based on actual equipment runtime rather than scheduling based on the passage of time
- Integrated electronics (a single board) for system reliability
- Precision manufacturing for USP, EP, and JP compliance
- Apparatus 1, 2, 5, 6 and Intrinsic

The most efficient and economical dissolution instrument on the market, the Varian 705-DS Dissolution Apparatus is designed with you, the user, in mind. It is intuitive to operate, with simple features that make analyst training and lab integration easy. Although elegantly simple, this unit meets all regulatory requirements of the USP, EP, and JP to further facilitate system integration.



Varian 705-DS

With ample room between the drive unit and the vessel plate, manual sampling is easy with the Varian 705-DS. This unit can be used as USP Apparatus 1, 2, 5, or 6, depending on the accessories ordered. The Varian 705-DS has eight vessel locations and spindle assemblies so it can be configured as either a six-spindle or eight-spindle device based on the accessories you choose.

Not only is the Varian 705-DS Dissolution Apparatus ideal for manual testing, it can be easily integrated into an automated system should workloads increase.

Varian offers an autosampler with resident probes* mounted in the evaporation covers that increase the functionality and throughput of the Varian 705-DS. Control is achieved via the RS-232 connection. Dissolution parameters such as RPM, temperature, and test length are programmed into the VK 8000 Dissolution Sampling Station, which then controls the dissolution apparatus.

*As with all dissolution methods, one should validate to show that any change in the agitation characteristics did not enhance the dissolution release rate.

Interchangeable Paddle/Basket Shaft System



Interchangeable Paddle/Basket Shaft System

Varian's latest innovation is a newly designed paddle and basket shaft system that allows the operator to switch between paddles and basket shafts without height readjustment. The system is a two-piece assembly engineered to easily set the shaft length to maintain consistent clearance from the bottom of the vessel. Carryover concerns, typically associated with two-part shafts, are eliminated in the Varian design by having the juncture above the liquid level. So, whether using a paddle or a basket, no height adjustments are required.

Touchscreen Technology

A key enhancement of the Varian 705-DS Dissolution Apparatus is the introduction of the chemical-resistant touchscreen. Allowing full control of the Varian 705-DS without a keypad, the touchscreen provides simple navigation within the menu structure. The water bath temperature, RPM, test duration, printer functions, and other operational functions can be set from this intuitive and simple-to-use touchscreen menu. In addition, administrative and service functions, such as setting the clock, entering the communication port identification number, and changing the screen contrast and brightness, are all available via the touchscreen. Moreover, you can take advantage of the quick-set functions to get commonly used parameters, including RPM or water bath temperature setting, with one touch to the system status screen.



Varian 705-DS Touchscreen

Safety in Mind

With a focus on safety, the Varian 705-DS meets all European (CE) and North American (cTUVus) safety directives. To protect the operator during use, the system has been designed for the spindles to automatically stop if the drive unit is inadvertently raised. However, to support quality control functions, a menu option has been included to allow spindle rotation in the raised position for the purpose of verifying physical parameter measurements.

EaseAlign Centering Rings

The patented EaseAlign rings center and align vessels accurately by using the inside diameter of the vessel. Inconsistencies inherent in glass wall thickness make attempting to align vessels by the outside diameter less accurate. EaseAlign centering rings allow simple, accurate vessel alignment.

Parameter Programming

A simple menu allows you to easily program your parameters including:

- RPM (10 250 RPM)
- Test Duration
- Water bath temperature

Spindle Motor Monitor

This apparatus reports the number of spindle motor hours that the instrument has been in use. This on-screen record allows you to schedule preventive maintenance on actual operating hours rather than arbitrary time periods.

Built-in Temperature Probe

The integrated temperature probe allows confirmation of actual vessel temperatures before, during, and after a run.



Individual Vessel Temperature Measurement



Varian 705-DS Dissolution Apparatus

Varian 705-DS System Configurations

Each Varian 705-DS ships standard as a eight-position apparatus and your choice of corresponding accessory kit.

Varian 705-DS Dissolution Apparatus

Dimensions and Weight						
Size:	Height	36.25 in. 92 cm	Width	24.5 in. 62.2 cm	Depth	23 in. 58.4 cm
Weight:	185 lb/8	33.91 kg		02.2 (111		30.4 CIII

Varian 705-DS

Item Description	Part Number
Varian 705-DS, 6-position, 115V	10-7555
Varian 705-DS, 6-position, 230V	10-7655
Varian 705-DS, 8-position, 115V	10-7550
Varian 705-DS, 8-position, 1230	10-7650

Varian 705-DS Accessory Kits

Select either a paddle or basket accessory kit. All kits include Interchangeable Paddle/Basket Shaft System (see page 2) and a set of 6 or 8 clear glass standard USP vessels with evaporation covers. Additional paddles, baskets, non-standard vessels and evaporation covers must be purchased separately. Contact your local Varian representative for details.

Item Description	Part Number
Accessory kit, 6-position, Teflon, 21 in. paddle	1001-1023
Accessory kit, 6-position, stainless steel, 21 in. paddle	1001-1024
Accessory kit, 6-position, stainless steel basket, standard clip, 21 in. shaft	1001-1025
Accessory kit, 6-position, stainless steel basket, 0-ring, 21 in. shaft	1001-1026
Accessory kit, 8-position, Teflon, 21 in. paddle	1001-1118
Accessory kit, 8-position, stainless steel, 21 in. paddle	1001-1119
Accessory kit, 8-position, stainless steel basket, standard clip, 21 in. shaft	1001-1120
Accessory kit, 8-position, stainless steel basket, 0-ring, 21 in. shaft	1001-1121

If you wish to use the Varian 705-DS as an eight-spindle unit, order the upgrade kit P/N 10-7900 and two additional interchangeable paddle or basket shafts of your choice. The upgrade includes two glass USP vessels, two receptor shafts, two EaseAlign centering rings, two hinged evaporation covers, and two locking rings. If ordering basket shafts, note the baskets must be ordered separately.

Varian 705-DS 6 to 8-spindle Accessory Upgrade

Item Description	Part Number
Varian 705-DS 6 to 8-spindle Upgrade	10-7900
Interchangeable Paddle, Teflon-coated	12-1420
Interchangeable Paddle, electropolished stainless steel	12-1421
Interchangeable USP Standard Basket Shaft w/clip	12-1430
Interchangeable Basket Shaft with O-ring	12-1431
USP Basket, 40 mesh, type 316 stainless steel	12-2100

Printer Option

Item Description	Part Number
Varian 705-DS Printer Option, RoHS, 115V/230V	12-0050

While the Varian 705-DS was designed for manual dissolution testing, it can also be adapted for use with the Varian sample collector. Since the manual apparatus does not have a motorized manifold, special resident sampling probes are available as part of the sampling kit listed below. The sampling kit includes tubing, sample and return cannulas, and disk filters.

Sampling Kits for Varian 705-DS

Item Description	Part Number
Sampling Kit for 6-position Peristaltic Pump, Varian 705-DS	11-7512
Sampling Kit for 8-position Peristaltic Pump, Varian 705-DS	11-7513
Sampling Kit for 6-position Syringe Pump, Varian 705-DS	11-7514
Sampling Kit for 8-position Syringe Pump, Varian 705-DS	11-7515

Cannula Housing Filter for 705-DS

Item Description	Part Number
Cannula Housing Filter, 35 μm, UHMWPE	17-4300
Cannula Housing Filter, 70 μm, UHMWPE	17-4310

Large Volume Conversion Kits

VK 7000/7010 USP Large Volume Conversion Kits

Varian large volume conversion kits offer great flexibility in changing from one vessel size to another. The 2L conversion kit makes your existing dissolution apparatus more flexible by providing leg extenders and an extra-deep water bath for use with either standard 1L vessels or the larger vessels provided with the 2L conversion kit.

2L Conversion Kits

The 2L conversion kit is available for the VK 7000/VK 7010 Dissolution Apparatus.



2L Conversion Kit

2L Conversion Kits

This system requires the 19 or 24 inch paddles and basket shafts, which are sold separately (see page 21).

Item Description	Part Number
VK 7000/7010, Conversion Kit, 3+3 units	12-0400
VK 7000/7010, Conversion Kit, 4+2 and 4+4 units	12-0420

Vessel Conversion Kits

Vessel conversion kits allow you to use your existing equipment for testing with smaller volumes of media.

Use the 100 or 200 mL conversion kits for tests where a smaller volume is required. Save money when preparing standards for automated analyses by preparing less. Both conversion kits work with EaseAlign centering rings (see page 27). The 200 mL kits work with stainless steel (see page 28) or EaseAlign centering rings.

Please note that if you intend to use automated sampling with a small volume conversion kit, you may need a new sampling manifold. Since the diameter of these vessels is smaller, the sampling position is different. Should you have any questions, contact your Varian representative.

The vessel conversion kit includes: vessel(s), mini paddle(s), evaporation cover(s), and centering ring assembly(ies) unless otherwise indicated. Shaft lengths and diameters as well as vessel types are specified where relevant.

See page 23 for 100 and 200 mL vessels. See page 37 for mini paddles. See page 32 for mini baskets.

100 mL Conversion Kit

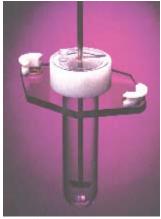


100 mL Conversion Kit (installed)

100 mL Conversion Kits

Item Description	Part Number
Kit with 14.5 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with TruCenter vessels	12-0308
Kit with 15 in. paddle (1/4 in. diameter), for use with EaseAlign centering rings for use with chuck assembly type spindles, includes collet, sold individually	12-0311
Kit with 19 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with O-ring spindle assemblies sold individually	12-0316
Kit with 19 in. paddle (3/8 in. shaft tapered to 1/4 in.), set of 8	12-0317

200 mL Conversion Kits



200 mL Conversion Kit

200 mL Conversion Kit

200 ML Conversion Kit			
Item Description	Part Number		
Kit with 14.5 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with TruCenter vessel, sold individually	12-0312		
Kit with 14.5 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with TruCenter vessel and AutoTemp, sold individually	12-0314		
Kit with 15 in. paddle (1/4 in. diameter), for use with stainless steel centering rings, including collets, set of 8	12-0307		
Kit with 15 in. paddle (1/4 in. diameter), for use with EaseAlign centering rings, includes collet, sold individually	12-0306		
Kit with 15 in. paddle (1/4 in. diameter), for use with EaseAlign centering rings, includes collets, set of 6	12-0305		
Kit with 15 in. paddle (1/4 in. diameter), for use with EaseAlign centering rings, includes collets, set of 8	12-0309		
Kit with 15 in. paddle (1/4 in. diameter), for use with EaseAlign centering rings, flat-bottom vessel, includes collet, sold individually	12-0313		
Kit with 15 in. paddle (1/4 in. diameter), for use with EaseAlign centering rings, flat-bottom vessel, includes collets, set of 6	12-0304		
Kit with 19 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with EaseAlign centering rings, for use with chuck assembly type spindles, sold individually	12-0318		
Kit with 19 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with EaseAlign centering rings, set of 8	12-0319		
Kit with 19 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with EaseAlign centering rings, flat-bottom vessel, sold individually	12-0301		
Kit with 19 in. paddle (3/8 in. shaft tapered to 1/4 in.), for use with EaseAlign centering rings, flat-bottom vessel, set of 8	12-0302		

Conversion Kit Accessories

The following items are for use with either the 100 mL Conversion Kit or the 200 mL Conversion Kit unless otherwise indicated.

Item Description	Part Number
Height Gauge, 15 mm. for use with 100/200 mL round- bottom vessel	12-0320
Spacers 3 1/4 in. for 100/200 mL manifold (snaps on leg of apparatus)	12-0321
Evaporation Cover for use with 100/200 mL vessel	12-6315
Vessel for VK 7025, 200 mL, adapter included	12-5034
Vessel for VK 7025, 200 mL, without adapter	12-5033

VK Verified Paddles, Baskets, Vessels

21

VK Verified

Paddles, Vessels

- Individual certificates for guaranteed conformance
- Critical dimensions measured and documented
- Measured with calibrated and traceable devices

The VK Verified program is your assurance that your accessories will conform to regulatory standards, as well as to the more stringent internal specifications of Varian.

All Varian accessories are lot inspected. Many customers request their accessories be individually inspected, measured, and documented. We now offer this service for a number of accessories (including vessels, paddles, baskets, and basket shafts). A certificate is included to provide the actual measured values, the measuring device used, and its NIST traceability.

Teflon-coated Paddles

Item Description	Part Number
15 in. shaft with individual inspection certificate	12-1000V
19 in. shaft with individual inspection certificate	12-1010V
24 in. shaft with individual inspection certificate	12-1015V

Electropolished Stainless Steel Paddles

Item Description	Part Number
15 in. shaft with individual inspection certificate	12-1030V
19 in. shaft with individual inspection certificate	12-1040V
24 in. shaft with individual inspection certificate	12-1045V

PEEK Paddles

Item Description	Part Number
15 in. shaft with individual inspection certificate	12-1201V
19 in. shaft with individual inspection certificate	12-1211V

Vessels

Item Description	Part Number
Vessel, clear glass, USP, 1000 mL with individual inspection certificate	12-5000V
Vessel, amber glass, 1000 mL with individual inspection certificate	12-5010V
Vessel, amber TruCenter glass, 1000 mL with individual inspection certificate with individual inspection certificate	12-5120V
Vessel, TruCenter glass, collar included, USP, 1000 mL with individual inspection certificate	12-5035V
Vessel, TruCenter glass with ground groove, DVH, 1000 mL with individual inspection certificate	12-5039V
Vessel, clear glass, 2L with individual inspection certificate	12-5070V
Vessel, clear glass, 4L with individual inspection certificate	12-5080V
Vessel, plastic, 1000 mL with individual inspection certificate	12-5200V

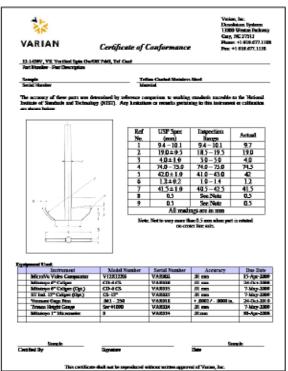
Certificates of Conformance

To meet FDA draft guidance and ASTM requirements for mechanical qualification $(MQ)^*$, measurements for baskets, paddles, shafts and vessels must meet USP specifications and tolerances, and those measurements must be documented on separate Certificates of Conformance (COC).

Rather than rely on generic statements of manufacturing or declarations of batch testing a representative number of components, COCs:

- Document individually measured dimensions and verify conformance to USP specifications and tolerances.
- Reference the unique, traceable serial number for each measured component.
- Provide traceability of NIST standards used to calibrate measuring devices.
- * FDA Draft Guidance for Industry: The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 Current Good Manufacturing Practice (cGMP). http://www.fda.gov/CDER/GUIDANCE/7232dft.pdf
- * CDER's Division of Pharmaceutical Analysis Document #DPA-LOP.002, "Mechanical Qualification of Dissolution Apparatus 1 and 2". http://www.fda.gov/cder/Offices/OTR/dissolution.pdf
- * ASTM E 2503-07 Standard, "Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus"





Certificate of Conformance

USB ACTUR, COC, PARMA, USP_SAMPLE A

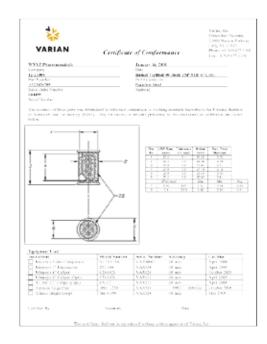
VK Verified Dissolution Vessels

Dissolution vessels are handmade from glass tubing. Due to handforming, as well as the properties of glass, no two vessels are exactly alike. This is particularly relevant for the bottom curvature. As of this publication, there are no published specifications as to the "hemisphericity" of the vessel. At Varian, we've created our own tolerances based on those the USP has recommended for the ID. The diameter has a USP tolerance of ± 4 mm. We have taken half of this value and created a requirement for the hemisphere to be ± 2 mm. We use laser inspection on each vessel and record the actual dimension. The result—you get vessels that are neither too shallow nor too deep and a certificate to verify the actual dimensions.

The benefit to you is greater consistency of test results. Although not exactly alike, these VK Verified vessels are held to very tight tolerances. Substituting a VK Verified vessel for a broken vessel should yield no perceptive difference in results. A certificate is included to provide the actual measured values, the type of measuring device used, and its traceability.

Dissolution Vessel

Item Description	Part Number
Certified Glass Vessel, serialized 1000 mL for Apparatus 1	12-5000V
and 2	12-30000



Glass Dissolution Vessels

- Serialized for traceability
- Wide range of sizes
- Amber-tinted or Teflon-lined vessels available
- Peak Vessel® to prevent coning

1000 mL Vessels

The standard 1000 mL vessels are designed to meet current USP specifications. Vessels are individually serialized for documentation purposes and easy relocation.

1000 mL Vessels

Item Description	Part Number
USP Vessel, 1000 mL standard	12-5000
USP Vessel, 1000 mL amber-tinted	12-5010
Vessel, 1000 mL Teflon-lined (interior lower hemispherical radius only)	12-5020
USP Vessel, TruCenter, with collar	12-5035

100 mL, 200 mL, 2L, and 4L Vessels

100 and 200 mL vessels are smaller in diameter (41 \pm 1.5 mm). These vessels require a conversion kit (see page 20). 2L vessels are the same diameter as standard 1L vessels and can be used with EaseAlign centering rings. Please note that a deeper water bath is required when using the 2L and 4L vessels. 4L vessels are larger in diameter (150 \pm 3.55 mm) and require a vessel plate conversion kit (see page 19).

100 mL, 200 mL, 2L, and 4L Vessels

Item Description	Part Number
100 mL, round-bottom	12-5040
100 mL, amber-tinted, round-bottom	12-5041
200 mL, round-bottom	12-5050
200 mL, amber-tinted, round-bottom	12-5051
USP 2L, round-bottom	12-5070
USP 2L, amber-tinted, round-bottom	12-5075
USP 4L, round-bottom	12-5080
USP 4L, amber-tinted, round-bottom	12-5090





1000 mL Vessel

Teflon-lined Vessel



200 mL 200 mL 100 mL



Amber-tinted Vessel



4L and 2L Vessels



Peak Vessels

The Peak VesselTM reduces the inherent inconsistencies in the hydrodynamics of standard hemispherical dissolution vessels. An inverted peak is designed into the bottom of the vessel, displacing the unstirred zone, preventing cone formation.

For more information regarding studies performed with the Peak Vessel, call the Dissolution Hotline for a reprint of the article: *Improved hydrodynamics for USP Apparatus 2.*

Peak Vessels

Item Description	Part Number
Peak Vessel, 1L	12-5500
Peak Vessel, 1L, Teflon coated bottom	12-5025
Peak Vessel, 2L	12-5510
Peak Vessel, 4L	12-5520

Did you know when using Peak Vessels, the height is set as if the indentation were not present? The height setting tool (P/N 12-7230) takes this into account, making it easy to set the height.



Peak Vessel





oventional Pe

Patented TruCenter™ Vessels

- Aligned from internal vessel diameter to find the exact center of each vessel
- Magnetic collar eliminates need for manual adjustment
- Synthetic flange reduces chance of breakage
- Empty vessels will not float
- Retrofit kits available

The TruCenter vessel provides perfect centering every time! Patented TruCenter vessels are the first to be individually ground on a lathe to find the exact center for each vessel.



TruCenter Vessel

All dissolution vessels have inconsistencies in the glass thickness. Consequently, centering from the outside of the vessel is time consuming and requires verification. Varian's innovative design has eliminated these problems by attaching a Delrin flange or centering collar to the concentric ring ground around the outside of the vessel wall.

The vessel is precisely aligned and locked in place by magnets embedded in the vessel support plate and vessel centering collar. The precision machined flange assures the vessel sits flat and parallel to the axis of the shaft and reduces the chance of breakage.

TruCenter Vessels

Item Description	Part Number
TruCenter Vessel, 1L, with ground centering groove	12-5035
TruCenter Vessel, 1L, amber	12-5120
TruCenter Vessel, 1L, peak	12-5125

Calibrated Volumetric Flasks

Be sure to start your test with the accurate volume. This volumetric dissolution flask meets class A specifications. Unlike other volumetric flasks. these are calibrated to contain (TC) as well as to deliver (TD) media at 37 °C. Standard glassware is calibrated at 20 °C.



Calibrated Volumetric

Volumetric Flasks Calibrated at 37 °C for use with preheated media

Item Description	Part Number
Calibrated Volumetric Flask, 900 mL	12-5315
Calibrated Volumetric Flask, 500 mL	12-5320

This volumetric dissolution flask meets Class A specifications. A stopper is included and the flask is designed with a space-saving square bottom. The flask is marked to deliver (TD) and to contain (TC). Flasks are calibrated at

Volumetric Flasks Calibrated to at 20 °C for use with room temperature media

Item Description	Part Number
Calibrated Volumetric Flask, 900 mL	12-5300
Calibrated Volumetric Flask, 500 mL	12-5310

Plastic Dissolution Vessels

Our standard 1000 mL plastic vessels are designed to meet current USP specifications. The plastic dissolution vessel has three molded feet in order to be free standing and is manufactured of styrene with acrylic mix. These vessels are molded and every one is identical. Although much harder to break than a glass vessel, they do have a lower degree of thermal conductivity than glass.



Plastic Dissolution Vessel

Plastic Dissolution Vessels

Item Description	Part Number
Plastic Dissolution Vessel, 1000 mL	12-5200

Did you know that the square shape of the 900 mL and 500 mL volumetric dissolution flasks allows more flasks to be heated in water baths than traditional round-shaped flasks? Conventional volumetric dissolution flasks are calibrated at 20 °C. Once roomtemperature medium is added to the flask, it may be stoppered and heated in a water bath to pre-equilibrate the medium to 37 °C. Alternatively, Varian provides a solution for preheating dissolution medium in bulk. Volumetric dissolution flasks calibrated at 37 °C are now available which allow preheated medium to be accurately measured and dispensed at the beginning of the test.

Direct Vessel Heating Vessels (DVH™)



Direct Vessel Heating Vessels (DVH)

Direct Vessel Heating technology precisely controls the heating of dissolution media and replaces traditional water baths. The unique Delrin flange helps prevent vessels from chipping.

DVH TruCenter Vessels ensure perfect centering and alignment every time. Environmental chambers isolate vessels from laboratory conditions and contain media in the unlikely event of vessel breakage. Dual-zoned heating elements allow precise control of media temperature from 500 mL to 1000 mL. DVH incorporates two temperature control mechanisms. The first monitors and controls temperature while the second measures and records temperature.

These vessels are for use with the VK 7030 Dissolution Apparatus. The heating film is permanently fused to the exterior of the vessel wall. These vessels are capable of being washed in commercial dishwashers at temperatures up to $60\,^{\circ}\text{C}$.

DVH Vessel

Item Description	Part Number
TruCenter Vessel, DVH, 1L	12-5039

Vessel Isolation Chambers



Vessel Isolation Chamber

Vessel isolation chambers are used with the DVH vessels. Since these vessels remove the need for a water bath, these specially designed chambers protect the vessels from environmental elements such as changes in temperature. They also serve as a containment chamber in the rare case of vessel breakage.

Vessel Isolation Chamber

Item Description	Part Number
Vessel Isolation Chamber	11-7100
Vessel Isolation Chamber, amber	11-7101

TruCenter™ System Conversion Kits



TruCenter System

This system assures perfectly centered vessels every time. We start by turning a dissolution vessel on a lathe and grinding a concentric ring around the outside of the glass vessel. Next we fasten a centering collar around the ground ring and place the system into the alignment plate. The result is a vessel that can be perfectly centered. One less variable for you to worry about. Once your vessels are in place, they will not float. This system can be retrofitted to any existing VK 7000 or VK 7010 Dissolution Apparatus. Simply order the appropriate number of conversion kits for your apparatus.

TruCenter System

Item Description	Part Number
TruCenter System Conversion Kit—includes 900 mL vessel with centering collar, alignment plate, and evaporation cover	12-6100
TruCenter System Conversion Kit, 900 mL, with manual sampling evaporation covers	12-6101
TruCenter Vessel, 1L, with ground centering groove and centering collar	12-5035
TruCenter Alignment Plate	12-6115
Hinged evaporation cover	12-6327

EaseAlign Centering Rings



EaseAlign Centering Ring

These centering rings position the vessels accurately using the inside diameter of the vessel. Empty vessels will not float. Locating pegs mounted on the vessel table ensure centering each time a vessel is placed in position. This does not include evaporation cover or pegs. For use with VK 700, VK 7000, VK 7010, and 705-DS.

EaseAlign Centering Rings

Item Description	Part Number
EaseAlign centering rings	12-6050

Vessel Evaporation Covers

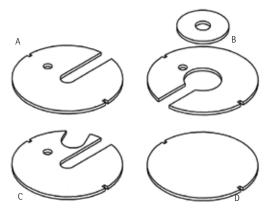
Evaporation covers slow the loss of media during dissolution testing.

Evaporation Covers for EaseAlign Centering Rings

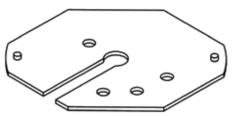
Item Description	Part Number
Standard, PETG construction (A)	12-6300
Standard, PVC construction	12-6301
For rotating basket - auto start (B)	12-6305
For Dosage Delivery Module type (C)	12-6310
For Dosage Delivery Module type, amber-tinted	12-6311
For use with 4L vessels	12-6326
Solid, for use in 7th or 8th position with an EaseAlign ring when no vessel is in use (D)	12-6330
For use with 200 mL vessels	12-6315
Evaporation Cover, amber-tinted, for use with standard vessels	12-6320
Evaporation Cover, basket with single opening for basket and two openings for sample cannula	12-0463
Evaporation Cover with single basket opening, for auto start with baskets	12-0464

Evaporation Covers for Stainless Steel Rings

Item Description	Part Number
Standard	12-6200
Robotic Caliper type	12-6205
Amber-tinted	12-6210
For use with baskets	12-6306
For use with 4L vessels	12-6325



Vessel Evaporation Covers for EaseAlign Centering Rings



Vessel Evaporation Covers for Stainless Steel Centering Rings



Standard Evaporation Cover shown with resident dwelling probe

Low Loss Evaporation Covers

Low Loss Evaporation Cover

The unique conical design of these low loss evaporation covers causes condensation to return to the vessel and is ideal for extended release testing. The low loss evaporation cover dramatically reduces media loss during long runs. Use with Varian's EaseAlign centering rings.

The volumetric accuracy of the media used in the test should be maintained at less than 2% evaporative loss over a 24-hour period. For longer tests, these evaporation covers should help you meet this requirement.

Low Loss Evaporation Cover

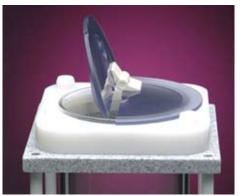
Item Description	Part Number
Low Loss Evaporation Cover for EaseAlign centering rings,	12-0469
conical shape for extended release analysis	



Low Loss Evaporation Cover

Hinged Low Loss Evaporation Cover

Varian's new, two-piece, hinged evaporation cover is designed for all systems where the evaporation cover sits directly on the 1L dissolution vessel. Its unique conical shape causes condensation to return to the vessel. Split-hinge design makes manual sampling easy.



Hinged Low Loss Evaporation Cover

Hinged Low Loss Evaporation Cover

Item Description	Part Number
Hinged Low Loss Evaporation Cover for TruCenter vessels	12-6327
Hinged Low Loss Evaporation Cover for EaseAlign system without Dosage Delivery Modules (DDMs)	12-6328
Hinged Low Loss Evaporation Cover for TruCenter vessels when using resident probes	12-6329

Evaporation Plugs

Press-fit plugs are used to close sampling holes in evaporation covers.



Evaporation Plugs

Evaporation Plugs

Item Description	Part Number
Evaporation plugs (set of 36)	12-6350



Two-piece Interchangeable Basket Assembly

Switching between paddles and basket just became easier. With Varian's new two-piece interchangeable paddle/basket assemblies, you don't have to reset the height of the drive unit when you change between dissolution apparatus. The special shaft stays securely in place. The lower section of the shaft unscrews for interchangeability. The paddle and basket shaft assemblies are designed so that the proper height is maintained after the changeover.

These shafts are manufactured to meet or exceed the USP specifications. The Varian design is precisely engineered to the same tolerances as the one-piece shaft, minimizing the risk of cross threading and ensuring a secure connection. In addition, the attachment area remains out of the media so there is less chance for contamination. These assemblies can be used in any dissolution apparatus, and precision manufacturing has assured USP compliance.

Each component is serialized for traceability.

Order the proper length (15, 19, or 24 inch – when fully assembled) receptor shaft (P/Ns 12–1400, 12–1401, or 12–1402). Then combine with the paddle or basket shaft assembly, or both.

Two-piece Interchangeable Assemblies

The shaft lengths indicated represent the total length with the paddle or basket assembly attached.

Item Description	Part Number
USP Standard Basket Assembly with Clips (basket must be ordered separately)	12-1430
Standard Basket Assembly with O-ring (basket must be ordered separately)	12-1431
Caliper/Zymark Type Basket Assembly, conical	12-1432
USP Standard Basket Assembly with Clips (basket must be ordered separately) for 2L vessel	12-1438
Standard Basket Assembly with O-ring (basket must be ordered separately) for 2L vessel	12-1439
Shaft assemblies can also be used with the paddle assemblies on page 34.	
Shaft 15 in., when fully assembled	12-1400
Shaft 19 in., when fully assembled	12-1401
Shaft 21 in., when fully assembled	12-1433
Shaft 24 in., when fully assembled	12-1402

One-piece Shaft with 40 mesh Basket



The rotating basket assembly is individually serialized with the serial number laser imprinted on the shaft for record keeping purposes. These assemblies meet USP specifications requiring three retention spring clips for Apparatus 1. The shaft is electropolished (except P/N 12-2030 which is Teflon coated) and constructed of type 316 stainless steel. Available in 15, 19, and 24 inch lengths with a 3/8 inch diameter. Each basket assembly comes with a Certificate of

Shaft with mesh basket

USP Rotating Basket Assembly

The following part numbers include a USP standard basket shaft and a 40 mesh basket

Item Description	Part Number
15 in. Shaft, standard, includes 40 mesh Basket	12-2000
19 in. Shaft, standard, includes 40 mesh Basket	12-2020
24 in. Shaft, standard, includes 40 mesh Basket	12-2025

Rotating Basket Assembly

Item Description	Part Number
15 in. Shaft, conical head, disperses bubbles more effectively	12-2010
15 in. Teflon coated Shaft, (lower 6 inches Teflon coated) and Teflon coated 40 mesh Basket	12-2030

Did you know the current USP Apparatus 1 basket shaft requires three retention clips on 120-degree centers to hold the basket in place?



Two-piece Interchangeable Basket/Paddle Assemblies

Basket Shafts

The electropolished basket shafts are individually serialized and are shipped with a Certificate of Lot Compliance. The drive shafts are for use with USP Apparatus 1. The 3/8 inch diameter shafts are manufactured of type 316 stainless steel. There is a clip assembly to attach baskets to the shafts. The USP design calls for a three-prong attachment on the basket shaft.

Basket shafts are available with a level or conical surface. The conical surface allows air bubbles to disperse. The flat surface is the standard USP design.







Conical Basket Shaft

Gold-plated Shaft

Teflon coated Shaft

Basket Shafts

Item Description	Part Number
15 in. Shaft, USP standard head	12-2070
19 in. Shaft, USP standard head	12-2080
24 in. Shaft, USP standard head	12-2095
15 in. Shaft, conical head	12-2075
19 in. Shaft, conical head	12-2081
15 in. Shaft, standard head, lower 6 in. gold plated	12-2085
19 in. Shaft, standard head, lower 6 in. gold plated	12-2086
15 in. Shaft, standard head, lower 6 in. Teflon coated	12-2090
19 in. Shaft, standard head, lower 6 in. Teflon coated	12-2091
15 in. Shaft, standard head, for Bolus basket (shaft only)	12-2097
24 in. Shaft, standard head, for Bolus basket (shaft only)	12-2098

Basket Shafts for use with V-Series Dissolution Apparatus

Item Description	Part Number
14.5 in. Shaft, USP standard head, for use with V-Series	12-2073
14.5 in. Shaft, conical head, for use with V-Series	12-2076
14.5 in. Shaft, USP standard head, lower 6 in. Teflon coated, for use with V-Series	12-2041
14.5 in. Shaft, conical head, lower 6 in. Teflon coated, for use with V-Series	12-2042

DuraFit Basket Shafts

The DuraFit Basket Shafts are individually serialized and are shipped with a Certificate of Lot Compliance. The 3/8 inch diameter shafts are manufactured of type 316 stainless steel. The heads have O-rings for press fit attachment of the baskets.



DuraFit Standard and DuraFit Conical

DuraFit basket shafts are available with the traditional flat-surface or conicalsurface design. The conical surface allows air bubbles to disperse.

DuraFit Basket Shafts

Item Description	Part Number
15 in. Shaft, standard head	12-2040
19 in. Shaft, standard head	12-2055
15 in. Shaft, conical head	12-2050
19 in. Shaft, conical head	12-2056
15 in. Shaft, standard head, lower 6 in. Teflon coated	12-2093

DuraFit Basket Shafts for use with V-Series Dissolution Apparatus

Item Description	Part Number
14.5 in. Shaft, standard head, for use with V-Series	12-2045
14.5 in. Shaft, conical head, for use with V-Series	12-2053
14.5 in. Shaft, standard head, lower 6 in. Teflon coated, for use with V-Series	12-2043
14.5 in. Shaft, conical head, lower 6 in. Teflon coated, for use with V-Series	12-2044

Shaft Locking Ring



Shaft Locking Ring

The shaft locking mechanism for the Varian 705-DS and VK 7025 engages the locking collar in the apparatus drive unit. An Allen wrench is used to tighten the set screw locking the shaft securely in place.

Shaft Locking Ring

Item Description	Part Number
Shaft Locking Ring	12-2096



Special-purpose Baskets

The following baskets fit the standard USP rotating shafts and the stationary basket shaft. USP standard 40 mesh baskets are serialized for traceability.







Suppository Basket



Teflon-coated Basket



3-fin Basket

Standard Baskets

Item Description	Part Number
USP Basket, 40 mesh, type 316 stainless steel, standard	12-2100
USP Basket, 40 mesh, gold plated*	12-2105
Basket, 40 mesh, Teflon coated, type 316 stainless steel	12-2110
Basket, 40 mesh, type 316 stainless steel, 3-fin assembly	12-2115
Basket, 20 mesh, 864 μm, type 316 stainless steel	12-2120
Basket, 10 mesh, 1905 μm, type 316 stainless steel	12-2125
Suppository Basket, slotted, plastic	12-2130

^{*}Gold plating and Teflon coating may reduce opening size (µm)

Mini Baskets



DuraFit Basket

This smaller diameter basket fits on a specially designed DuraFit basket shaft. The shaft is 3/8 inch in diameter. Use with 100 and 200 mL vessels. Custom mesh and μm sizes are available.

Mini Baskets

Dimensions and Diameter		
Size:	Height 1.26 in. 32 mm	
Inside Diameter:	0.39 in./9.9 mm	

Mini Baskets

Item Description	Part Number
Mini Basket, 40 mesh, and DuraFit Shaft, 15 in.	12-2057
Mini Basket, 40 mesh (basket only)	12-2102
DuraFit Shaft, 14.5 in. for V-Series (shaft only)	12-2079
DuraFit Shaft, 15 in. for 1/4 in. drive (shaft only)	12-2077
DuraFit Shaft, 15 in. for 3/8 in. drive (shaft only)	12-2078

Did you know all stainless steel baskets are vulnerable to wear over time? Acidic media will slowly attack stainless steel surfaces, openings enlarge and your results could vary. Replace your baskets on a regular basis.

Custom Baskets

Varian can manufacture custom-made baskets to your specifications. We have manufactured the following basket configurations which fit standard USP shafts in the past. Contact your Varian representative if you are interested in one of these or one with different specifications.

Custom Baskets

Item Description	Part Number
450 x 2750 mesh, 1 μm	12-2140
400 x 2800 mesh, 2 μm	12-2145
325 x 2300 mesh, 5 μm	12-2146
200 x 1400 mesh, 10 μm	12-2148
165 x 800 mesh, 20 μm	12-2149
325 x 325 mesh, 43 μm	12-2150
270 x 270 mesh, 53 μm	12-2151
150 x 150 mesh, 104 μm	12-2152
100 x 100 mesh, 140 μm	12-2154
50 x 50 mesh, 280 μm	12-2155
30 x 30 mesh, 533 μm	12-2160

Baskets – mesh vs. µm: Fabricated with 316 stainless steel, baskets have a standard screen mesh of 40. Mesh is defined as the number of openings per linear inch. Another term often associated with mesh size is µm (or micron), which is defined as the size of the openings. The number of openings per linear inch and the diameter of the wire determine µm size.

Bolus Baskets



Bolus Baskets

The bolus basket is typically used in veterinarian applications. Tests may need to be run in 2L or 4L vessel to maintain proper sink conditions. The following bolus baskets require a special shaft, P/N 12-2097 (see page 31).

Bolus Baskets

Dimensions and Diameter	
Size:	Height 3.74 in. 95 mm
Inside Diameter:	1.18 in./30 mm

Bolus Baskets

Item Description	Part Number
20 x 20 mesh, 864 μm	12-2180
40 x 40 mesh, 381 μm	12-2185

Two-piece Interchangeable Paddle Assembly



Two-Piece Paddles

The easiest way to switch over between paddles and baskets. This new Varian design allows you to switch assemblies without resetting the height of the dissolution apparatus. The special shaft stays securely in place. The lower section of the shaft unscrews for interchangeability. The paddle and basket shaft assemblies are designed so that the proper height is maintained after change over.

These shafts are manufactured to the USP specification. The Varian design is precisely engineered to the same tolerances as the one-piece shaft, minimizing the risk of cross threading and ensuring a secure connection. In addition, the attachment area remains out of the

media so there is less chance for contamination. These assemblies can be used in any dissolution apparatus and precision manufacturing has assured USP compliance.

Both the receptor shaft and the shaft assemblies are serialized for traceability. The receptor shafts are utilized with the basket assemblies (see page 30).

Order the proper length (15, 19, or 24 inch – when fully assembled) receptor shaft (P/Ns 12–1400, 12–1401, or 12–1402). Then combine with the paddle or basket assembly, or both.

Two-piece Interchangeable Assemblies

The shaft lengths represent the total length with the paddle or basket assembly attached.

Item Description	Part Number
Paddle Assembly, Teflon coated	12-1420
Paddle Assembly, electropolished	12-1421
Paddle Assembly, PEEK	12-1440
Paddle Assembly, Teflon coated for 2L vessel	12-1436
Paddle Assembly, electropolished for 2L vessel	12-1437
Shaft assemblies can also be used with the basket assemblies on page 30.	
Shaft 15 in., when fully assembled	12-1400
Shaft 19 in., when fully assembled	12-1401
Shaft 21 in., when fully assembled	12-1433
Shaft 24 in., when fully assembled	12-1402

One-piece Paddle Assembly, Teflon coated

These paddles are serialized and designed to meet current USP specifications for Apparatus 2. They are constructed of type 316 stainless steel and have a 3/8 inch diameter shaft. The blade and lower part of the shaft are Teflon coated

Teflon coated Paddles

Item Description	Part Number
14.5 in. shaft, Teflon coated, for use with V-Series	12-1005
15 in. shaft, Teflon coated	12-1000
19 in. shaft, Teflon coated	12-1010
24 in. shaft, Teflon coated	12-1015



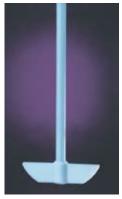
Electropolished Stainless Steel Paddles

These paddles are serialized and designed to meet current USP specifications for Apparatus 2. They are electropolished and constructed of type 316 stainless steel. The shaft is 3/8 inch diameter.

Uncoated Electropolished Stainless Steel Paddles

Item Description	Part Number
14.5 in. Shaft, electropolished, for use with V-Series	12-1035
15 in. Shaft, electropolished	12-1030
19 in. Shaft, electropolished	12-1040
24 in. Shaft, electropolished	12-1045

Dura-Tef Replacement Blade and Shafts



Dura-Tef Shaft

These paddles consist of two pieces: a 3/8 inch shaft and a detachable/replaceable all-Teflon blade.

Dura-Tef Shaft

Item Description	Part Number
15 in. Shaft only 1/4 in. threads	12-1221
19 in. Shaft only 1/4 in. threads	12-1222
24 in. Shaft only 1/4 in. threads	12-1223

Teflon Replacement Blade

Item Description	Part Number
Blade with 1/4 in. diameter opening, meets USP	12-1226
dimensional specifications	

PEEK Paddles

Perhaps the last paddle you'll purchase!

These paddles are serialized and are of single-entity construction. The shaft is manufactured of type 316 stainless steel with a 1/16 inch thick PEEK sleeve and solid PEEK blade. These paddles meet all the dimensional specifications of the USP, EP, and JP for Apparatus 2. PEEK paddles are impervious to most types of media used in dissolution. They offer greater chemical resistance and have greater rigidity than Teflon (thereby ensuring the proper shape is maintained).

PEEK Paddles

Item Description	Part Number
14.5 in. Shaft, PEEK, for use with V-Series	12-1205
15 in. Shaft, PEEK	12-1201
19 in. Shaft, PEEK	12-1211

Did you know PEEK (polyetheretherketone) is biocompatible, chemically inert, and can be used to replace stainless steel?



PEEK Paddle

Suspended Basket Assembly

The Suspended Basket Assembly is a stationary basket attached to the evaporation cover, which is held in place above a rotating paddle by a 1/4 inch diameter shaft. The 4 inch long shaft constructed of type 316 stainless steel is threaded at one end for attachment to the evaporation cover. The assembly includes one mesh basket, one basket shaft, and fasteners. This basket is used for applications that are testing dosage forms requiring a higher agitation rate.



Suspended Basket Assembly

Suspended Basket Assembly

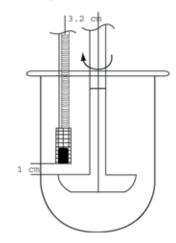
Item Description	Part Number
Basket Shaft and 20 mesh Basket	12-2060
Basket Shaft and 10 mesh Basket	12-2061
Basket Shaft and 40 mesh Basket	12-2063

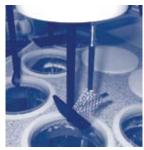
Felodipine Quadrangular Baskets

Recently introduced in the USP, the quadrangular basket conforms to the specification required for Felodipine extended-release products. Used in conjunction with an Apparatus 2, the quadrangular basket is suspended above the paddle blade. The quadrangular basket consists of a diamond shaped stainless steel wire basket (8 mesh) that is 35.4 mm from top to bottom and about 10.0 mm wide.

The extended-release tablet is to be placed in an open end of the basket and covered with a horizontal stainless steel cover, which bisects the middle of the basket. The basket is attached via a shaft to the evaporation cover which is secured by two nuts. The height of the basket is adjusted to a position 1 cm above the rotating paddle and oriented tangential to the rotational flow of media within the vessel.

Drug Release Stationary Tablet Basket Configur





Quadrangular Baskets

Quadrangular Basket

Item Description	Part Number
Quadrangular Basket	12-2069

Apparatus 2 Modifications

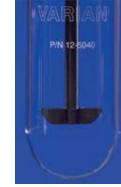
37

Mini Paddles for 100 and 200 mL Vessels

The mini paddle is made of type 316 stainless steel. It has a 1.174 inch (29.8 cm) paddle diameter and is available in either a 1/4 inch or 3/8 inch diameter shaft.

The Varian-designed mini paddle and 100 mL and 200 mL vessel are designed to be proportionally the same as the standard USP paddle and 1L vessel.

To use the 1/4 inch diameter shaft mini paddles with stainless steel chuck assemblies, you need the 1/4 inch collets (see Replacement Collets for Chuck Assemblies on this page).



Mini Paddles

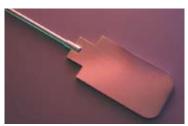
The 3/8 inch diameter shafts require no replacement collet.

Mini Paddle

Item Description	Part Number
Mini Paddle, Teflon coated, 14.5 in. (3/8 in. shaft tapered to 1/4 in.)	12-1228
Mini Paddle, electropolished, 14.5 in. (3/8 in. shaft tapered to 1/4 in.)	12-1229
Mini Paddle, Teflon coated, 15 in. (1/4 in. shaft diameter)	12-1300
Mini Paddle, Teflon coated, 15 in. (3/8 in. shaft tapered to 1/4 in.)	12-1305
Mini Paddle, electropolished, 15 in. (1/4 in. shaft diameter)	12-1310
Mini Paddle, electropolished, 15 in. (3/8 in. shaft tapered to 1/4 in.	12-1315
Mini Paddle, Teflon coated, 19 in. (3/8 in. shaft tapered to 1/4 in.)	12-1306
Mini Paddle, electropolished, 19 in. (3/8 in. shaft tapered to 1/4 in.)	12-1316
Mini Paddle, electropolished, 24 in. (3/8 in. shaft tapered to 1/4 in.)	12-1317
Mini Paddle, Teflon coated, 24 in. (3/8 in. shaft tapered to 1/4 in.)	12-1307

Mega Paddle

This paddle can be used in 2L and 4L vessels when greater fluid movement is required.



Mega Paddle

Mega Paddle

Item Description	Part Number
Mega Paddle 24 in., 3/8 in. diameter shaft	12-1318

Replacement Collets for Chuck Assemblies

Interchangeable collets allow the use of 3/8 inch or 1/4 inch shafts. Collets are ideal for use with mini paddles or baskets. Collets have three-point shaft alignment and support. They are for use with stainless steel spindles.



Collet for Mini Paddle/Basket Shaft (left); Collet for Standard Shaft (right)

Collets

Item Description	Part Number
Collet for use with 3/8 in. diameter shaft	12-1320
Collet for use with 1/4 in. diameter shaft	12-1330

Paddle/Basket Shaft Support Rack

Protect your investment—avoid bends and nicks. The support rack, with sturdy acrylic construction, holds 12 dissolution paddles or basket shafts.



Paddle/Basket Shaft Support Rack

Paddle/Basket Shaft Support Rack

	Item Description	Part Number
I	Paddle/Basket Shaft Support Rack	12-1350



Capsule Weights and Sinker Baskets

Stainless Steel Wire

This wire is flexible enough for weighting capsules. It is type 316 stainless steel wire, 0.032 inch diameter.

Stainless Steel Wire

Item Description	Part Number
Stainless steel wire, 50-foot roll	12-3000

Three-prong Capsule Weights

The three-prong assembly retains the capsule. Capsule weights fit capsules sizes three through one. Capsule weights are sold individually.

Three-prong Capsule Weights

Item Description	Part Number
Capsule Weight, three-prong	12-3050
Capsule Weight, three-prong robotic-type with magnetic contact on end of capsule weight	12-3055
Capsule Weight, robotic, with steel embedded in each	40.0056
capsule leg assuring better contact during magnetic retrieval	12-3056

Sinker Baskets

The sinker baskets are designed to retain the dosage form at the bottom of the vessel. They are made of type 316 stainless steel and use press-on caps (with O-rings). They are currently manufactured in six mesh sizes. Custom mesh sizes are available—contact us for details.

Sinker Baskets

Dimensions and Diameter	
Inside Diameter:	0.8 in./20.3 mm
Inside Height:	0.46 in./11.7 mm

Sinker Baskets

Item Description	Part Number
Enclosure 10 mesh, 1905 µm	12-3060
Enclosure 8 mesh, 2591 μm	12-3062
Enclosure 40 mesh, 381 µm	12-3064
Enclosure 60 mesh, 229 μm	12-3066
Enclosure 270 mesh, 53 μm	12-3068
Enclosure 325 mesh, 45 μm	12-3072
USP Japanese Sinker Basket, JP 13 version	12-3070

*Official Japanese sinker basket (alternative USP <711> sinker)

Did you know sinkers are used during a dissolution test to sink a drug delivery system that would otherwise float? USP specifies a small piece of nonreactive material such as a few turns of Stainless Steel wire attached to the dosage unit. Other validated sinkers can be used.



Stainless Steel Wire



Three-prong Capsule Weights



Sinker Baskets



Japanese Sinker Basket, P/N 12-3070

Manual Sampling Cannula Assembly

39

Cannula Luer Lock Type

The cannula is bent for easier accessibility to USP sampling position. Type 316 stainless steel with stainless steel Luer Lock fitting. Use with Full Flow Filters (see page 40).



Luer Lock Cannula

Cannula Luer Lock Type

Item Description	Part Number
Bent cannula, 4.75 in., for sampling 900 mL for use in 1L vessels (A)	12-3200
Bent cannula, 7.75 in., for sampling 500 mL in 1L vessels or for use with 2L vessels	12-3210
Bent cannula, 4.75 in., for sampling 900 mL with adjustable gauge for setting proper height	12-3215
Bent cannula, 7.75 in., for sampling 500 mL with adjustable gauge for setting proper height	12-3216
Filter holder, 25 mm	12-3220
Sampling cannula for sampling through the V-Series drive unit, 12 in. in length	12-3315



Filter Holder, 25 mm

Glass Syringe

This 20 mL syringe with Luer Lock fitting, 12 inch in length is graduated in 1 mL increments.

Glass Syringe

Item Description	Part Number
Glass Syringe only, 20 mL(B)	12-3230

Sampling Syringe Assembly

The sampling syringe assembly includes a 20 mL syringe and a cannula.



Manual Sampling

Sampling Syringe Assembly

Item Description	Part Number
Syringe with 4.75 in. cannula (A & B)	12-3240
Syringe with 7.75 in. cannula	12-3250

Did you know that Varian offers a variety of spacers to increase the working space when performing manual sampling? These spacers require a longer shaft but allow for easier access when sampling. See page 49 for ordering information.



Full Flow Filters®

Not All Filters Are The Same!



Full Flow Filters

Because dissolution continues until the sample is filtered, it is critical to filter immediately. The Full Flow Filter, when attached to a manual or automated sampling cannula, provides immediate filtration which preserves the integrity of the dissolution sample.

Filters are made of ultrahigh molecular weight polyethylene (UHMWPE) or for even greater chemical resistance polyvinylidene fluoride (PVDF). The increased surface area of the Full Flow Filter versus conventional filter tips optimizes filter life. Use with 1/8 inch diameter cannulas. Sold in packs and case quantities.

Ultrahigh Molecular Weight Polyethylene (UHMWPE) Cannula Filters

Item Description	Part Number
Blue, 10 μm, (UHMWPE) pk of 100	17-4000
White, 35 µm, (UHMWPE) pk of 100	17-4010
Red, 70 μm, (UHMWPE) pk of 100	17-4020



Polyvinylidene Fluoride (PVDF) Cannula Filters

The PVDF filter offers greater integrity of samples. It is a low protein-binding material which filters a greater variety of active drugs substances. Some drugs bind to other filters or even react them. The new PVDF Full Flow Filter offers a solution for those active drug substances which may absorb onto polyethylene fluoride materials.

Polyvinylidene Fluoride (PVDF)

Item Description	Part Number
Green, 10 µm, (PVDF) pk of 100	17-4040
Yellow, 35 µm, (PVDF) pk of 100	17-4050

Conventional Filter Tips



Manual Sampling

Filter tips are made of polyethylene fluoride and are for use with 1/8 inch diameter cannulas. Sold in package and case quantities.

Filter Tips

Also available in cases of 1000.

Item Description	Part Number
2 μm, pk of 100	17-4100
5 μm, pk of 100	17-4110
10 μm, pk of 100	17-4120
20 μm, pk of 100	17-4130
45 μm, pk of 100	17-4140

Cannula Housing Filter for use with Varian 705-DS

These filters are specially designed to be easily removed from the 705-DS cannula housing. They are available in your choice of 35 or 70 μ m ultrahigh molecular weight polyethylene (UHMWPE).

Cannula Housing Filter for Varian 705-DS

Item Description	Part Number
Cannula Housing Filter, 35 μm, UHMWPE, pk of 100	17-4300
Cannula Housing Filter, 70 µm, UHMWPE, pk of 100	17-4310

Proper sampling position: When sampling, withdraw a sample from a zone midway between the surface of the dissolution medium and the top of the rotating basket or blade, not less than one centimeter from the vessel wall.

Resident Cannula Kits



Automation Filters

These 25 mm disk filters are individually lot analyzed and designed to work with Varian's Automated Filter Changer (see page 57) as well as the Caliper Multidose and Tablet Processing Workstation (TPW). The specially designed housing prevents the membrane from being compressed. Varian offers glass fiber, nylon, and PVDF filters as standard products. Filters are packaged in boxes of 200 and pre stacked in tubes of 25 for easy loading. Other membrane types are available—call Varian for details.



Automation Filter Validation Kit

Varian has prepared a Filter Validation Kit for use with the VK 808 Filter Changer. This kit is a sample pack that includes 25 each of eight different Schleicher & Schuell ROBY25 automation filters and a filter validation guide. The filter housing is made from rigid polypropylene and is pressure resistant. They provide reproducible results and have been thoroughly tested in the VK 808 Filter Changer. The filters are available in a variety of membranes and will be offered in packages of 200 or 1000.

Item Description	Part Number
Filter, 1.0 µm APFB glass fiber prefilter for processing and clarification of aqueous and organic solutions containing high particle levels	17-4200
Filter, 0.45 µm how protein binding PVDF membrane for processing and clarification of aqueous and mile organic solutions	17-4210
Filter, 0.45 µm nylon membrane for processing and clarification of aqueous and mile organic solutions	17-4220

25 mm Filters used in Automated Systems

Varian offers a complete selection of filters designed to be used in automated systems. These include our own VK 808 Filter Changer as well as the Caliper/Zymark MultiDose and TPW systems.

For information on Automation Filters for use with your VK 808 Filter Changer, see page 67.

Resident Cannula Kits

Where the insertion and removal of a sampling cannula is not mechanically practical, the resident cannula kit allows you to pull samples from a resident-dwelling probe.

Resident Cannula Kits

Item Description	Part Number
Resident Cannula Kit for Stainless Steel centering rings (set of 6)	12-0450
Resident Cannula Kit for EaseAlign centering rings for use with paddles (set of 6)	12-0455
Cannula and Bushing only (sampling 4.5 in.)	12-0447
Resident Cannula Kit for EaseAlign centering rings for use with baskets (set of 6)	12-0460
Resident Cannula Kit for EaseAlign centering rings (1 each)	12-0465
Cannula and Bushing (return 2.5 in.)	12-0467
Evaporation Cover only with UV-Vis adapter for use with EaseAlign centering rings	12-0468

Did you know that probes left in the media during a dissolution run will alter the hydrodynamics and hence the release rate? Most Varian dissolution apparatus offer motorized cannula insertion and removal capabilities as standard equipment or as an option. Should you elect to use resident dwelling probes, you should validate your method to ensure the release characteristics are not altered by the increased hydrodynamic disturbance.



Resident Cannula Kit



Sampling Manifold/Temperature Measurement

Motorized Sampling Manifold



Motorized Sampling Manifold

The motorized sampling manifold lowers with the touch of a button on the front panel of the VK 7000 or VK 7010. All of the sampling cannulas are lowered into the vessels simultaneously. Included is the manifold, internal drive motor, and all tubing and connections. The standard sampling manifold accommodates sampling within media volumes between 750 mL and 1L. Should your method require either a smaller or larger amount of media, other configurations are available. Ask your Varian representative for details.

Motorized Sampling Manifold

Item Description	Part Number
3+3 configuration	17-3350
4+2 or 4+4 configuration	17-3355

Manual Sampling Bracket



Manual Sampling Bracket

A semiautomated solution to single-timepoint tests

This simple attachment is ideal for single-timepoint dissolution tests where automation is not an efficient solution due to post-test cleaning requirements. The Varian manual sampling bracket increases reproducibility by reducing human error.

A Luer Lock connection is used to attach the syringe to the sampling bracket. At the correct time, lower the motorized manifold to the correct sampling location with the simple touch of a button. Samples are then manually pulled and filtered.

Manual Sampling Bracket

Item Description	Part Number
Luer Lock Fitting Bracket for manual sampling (requires	17-3150
sampling manifold)	17-5150

Temperature Measurement



Temperature Measurement with probe on left

AutoTemp In-vessel Temperature Sensing System

- · Individual vessel temperatures measured and recorded
- Monitor media temperatures and automatically start a test once all the vessels have stabilized

The AutoTemp System board plugs directly into the RS-232 serial port on your VK 7000/7010. AutoTemp measures individual in-vessel temperatures, transmitting them via the RS-232 serial port and displaying them on the status screen of your VK 7000/7010. Temperature probes are lowered into the vessels by a motorized manifold and then removed as soon as temperatures have been measured to eliminate disturbances associated with resident dwelling probes during the test. The AutoTemp accessory is available factory installed when ordered with a new apparatus or can be retrofitted to an existing unit. You can program the frequency at which you wish to monitor and record the temperature.

AutoTemp with Internal Mounted Motor Drive

Item Description	Part Number
AutoTemp for 6 vessels, 3+3	12-0601
AutoTemp for 6 vessels, 4+2	12-0606
AutoTemp for 7 vessels, 4+3	12-0611
AutoTemp for 8 vessels, 4+4	12-0616

AutoTemp with Internal Connection, Without Motor Drive

Item Description	Part Number
AutoTemp for 6 vessels, 3+3	12-0651
AutoTemp for 6 vessels, 4+2	12-0656
AutoTemp for 7 vessels, 4+3	12-0661
AutoTemp for 8 vessels, 4+4	12-0666

Intrinsic Dissolution Apparatus/USP Apparatus 6

43

Intrinsic Dissolution Apparatus



Intrinsic Dissolution Apparatus

The Intrinsic Dissolution device allows the determination of the dissolution rate of a pure active pharmaceutical ingredient (API) by exposing the API with a constant surface area to dissolution medium. The Varian design is based on the modified Woods apparatus, as described in the USP, which has threaded rings on the inside of the die cavity to prevent the compacted API from falling out of the die cavity during analysis. The Varian device includes a stainless steel die cavity along with a hardened-steel, mirrored surface plate and punch used to compress the API into a pellet with the aid of a laboratory press. Also included are a shaft/holder and gasket ring to securely affix the die containing the API pellet to the dissolution apparatus. The intrinsic rate is determined by lowering and rotating the device into a dissolution vessel containing 37 °C dissolution medium and pulling samples until at least 10% of the API contained in the die has dissolved. The intrinsic dissolution rate is calculated by plotting the cumulative amount of API dissolved from the exposed surface area with respect to time.

Intrinsic Dissolution Apparatus

Item Description	Part Number
Standard USP design consists of holder, punch, and die with 0.5 cm ² exposed surface area (one set—surface plate	12-4100
not included)	
Standard USP design consists of holder, punch, and die with 0.5 cm ² exposed surface area (one set—surface plate not included) for use with V-Series	12-4105
0.125 cm² holder, punch, and die with 0.125 cm² exposed surface area (one set—surface plate not included)	12-4110
Intrinsic Die only for 0.5 cm ² exposed surface area	12-4120
Surface Plate (only one is required)	12-4130
Punch only	12-4140
Shaft and holder only	12-4150
Intrinsic Dissolution Apparatus for use with Varian 705-DS	12-4101

USP Apparatus 6 Rotating Cylinder



USP Apparatus 6 Rotating Cylinder

USP Apparatus 6 is used for testing transdermal patches. The rotating cylinder is manufactured of type 316 stainless steel. The two-piece design has a removable extension for larger patches. The four slots at the top of the cylinder improve media circulation.

USP Apparatus 6 Rotating Cylinder

Item Description	Part Number
USP 4.45 cm outside diameter	12-1360
2.5 cm outside diameter	12-1365
USP 4.45 cm outside diameter for use with VK 7025	12-1380
2.5 cm outside diameter for use with VK 7025	12-1385
Apparatus 6 for use with Varian 705-DS	12-1361

Did you know that intrinsic dissolution is the dissolution of an active substance under conditions of constant surface area expressed in terms of mg/time/cm²? Intrinsic dissolution is useful in studying the solubility characteristics of a pure drug substance.

Apparatus 5 - Paddle Over Disk Assembly

The Paddle Over Disk Assembly comes with the 316 stainless steel disk and Teflon locking ring (screens must be ordered separately). The Teflon ring holds the removable, replaceable screen in place.

Paddle Over Disk Assembly

Item Description	Part Number
Paddle Over Disk Assembly, 40 mesh screen, meets USP Apparatus 5 specifications	12-4200
Replacement Screens for P/N 12-4200, type 316 stainless steel (40 mesh screens), pack of 100	12-4210
Disassembly Tool for P/N 12-4200	12-4211
Paddle Over Disk Assembly, 56 mm opening (120 mesh screen)	12-4230
Replacement Screens for P/N 12-4230, pack of 100	12-4231
Disassembly Tool for P/N 12-4230	12-4232

Transdermal Patch Holder System

This type 316 stainless steel two-piece assembly provides an easy-to-use alternative to the USP Apparatus 5. The O-ring assembly eliminates the need for adhesives. The clam shell design secures the transdermal patch in place exposing only the active release area. It is designed for patches with an inactive perimeter around the release area. Custom holders (square, oblong) are also available—contact us!

Transdermal Patch Holder System

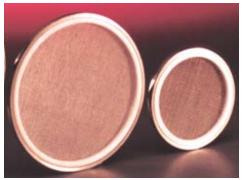
Item Description	Part Number
Release area 2.5 cm ²	12-4300
Release area 5.0 cm ²	12-4310
Release area 7.0 cm ²	12-4320
Release area 10.0 cm ²	12-4330

Suspension Cup

The suspension cup is a Teflon two-piece assembly. The weighted holder has a hemispheric bottom designed to sit in the bottom of a 1L dissolution vessel. The principle behind this is to control the surface area exposed to the media. The suspension is weighed in the center cup prior to the analysis. The removable center cup, available in two sizes, allows the suspension to be weighed and recorded and provides a controlled surface. Insert cup are sold separately.

Suspension Cup

Item Description	Part Number
Weighted Holder only, 5.72 cm outside diameter, 2.52 cm	12-4050
inside diameter, for suspensions	12-4050
Insert Cup only, 17.5 x 8.2 mm, use with P/N 12-4050	12-4055
(exposed surface area 2.405 cm², vol. 1.972 cm³)	12-4055
Insert Cup only, 20 x 8.2 mm, use with P/N 12-4050	12-4060
(exposed surface area 3.14 cm², vol. 2.576 cm³)	12-4060



Paddle Over Disk Assembly



Transdermal Patch Holder System



Suspension Cup

Products for Release Rate Studies

Enhancer Cell®

- Meets SUPAC stainless steel guidelines
- Ideal for use with topicals, such as ointments, creams and suspensions
- Can be used with traditional dissolution apparatus
- Available in surface areas of 4.0, 2.0, and 0.5 cm²
- Cost-effective alternative to the Franz Cell

The Enhancer Cell is a Teflon cell with adjustable volume and retaining cap to eliminate air pockets trapped against the skin or artificial membrane. The result is more consistent release rate data comparable to Franz cell technology. Designed for research, quality control, and product development laboratories, the Paddle over Enhancer Cell method provides release rate data for quality control of topicals using readily available dissolution apparatus, including 200 mL or standard 900 mL dissolution vessels, without the investment in fragile Franz Cells, pumps, and stirrers.

An alignment tool is used to hold the membrane in place while using the adjustment tool to set the volume adjustment plate. Only one alignment and adjustment tool are required per size. Enhancer Cells are sold separately.

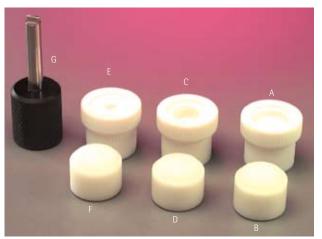
The Enhancer Cell does not include the vessel, paddle, or membrane/skin.

Enhancer Cell

Item Description	Part Number
Enhancer Cell, 4 cm ² only (A)	12-4000
Alignment Tool, 4 cm² only (B)	12-4010
Enhancer Cell, 2 cm ² only (C)	12-4001
Alignment Tool, 2 cm2 only (D)	12-4011
Enhancer Cell, 0.5 cm ² only (E)	12-4002
Alignment Tool, 0.5 cm ² only (F)	12-4012
Adjustment Tool only, for all sizes (G)	12-4015
Vessel, 200 mL, flat-bottom, self-aligning indentation, for use with Enhancer Cell	12-5055



Adjustment Tool, Enhancer Cell (disassembled), and Alignment Tool



Adjustment Tool, Enhancer Cells (assembled), and corresponding Alignment Tools

Did you know that many papers have been published using the Enhancer Cell technique? For more details, visit our Web site at www.varianinc.com or contact your Varian representative.



Vessel, Mini Paddle, and Enhancer Cell



QAII C[™] Dissolution Systems Suitability Station

Verify the key physical parameters of your dissolution apparatus

- No PC required
- Universal vessel adapter included for use with non-Varian dissolution Apparatus
- Designed to work in a 21 CFR Part 11 environment
- Works with most major brands of dissolution apparatus
- Supplied with NIST-traceable Certificate of Calibration
- Shipped in molded plastic case for storage and transportation of system

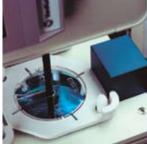
System Suitability Test Station

The QAII C base unit is the heart of the suitability testing system. It contains the keypad, LCD, and Report Center Printer. Five remote sensors plug into keyed jacks on the base unit's rear panel. Test data can even be downloaded to a PC through the RS-232 interface. The unit has a rechargeable battery for portable use, plus its own AC power supply for printing or recharging the battery. With its built-in handle, it can easily be transported from one dissolution apparatus to the next. This independent unit does not require a PC for use. Data output requires no user manipulation or interpretation.

Easy to Use, Traceable Results

A complete hard-copy printout from the station's dot matrix printer provides complete test results including space for approval signatures. Navigate easily through the intuitive menu to measure all parameters or only those of interest. The menu allows users to enter an identification number for each dissolution apparatus and the serial number for the vessel and paddle or basket shaft for each location. These values can also be printed on the test report.





Digital Wobble Gauge

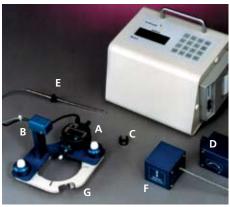
Vibration Sensor

21 CFR Part 11 Compliance

The OAII C has the ability to send data, as it is acquired, via the RS-232 port to a specially designed Excel™ spreadsheet application (included with each instrument) to capture the data. The user incorporates the data into their 21 CFR Part 11-compliant environment.

Stations include the following, as pictured below:

- Digital wobble gauge, mounted to an EaseAlign mounting bracket (A)
- Magnetic tachometer sensor attached to the EaseAlign mounting bracket (B)
- Magnetic RPM sensor (C)
- Electronic level sensor (also measures shaft perpendicularity) (D)
- Precision temperature probe (E)
- Electronic vibration sensor (F)
- Universal adapter for use with apparatus without EaseAlign centering systems (G)
- Calibrated shaft (not shown)



QAII C Dissolution System Suitability Test Station

Measures Essential Parameters Without the Guesswork

A specially designed bracket holds a wobble gauge and magnetic tachometer. The wobble gauge shows wobble in either inches or millimeters. The magnetic tachometer makes use of a collar with an embedded magnetic sensor which clips onto the paddle or basket shaft. With each revolution, the rotation is recorded and displayed on the LCD screen of the base unit.

An electronic level sensor measures the level of the vessel table as well as the perpendicularity of each shaft from side-to-side and front to back, and displays this in degrees.

To verify vessel as well as water bath temperature, a calibrated temperature probe is included.

The QAII C measures the four parameters of vibration: acceleration (g force), frequency (Hz), velocity (mm/sec.) or (in./sec.) and displacement (mm). Each of these is recorded in the X, Y, and Z axes via an electronic sensor.

Built-in Dot Matrix Printer

Test data can be printed via the Report Center Printer or, if desired, downloaded to a spreadsheet application for storage on a personal computer.

NIST-traceable Recertification of QAII Station

Varian will recertify your OAII or OAII C Station. Call our Service Department for packing instructions and Return Authorization Number (for tracking purposes) before returning your instrument. Equipment should be shipped in the original packaging to prevent damage during shipping.

NIST-traceable items include the wobble gauge, level sensor, temperature

Item Description	Part Number
Recertification of QAII C Station	12-7500

probe and the tachometer sensor. Call our Technical Service Department to have your OAII or OAII C Station recalibrated. Your calibration will be expedited and your instrument will be back in service as quickly as possible.

NIST Recertification

QAII Upgrade

If you own one of the earlier model units (QAII), it can be upgraded to a QAII C. The upgrade (P/N 12-0580) includes the new firmware chip and the disk containing the spreadsheet application. The QAII C upgrade changes the design of the QAII to facilitate use in 21 CFR Part 11 environments.

Also, if your OAII Station uses optical reflective clips, your station can be upgraded to use the magnetic tachometer sensor and clip. Call Varian for details.

Upgrade options

Item Description	Part Number
OAII Sensor Upgrade (magnetic)	12-7505
OAII to OAII C Firmware Upgrade	12-0580
Top Cover and Overlay Upgrade for existing QAII units	12-0585

Did you know deaeration is the process of removing dissolved gases from a liquid media? According to the USP, the method of deaeration is to heat the media to 41 °C with gentle stirring. "Filter under vacuum using a filter having a pore size of 0.45 μm or less with vigorous stirring and continue stirring under vacuum for approximately five minutes. Other validated deaeration methods can be used."



Protect your investment by shipping your QAII in this hard plastic carrying case.

QAII C

Item Description	Part Number
QAII C Station 115V, 60 Hz	12-0550
QAII C Station 230V, 50 Hz	12-0560

QAII C Replacement Parts

Item Description	Part Number
Universal Adapter for dissolution apparatus without the	12-9005
EaseAlign centering system	
Replacement Adapter, 4L vessels	12-9006
Replacement Calibration Shaft	12-9010
RPM Sensor Reflective Clip, black	12-9015
RPM Sensor Reflective Clip, white	12-9020
Magnetic RPM Sensor for 1/4 inch shaft	12-9021
Magnetic RPM Sensor for 3/8 inch shaft	12-9025
Plain Paper for Report Center II Printer, (pk of 10 rolls)	12-9995
Plain Paper for Report Center II Printer, (pk of 100 rolls)	12-9996
Ribbon Cartridge for Report Center II Printer, (pk of 5)	12-9997
Replacement Carrying Case for QAII C-hard plastic case	12-0531
with foam support inside	12-0551



VK 5010 CLH Measurement System

VK 5010 - Measures Shaft Centering and Height

Portable Traceable System for Physical Parameter Verification

- Provides absolute readings for shaft centering and paddle or basket height measuring
- Improves accuracy over manual gauges
- Takes digital measurements
- Shipped in molded plastic case for storage and transportation of system



For increased overall accuracy of your dissolution tests, this system utilizes easily calibrated and traceable gauges to measure the actual centerline offset for a shaft. It also measures the distance between the bottom of the paddle or basket and the inner apex of the bottom of the vessel.

Digital Measurements

The VK 5010 takes measurements digitally, eliminating visual interpretation and estimation and removing the likelihood of human error.

Reproducible Results and Hard Copy Printouts

Consistently reproducible results are viewable on the LCD display, and hard copy printouts are provided by the onboard printer.

Nonvolatile Memory

The VK 5010 is also capable of storing the following data in nonvolatile memory:

- Apparatus serial number
- Shaft ID
- Vessel ID
- Vessel position

The VK 5010 can store information for up to 30 apparatus at eight vessels per apparatus.

VK 5010

Item Description	Part Number
VK 5010 CLH Measurement System—centerline offset and height measurement, 115V or 230V, includes all necessary gauges	12-0540
Replacement Carrying Case—hard plastic case with cutouts for instrument and gauges	12-0531



VK 5010



VK 5010 Basket Height



VK 5010 Paddle Centering



VK 5010 Paddle Height Closeup

Height Spacers for USP Apparatus 1 and 2

The height spacers are easy to use and are designed for use with the VK 7000 and VK 7010. Height spacers (A) through (E) snap on the leg of the VK 7000-series apparatus and the one spacer sets all paddle or basket heights at the same time.

Height Spacers for USP Apparatus 1 and 2

Item Description	Part Number
Height Spacer, 3.25 in., for use with 100/200 mL vessels. Can also be used with standard dissolution vessels when more space between the head and the vessel plate is desired, simplifying manual sampling. This application requires 19 in. paddles. (A)	12-0321
Height Spacer for basket (B)	12-7210
Height Spacer for paddle (C)	12-7200
Height Spacer for use with 15 mm paddle and 100/200 mL round-bottom vessel (D)	12-0320
Height Spacer for use with Peak Vessels (E)	12-7220
Spherical Height Gauge (for use with paddles), without retrieval string, 25 mm	12-7240
Spherical Height Gauge (for use with paddles), with retrieval string, 25 mm	12-7250
Spherical Height Gauge, 38 mm for intrinsic dissolution (not shown)	12-7260
Height Gauge for paddles—attaches to paddles to position 25 mm above bottom of vessel. Serialized. (F)	12-7270
Calibrated, traceable certification for height gauge for paddles	12-7270V
Height Gauge for baskets—attaches to basket shaft to position 25 mm above bottom of vessel (G). Allows height to be set without using a basket.	12-7280
Calibrated, traceable certification for height gauge for baskets	12-7280V

Shaft Wobble Gauge

Designed to work with the EaseAlign pegs, these gauges indicate shaft wobble in 0.001 inch or 0.01 millimeter graduations and include a snap-in adapter for non-EaseAlign instruments.

Wobble Gauges

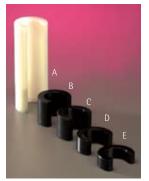
Item Description	Part Number
Digital Wobble Gauge	10-2429
Analog Wobble Gauge, reads in 0.001 inch increments	12-7000
Analog Wobble Gauge, reads in 0.01 mm increments	12-7020
Calibration Certification for thickness and wobble gauge	12-7520

Tachometer, Handheld

The handheld tachometer measures RPM with continuous updates each second. The measured value can be stored and read on the display by use of a slide switch. Unit includes conical and disk tips. The range is 1 to 19,999 with accuracy of \pm 1.0, \pm 0.5% of mean value. The power supply is a 9V battery.

Tachometer, Handheld

idenometer, mananera	
Item Description	Part Number
Tachometer	12-7100
Calibration Certificate for handheld tachometer	12-7110
Calibration Certificate with Calibration Data Sheet for handheld tachometer	12-7120



Height Spacers



Height Spacers



Analog Wobble Gauge

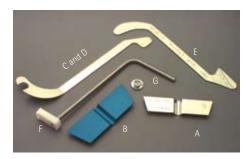


Handheld Tachometer



Height and Centering Tools

Height tools can be used with dissolution apparatus from any manufacturer.



Height Spacers for USP Apparatus 1 and 2

Item Description	Part Number
Centering Tool for use with stainless steel centering rings. Stainless steel gauge for setting the centering of 3/8 in. diameter basket or paddle shafts with dissolution vessels. (A)	12-7311
Centering Pass / Fail Gauge for use with EaseAlign centering rings. Aluminum gauge for checking the centering of 3/8 in. diameter basket or paddle shafts with dissolution vessels. (B)	12-7310
Height Tool, stainless steel, to accurately set the depth (25 mm) of the paddle or basket for USP Apparatus 1 and 2 dissolution tests. (C)	12-7300
Height Tool, stainless steel, similar to item (C) designed to accurately set the depth (25 mm) of the paddle or basket for 2 liter vessels with longer handle for deeper vessel. (D)	12-7301
Height Tool, stainless steel, similar to item (C) designed to accurately set the depth (45 mm) of the paddle or basket as required in some instances for dissolution testing of antibiotics. (E)	12-7330
Height Tool, special design, made of stainless steel and Delrin, to be used with Peak Vessels. (F)	12-7230
Circular Level for all-directional horizontal leveling. Base of level is 3/4 in. diameter. (G)	12-7320

Calibrated Timer

The dissolution rate is a function of time. It is critical you accurately withdraw sample within the USP-specified time frame (\pm 2% of the timepoint). This calibrated timer comes with an NIST-traceable certificate.



Calibrated Timer

Item Description	Part Number
Calibrated Timer with certificate	12-0040

Varian HPLC Columns



Varian HPLC Columns

Liquid chromatography instruments are widely used in dissolution testing in the pharmaceutical industry for multicomponent dosages. Varian has over 30 years of experience in the design and manufacturing of HPLC columns, which are at the core of any liquid chromatographic separation. We offer superior and rugged column lines for use in drug release profiles and content uniformity applications.

The basis of good chromatography is quality of the bonded phase and the bonding process. Varian HPLC columns are made in an ISO-regulated environment. As a result, performance of our columns from batch-tobatch is reproducible.

Guaranteed Performance

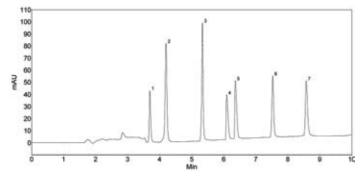
Varian HPLC columns undergo rigorous quality control testing to ensure long term reproducibility. Varian supplies each column with its actual Quality Control Certificate of Analysis showing the results with a standard test mixture of compounds.

Varian HPLC Columns for Dissolution Testing

Pursuit® XRs, Pursuit® and Polaris® lines of HPLC columns are ideally suited for dissolution testing applications. With its high resolution capabilities, Pursuit XRs is an excellent bonded phase for resolving multicomponent pharmaceutical tablets and dosages. For dissolution analysis applications that require high-speed chromatographic separation, Pursuit HPLC columns are recommended. The Polaris family of HPLC columns is ideal for pharmaceutical dosages that have polar active ingredients.

Resolution of Multicomponent Drugs

Varian's HPLC phases are ideal for separating multicomponent dosages, are robust and provide exceptional lifetime. Pursuit XRs columns provide excellent performance in separating multicomponent mixtures such as cold medicine seen below. Under generic mobile phase conditions, using UV detection, the Pursuit XRs C8 column provides excellent resolution of compounds widely used in cold medicine.



Pursuit XRs C8 Column: 150 x 4.6 mm, 5 μ Dimensions:

A: H₂O + 0.1% HCOOH, B: CH3CN + 0.1% HCOOH Mobile Phase:

Gradient: 10% - 75% B in 10 mins

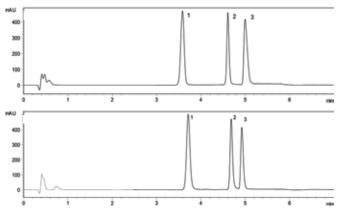
Flow Rate: 1.0 mL/min. Temperature: Ambient Detection: 254 nm

1. Doxylamine succinate, 2. Acetaminophen, 3. Chlorphenira Sample: mine maleate, 4. Dextromethorphan, 5. Diphenhydramine,

6. Acetylsalicylic acid (aspirin), 7. Salicylic acid

Robustness and Exceptional Lifetimes

Most dissolution systems operate in QA/QC laboratories. HPLC columns under such an environment have to be robust and have good longevity to minimize cost of analysis. Varian's HPLC columns have exceptional mechanical stability and excellent column life as seen in the chromatograms below.



Exceptional Pursuit XRs C18 Stability Shown in Injection 1 (top) and Injection 5000 (bottom)

Column: Pursuit XRs C18 50 x 2.0 mm, 5 μ Dimensions:

Mobile Phase: A: CH₃OH:H₂O - 10:90 + 0.1% HCOOH,

B: CH₃OH:H₂0 - 90:10 +0.1% HCOOH,

Gradient: 0% - 100% B in 3 minutes, back to 0% B in 0.5 mins, stay at

0% B for 3.5 mins

Flow Rate: 0.4 mL/min. Temperature: Ambient Detection: 254 nm

Sample: DMSO mix containing 1. 4-Methoxybenzenesulfonamide, 2. Methyl 3-aminothiophene-2-carboxylate, 3. Trimipramine

HPLC Column Selection

Choosing the type of HPLC column to use in a dissolution application depends on the column specifications in a validated test protocol or a pharmacopeial method. Though the protocol specifies the type of HPLC column (specifically bonded phase), the diameter, particle size and the length of the column are dependent on the flow and performance requirements.

USP Column Specification

Most dissolution applications are based on column specifications set forth by the USP or a similar standard. The chart on the next page is provided as a guide to selecting Varian's HPLC columns that can be referenced by a USP classification. USP specifications are quite broad and several column types meet the basic specifications. For example, an L1 specification calls for a column containing silica or ceramic particle bonded with octadecyl (C18) silane.

USP Column Specifications

USP Classification	Description	Varian Family of HPLC columns
L ₁	Octadecyl silane (ODS or C_{18}) chemically bonded to porous silica or ceramic particles – 3 to 10 μ m in diameter	Pursuit XRs C18 Pursuit C18 Polaris C18 A
L ₇	Octyl silane (C8) chemically bonded to porous silica or ceramic particles - 3 to 10 µm in diameter	Pursuit XRs C8 Pursuit C8 Polaris C8-A
L _{8*}	An essentially monomolecular layer of amino propylsilane (NH ₂) chemically bonded to porous silica gel support - 10 µm in diameter	Polaris 5 µm NH2
L ₂₁	A rigid, spherical styrene/divinylbenzene copolymer, 5 to 10 μm in diameter	PLRP-S

Varian offers 3 and 5 µm particle size alternatives where strict L8 compliance is not required and higher performance is desired.

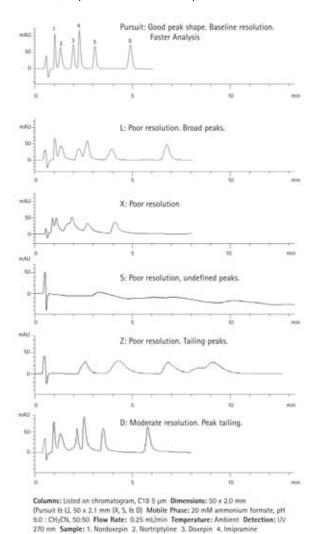
Particle Size of HPLC Bonded Phase

For increased efficiency and resolution, we recommend HPLC bonded phases that have spherical particles in 3 to 5 µm diameter.

Column Diameter and Length

Analytical column lengths and internal diameters such, as 150×4.6 mm column, is the commonly used dimension for most HPLC columns. However, unless resolution of different components is a major criterion, shorter length columns such as the 50×2.0 mm dimension, is most appropriate for dissolution applications.

TCAs at pH 9 on Pursuit C18 and competitive columns



5. Amitriptyline 6. Trimipramine

Many commercially available columns meet the basic USP specifications. However, all C18 columns are not alike. In side-by-side tests, Varian C18 columns outperform most equivalent phases when separating complex samples as seen in the chromatograms to the left.

Pursuit XRs – Ultrapure silica, 100 Å, 440 m²/g surface area – for extra resolution

USP Column	Phase	Particle Size	150 x 4.6 mm	50 x 2.0 mm
,	C10	3 μm	A6001150X046	A6001050X020
L ₁	C18	5 μm	A6000150X046	A6000050X020
_	00	3 μm	A6011150X046	A6011050X020
L ₇	C8	5 μm	A6010150X046	A6010050X020

Pursuit - Ultrapure silica, 200 Å - for rapid separations

USP Column	Phase	Particle Size	150 x 4.6 mm	50 x 2.0 mm
,	C18	3 μm	A3001150X046	A3001050X020
L ₁	CI8	5 μm	A3000150X046	A3000050X020
	Co	3 μm	A3031150X046	A3031050X020
L ₇	C8	5 μm	A3030150X046	A3030050X020

Polaris - Ultrapure silica, 200 Å, Polar embedded - for polar compounds

USP Column	Phase	Particle Size	150 x 4.6 mm	50 x 2.0 mm
	3 µт		A2001150X046	A2001050X020
L ₁	C18-A 5 μm	5 μm	A2000150X046	A2000050X020
	C8-A	3 μm	A2011150X046	A2011050X020
L ₇	Co-A	5 μm	A2010150X046	A2010050X020
	NH2	3 μm	A2014150X046	A2014050X020
L8*		NHZ	5 μm	A2013150X046

 $\textit{Varian offers 3 and 5} \ \mu \textit{m particle size alternatives where strict L8 compliance is not required and higher performance is desired.}$

PLRP-S – Copolymer of styrene and divinylbenzene – for analyses requiring extremes of pH and temperature

USP Column	Phase	Pore Size	Particle Size	250 x 4.6 mm	150 x 4.6 mm	50 x 2.0 mm						
			3 µm			PL1512-1300						
		100 Å	5 μm	PL1512-5500								
			8 µm	PL1512-5800								
	DC /DV/D	300 Å	5 μm	PL1512-5501								
L21	L ₂₁ PS/DVB	L ₂₁ PS/LVB	rs/DVB	rs/DVB	rs/byb	LOLDAD	rs/DVD	300 A	8 µm	PL1512-5801		
			1000 Å	8 µm	PL1512-5802							
		1000 A	10 µm	PL1512-5102								
		4000 Å	8 µm		PL1512-3803							

Ordering Information

For help with ordering, please contact our Technical Help Desk: helpdesk.us@varianinc.com (North and South America) helpdesk.eu@varianinc.com (Europe, Asia, Africa, Australia)

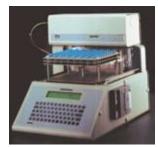


VK 8000 Dissolution Sampling Station for use with Apparatus 1 & 2

VK 8000 Dissolution Sampling Station

- Designed and built for one purpose—dissolution sampling
- Operates as an integrated system for fully automated sampling
- Patented autocalibration block (when used with peristaltic pump)
- Septum piercing capability—eliminates evaporative loss
- Retains up to 15 programs—including all pertinent dissolution apparatus parameters (when used with Varian dissolution apparatus)

The VK 8000 automates the tedious task of manually pulling samples. The sampling station can be configured with new dissolution apparatus or retrofitted to older models (Varian or other manufacturers). It is flexible enough to sample up to ten timepoints on a single tray (or twenty when two programs are linked). Media replacement is available as an option. Offered with a choice of Peristaltic or Syringe Pumps, it can even incorporate a filter changing option.



VK 8000 Sampling Station

The VK 8000 integrates with all models of Varian dissolution apparatus, as well as the BIO-DIS III (Apparatus 3) and Apparatus 7 (see page 98 for information on the VK 8000 for use with Apparatus 3 and 7). The system includes the VK 8000 Sampling Station, Peristaltic Pump (standard) for sample transfer, autocalibration block for volume accuracy, and automated sampling cannulas for use with Varian VK 7000/7010 (the V-Series, BIO-DIS III, and Apparatus 7 do not require a motorized manifold).

The VK 8000 can be used with all of Varian's dissolution apparatus from the Varian 705-DS to the all new V-series apparatus. Varian recommends the use of automated manifolds or cannulas to minimize hydrodynamic disturbances. For this reason we recommend the VK 7000-series or V-Series for automated sample collections. The Varian 705-DS can also be used, however it requires the use of resident dwelling probes.

Automatic Calibration

The patented autocalibration block is used in conjunction with the Peristaltic Pump to ensure accurate volume replacement. Calibration is as easy as pressing the calibration key. The volume removed is based on the time each individual valve is left open. The amount dispensed is individually determined for each line. The accuracy is independent of volume differences in the various tubing configurations.



Autocalibration Blocks (used with the Peristaltic Pump only)



VK 8000 Keypad



Septum Piercing

Septum Piercing Capability

Because the VK 8000 can pierce septa, you do not have to worry about evaporation distorting your results. The unique two-barrel needle design eliminates overpressurizing of the vial during filling. Overpressurized vials lead to reproducibility problems in autosamplers.

Motorized Manifold

The motorized manifold is utilized on the VK 7000 and VK 7010 to raise and lower sampling cannulas to the USP sampling location. The V-Series apparatus has individually controlled cannulas built into the drive unit. These cannulas are lowered into the precise sampling location, thus correcting the inaccuracy associated with the manual positioning of a handheld syringe. There are no stationary probes to change the hydrodynamics in the vessel.

Note that if you plan to use a VK 7000 or VK 7010 with a media volume other than 900 mL, please bring this to our attention. We will modify the sampling manifold so the sampling cannulas will be located in the correct sampling location The V-Series automatically samples from the correct location based on the programmed media function.

Media Replacement

The VK 8000 can be upgraded to include a media replacement option. This feature allows you the programming flexibility to return an equal volume of preheated media to each dissolution vessel after each sampling timepoint.

Simplified Control

When used in conjunction with a Varian dissolution apparatus, the VK 8000 controls the dissolution apparatus parameters. This means all of your operating parameters, including those of the dissolution apparatus, can be entered using the VK 8000 keypad. Additionally you can get a single printout of your test from the VK 8000 printer.

Sealed Switch-type Keypad

A fully functional keypad has been incorporated into the VK 8000 for the entry of methods and information. The control keys along the bottom row provide programming, calibration and program-cleaning functions in addition to manual control.

Automatic Documentation

No need to buy another printer. The built-in Report Center II Printer lets you print everything from system calibration verification to comprehensive test data even when the unit is unattended. Print full batch information downloaded from the dissolution apparatus—including unit ID number; operating temperature; water bath temperature; elapsed time; test length; RPM; sample timepoints; and depending on the model and configuration of the apparatus, vessel temperature and dosage delivery time.

VK 8000 Configurations/VK 8000 With Peristaltic Pump

55

VK 8000 with Peristaltic Pump



The VK 8000 is normally configured with a specially designed Peristaltic Pump. The bidirectional Peristaltic Pump is specifically designed to be used in dissolution (even allowing the use of surfactants without excessive foaming). By reversing directions, the lines can be purged while at the same time backflushing either in line or cannula tip filters. When used in conjunction with the patented autocalibration block, you are assured of accurate volume removal and replacement. We are able to achieve accurate volume removal using a Peristaltic Pump because the amount withdrawn is based on the time the sample valve is open to dispense. This time constant is different for each sampling line. In this manner, we are able to accurately withdraw to $\pm 0.5 \, \text{mL}.$

Each VK 8000 includes the following:

- Set of color coded Teflon tubing
- Set of 6 or 8 PEEK body sampling valves with needles for piercing septa—eliminating evaporation concerns
- 80-position sample tray (8 x 10) for 16 mm sample tubes (tubes included) or HPLC autosampler vials (vials not included); please specify type and size of tray; see page 63 for options
- Bidirectional Peristaltic Pump with transistor-transistor logic (TTL) actuated auto-reverse function
- Built-in Report Center II Printer
- 6- or 8-probe sampling manifold including motor drive if ordering for a VK 7000 or VK 7010 (not required for V-series)
- Accessory kit (includes pack of Peristaltic Pump tubing and starter packs of Full Flow Filters, 10, 35, and 70 µm pore size (50 each))

The VK 8000 easily accommodates optional media replacement (see page 59).

VK 8000 for use with Apparatus 1 & 2

VK 8000 Dissolution Sampling Station

Dimensions and Weight						
Size: Height 16 in. Width 16 in. Depth						
		40.6 cm		40.6 cm		50.8 cm
Weight:	72 lb/3:	2.4 kg	•			

Be sure to specify the configuration of your dissolution apparatus, including model, number of vessels, and volume.

VK 8000 with Peristaltic Pump

Item Description	Part Number
For use with Benchsaver, 3+3, 115V	15-1000
For use with Benchsaver, 3+3, 230V	15-1100
For use with 6-position apparatus, 4+2, 115V	15-1020
For use with 6-position apparatus, 4+2, 230V	15-1120
For use with 8-position apparatus, 4+4, 115V	15-1400
For use with 8-position apparatus, 4+4, 230V	15-1500
For use with V-Series and Varian 705-DS, 6-position configuration, 115V	15-3600
For use with V-Series and Varian 705-DS, 6-position configuration, 230V	15-3660
For use with V-Series and Varian 705-DS, 8-position configuration, 115V	15-3610
For use with V-Series and Varian 705-DS, 8-position configuration, 230V	15-3670

For information on the VK 8000 for use with Apparatus 3/Apparatus 7, see page 98.

VK 8000 Accessory Kits

Item Description	Part Number
Accessory kit, 6 or 8 valve, 16x100 mm vial tray	1001-1017
Accessory kit, 6 or 8 valve, 12x32 mm vial tray	1001-1018
Accessory kit, 12x12 mm Alza vial tray	1001-1019
Accessory kit, 12x12 mm vial tray	1001-1020



VK 8000 Configurations/VK 8000 With Syringe Pump

VK 8000 with Syringe Pump



VK 7010, Syringe Pump, and VK 8000

If chemical compatibility is a concern, or if you require even greater accuracy and reproducibility, then consider using a Syringe Pump with your VK 8000. This pump creates greater pressure to allow the use of an in-line filtering system with 0.45 μm filters. When using the Syringe Pump system, the volume accuracy is \pm 0.2 mL. When using the Syringe Pump in conjunction with the Filter Changer, the accuracy is \pm 0.3 mL.

The Filter Changer requires the greater pressure generation of the Syringe Pump. If your analytical finish is HPLC or if you may need this capability in the future, we suggest the Syringe Pump version which can be later upgraded to integrate the Filter Changer (see page 102 & 103).

VK 8000 for use with Apparatus 1 & 2

Be sure to specify the configuration of your dissolution apparatus, including model, number of vessels, and volume.

Note that if you have a 4+3 configuration apparatus, you should specify a 4+4 configuration Syringe Pump.

VK 8000 with Syringe Pump

Item Description	Part Number
For use with 6-position VK 7000/7010, 3x3, 115V,	15-7000
For use with 6-position VK 7000/7010, 3x3, 230V	15-7100
For use with 6-position VK 7000/7010, 4x2, 115V	15-7020
For use with 6-position VK 7000/7010, 4x2, 230V	15-7120
For use with 8-position VK 7000/7010, 4x4, 115V	15-7040
For use with 8-position VK 7000/7010, 4x4, 230V	15-7140
For use with V-Series, 6-position configuration, 115V	15-3620
For use with V-Series, 6-position configuration, 230V	15-3680
For use with V-Series, 8-position configuration, 115V	15-3630
For use with V-Series, 8-position configuration, 230V	15-3690

For information on the VK 8000 for use with Apparatus 3/Apparatus 7, see page 98.

VK 8000 Syringe Pump and Filter Change



VK 8000 with Filter Changer and Syringe Pump

- Filters and collects samples automatically (a variety of 25 mm filter types are available-see page 106)
- Changes filters (down to 0.45 μm membrane pore size) automatically between sample timepoints
- Programming is controlled from the VK 8000 base unit
- Utilizes a wide variety of automation-ready filters



Syringe Pump, Filter Changer

Next Step in Automation; Ideal for LC Methods

The combination of the VK 8000 with the Filter Changer and Syringe Pump allows you to take the next step in automating your dissolution testing. It provides a level of automation that was previously only found in full robotic systems.

The combination of the VK 8000 with Syringe Pump and Filter Changer allows you to run long dissolution tests with multiple timepoints unattended while guaranteeing precise sample volumes. In addition, you do not have to manually filter each individual sample prior to analysis. The samples collected on the VK 8000 will be taken at the correct time and will be ready for immediate analysis once acquired.

The Syringe Pump draws samples from a standard dissolution apparatus (Varian or other manufacturer) and ensures precise sample volumes.

Each sample is passed through a 25 mm membrane filter before being stored in a sealed collection tube or vial on the VK 8000 base unit. Varian offers special automation-ready filters (see page 106). Because the dissolution process continues until the filtration step is complete, it is important that filtration occur as soon as the sample is withdrawn. This equipment allows you to filter down to 0.45 µm at the time you take your sample.

The VK 8000 controls the Filter Changer to change the filters between each sample timepoint. It is possible to use the filters for a second timepoint before changing them.

Media replacement is available with the Filter Changer option.

VK 8000 with Syringe Pump and Filter Changer

Item Description	Part Number
For use with 6-spindle Benchsaver, 3+3, 115V, 60 Hz	15-2000
For use with 6-spindle Benchsaver, 3+3, 230V, 50 Hz	15-2100
For use with 6-spindle Easy Access, 4+2, 115V, 60 Hz	15-2020
For use with 6-spindle Easy Access, 4+2, 230V, 50 Hz	15-2120
For use with 8-spindle Easy Access, 4+4, 115V, 60 Hz	15-2400
For use with 8-spindle Easy Access, 4+4, 230V, 50 Hz	15-2500
For use with V-Series, 6-vessel configuration, 115V	15-3640
For use with V-Series, 6-vessel configuration, 230V	15-3700
For use with V-Series, 8-vessel configuration, 115V	15-3650
For use with V-Series, 8-vessel configuration, 230V	15-3710

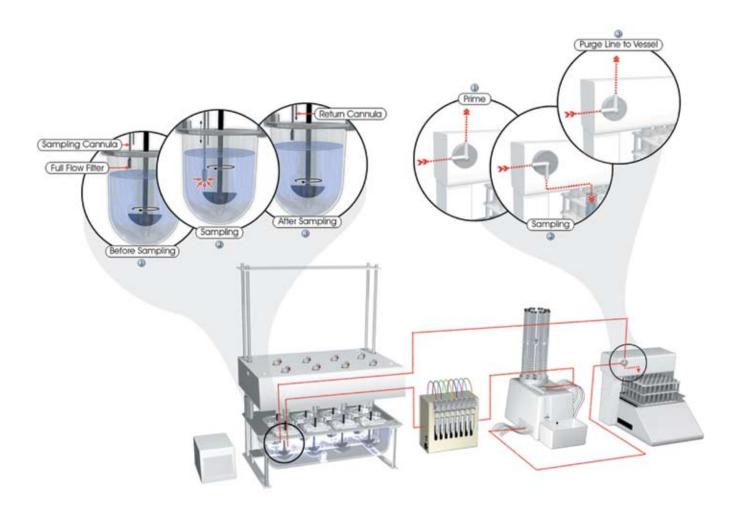


VK 8000 Syringe Pump and Filter Changer

VK 8000 with Filter Changer and Syringe Pump in conjunction with the VK 7000 or VK 7010

Media Flow Diagram

The VK 8000 signals the manifold to lower prior to a timepoint. The lines are then primed. At the appropriate sample timepoint the valves are opened and the sample is dispensed into the tube or vial. After sample collection, the manifold is raised and the Syringe Pump forces any media in the lines through the return cannula back into the vessel. The filters are automatically ejected and fresh ones moved into place.



VK 8000 Media Replacement Options

VK 8000 Media Replacement Options

- Accurately replaces media
- Media is preheated to 37 °C
- Quiet operation

These media replacement options are designed to work in conjunction with the bidirectional Peristaltic Pump as well as the Syringe Pump.

Internal Media Replacement Option for Easy Access Dissolution Apparatus



Internal Media Replacement Option for Easy Access Dissolution Apparatus

The internal media replacement option allows the operator to replace media equal to the programmed aliquots removed by the VK 8000. The right side panel is replaced with a panel that incorporates the Report Center printer and two pumps. All media replacement parameters are input via the VK 8000 keypad. This system requires one spare vessel be used as the media reservoir. Replacement medium is stored and kept at temperature in one of the unused vessels in the rear row of the dissolution apparatus. This option includes two pumps; one pump transfers medium from the vessel to the media rinse reservoir of the collector, and the other recirculates the medium to the vessel. Pumps are designed to minimize vibration and are chosen for their low shear-especially important where surfactants are used.

Media Replacement Option

Item Description	Part Number
Internal Media Replacement (requires VK 8000 sold separately)	17-0110

Did you know loss of active and media must be accounted for in the calculations? If media is replaced after each sample pull, then only the amount of active needs to be corrected. Both the amount of sample pulled and the concentration of active must be accounted for if media is not replaced after each pull.

Did you know Varian offers a FREE calculation program—available online at www.varianinc.com? This spreadsheet makes it easy to determine the precise amount of the active in your sample, taking into account the amount of media withdrawn at each timepoint (whether media is replaced or not) and the amount of active withdrawn in each previous sample. Go to the Dissolution section of the Varian, Inc. web site. Click on Laboratory Services.



Peristaltic Pump/Cartridges/Tubing

Peristaltic Pump

- Flexible—can be configured for 6, 7, 8, 12, 14, or 16 channels
- Bidirectional
- Low gear ratio—allows use with surfactants



Peristaltic Pump

The Peristaltic Pump has a 16-channel maximum capacity for sample transfer in all Varian dissolution sampling systems, and an 8-roller design for smooth flow. There is bidirectional TTL actuated operation for pumping and purging. The flow rate is 25 mL/min. (nominal). Part numbers listed below include 0.110 in. inside diameter Marprene tubing and adjustable pump cartridges. The patented autocalibration block on the VK 8000 ensures accurate volume removal and replacement. The Peristaltic Pump has a sampling accuracy of \pm 0.5 mL.

Peristaltic Pump

Dimensions and Weight						
Size:	Height 5.5 in. Width* 6 in. Depth 18 in.					
		13.97 cm		15.2 cm		45.72 cm
Weight:	19 lb/9	19 lb/9 kg				

^{*} With cartridge and tubing connectors

Peristaltic Pump

Item Description	Part Number
6-channel Peristaltic Pump, 115V, 60 Hz	17-2000
6-channel Peristaltic Pump, 230V, 50 Hz	17-2100
8-channel Peristaltic Pump, 115V, 60 Hz	17-2200
8-channel Peristaltic Pump, 230V, 50 Hz	17-2300
16-channel Peristaltic Pump, 115V, 60 Hz	17-2600
16-channel Peristaltic Pump, 230V, 50 Hz	17-2700

Includes Marprene pump tubing and adjustable pump cartridges.

Did you know surfactants are substances that lower the resistance between immiscible liquids? Surfactants fall into three categories:

- 1. Detergents
- 2. Wetting agents
- 3. Emulsifiers

Peristaltic Pump Cartridge

Individual replacement cartridge for Peristaltic Pumps with adjustable tensioning arm (P/N 17-2000 through P/N 17-2700).



Peristaltic Pump Cartridges

Replacement Peristaltic Pump Cartridge

Item Description	Part Number	
Peristaltic Pump Replacement Cartridge, sold separately	17-6020	

Peristaltic Cartridge Tubing

Peristaltic Pump cartridge tubing is available in durable and chemicalresistant Neoprene, conventional silicone, and Viton. All types are coded purple and white with a 0.110 inch inside diameter. Package of eight pieces.

Peristaltic Cartridge Tubing

Item Description	Part Number
Peristaltic Cartridge Tubing, silicone	17-6010
Peristaltic Cartridge Tubing, Viton	17-6005
Peristaltic Cartridge Tubing, Neoprene	17-6000

Replacement Teflon Tubing for use with Peristaltic Pump

Item Description	Part Number
Teflon Tubing for 3+3 Benchsaver, 6 lengths of 50 feet	17-6030
Teflon Tubing for 4+2 Easy Access and VK 7025/7030, 6 lengths of 50 feet	17-6031
Teflon Tubing for 4+2 Easy Access and VK 7025/7030, 8 lengths of 50 feet	17-6035

Teflon tubing is used from the sample and return cannula to the peristaltic pump.

VK 806 Syringe Pump



VK 806 Syringe Pump

- Precise delivery
- 10 mL syringes standard
- Uses Teflon tubing and PEEK valves

The Syringe Pump draws samples from a Varian dissolution apparatus and ensures precise sample volumes. Due to the accuracy of the Syringe Pump, the auto calibration block which is used with the Peristaltic Pump is not required.

The Filter Changer requires the greater pressure generation of the Syringe Pump. If you plan to add this capability to your system at a later date, we suggest you consider the Syringe Pump. See page 62 for information on this combination of accessories.

When using the Syringe Pump we recommend Teflon tubing with an inside diameter of 0.04 in. This tubing is supplied with all new sampling cannulas ordered with Syringe Pumps. If you are retrofitting an existing sampling manifold, tubing is available in six or eight individual 50 foot color coded lengths. When changing the tubing it is important to maintain the proper tubing lengths between components. Detailed instructions are included with the tubing packages.

VK 806 Syringe Pump

Dimensions and Weight						
Size:	Height	10.75 in.	Width	9.5 in.	Depth	6 in.
		27.31 cm		24.13 cm		5 cm
Weight:	14 lb/6	kg				

Specifications			
	Syringe Pump and VK 8000	Syringe Pump with Filter Changer and VK 8000	
Sampling Accuracy	± 0.2 mL (2%)	± 0.3 mL (3%)	
Minimum Sample Interval	5 min.	6 min.	
Sample Volume	1 - 14 mL	1 - 14 mL	
Filter Type	Full Flow Cannula UHMWPE	Syringe ≥ 0.45 μm (Automation Certified)	

The following part numbers are for upgrading your existing VK 8000 with Peristaltic Pump to a VK 8000 with Syringe Pump.

Syringe Pump for VK 8000 Upgrade

Includes all the necessary accessories required, including the new ROM chip and sampling cannulas, Teflon tubing, and cables.

Item Description	Part Number
Syringe Pump Upgrade for 6-channel system 115V, 60 Hz	15-5101
Syringe Pump Upgrade for 6-channel system 230V, 50 Hz	15-5111
Syringe Pump Upgrade for 8-channel system 115V, 60 Hz	15-5100
Syringe Pump Upgrade for 8-channel system 230V, 50 Hz	15-5110

Replacement Syringes for the VK 806 Syringe Pump

Replacement Syringes for the VK 806 Syringe Pump

Item Description	Part Number
Glass Syringe with threaded fitting, 10 mL	1003-0167

VK 808 Filter Changer

- Automatic filter changing between each sample timepoint
- Special 25 mm filters designed for automation
- A full range of filters are available (see page 106)
- Pore sizes down to 0.45 µm



VK 808 Filter Changer

The Filter Changer is designed to be used in conjunction with the Syringe Pump. This unit can easily be added to an existing VK 8000 AutoSampler.

The Filter Changer is designed to filter six, seven, or eight lines simultaneously and can store up to 200 filters at a time. The filters come prepackaged in tubes of 25 for easy loading. See page 106 for automation filters.

When used with the VK 8000, all of the parameters are set using the VK 8000 keypad. A complete sequence of operations can be found on page 103.

You are assured of the proper sample volume being withdrawn due to the accuracy of the Syringe Pumps. These syringes provide a sampling accuracy of \pm 3% when used with the Filter Changer and \pm 2% when used without the Filter Changer.

You can order the Filter Changer to retrofit existing VK 8000s. For these systems a new ROM chip is installed in the VK 8000 and the unit is retrofitted with a Syringe Pump to replace the existing Peristaltic Pump.

See pages 102–103 for additional information.

When ordering, please specify the serial number of your existing VK 8000.

VK 806 Syringe Pump and VK 808 Filter Changer

The following part numbers are for upgrading your existing VK 8000 with Peristaltic Pump to a VK 8000 with Syringe Pump and Filter Changer.

Syringe Pump and Filter Changer for VK 8000 Upgrade

Includes all the necessary accessories required, including the new ROM chip and sampling cannulas, filter catch basin, Teflon tubing, and cables.

Item Description	Part Number
Syringe Pump/Filter Changer Upgrade for 8-channel system 115V, 60 Hz	15-5000
Syringe Pump/Filter Changer Upgrade for 8-channel system 230V, 50 Hz	15-5010

The following part numbers are for upgrading your VK 8000 with Syringe Pump to include a Filter Changer.

Filter Changer for VK 8000 with Syringe Pump Upgrade

Includes all the necessary accessories required, including the new ROM chip and sampling cannulas, filter catch basin, Teflon tubing, and cables.

Item Description	Part Number
Filter Changer Upgrade for 6-channel system, 115V	15-5004
Filter Changer Upgrade for 6-channel system, 230V	15-5008
Filter Changer Upgrade for 8-channel system, 115V	15-5002
Filter Changer Upgrade for 8-channel system, 230V	15-5006

VK 808 Filter Changer

Dimensions and Weight						
Size:	Height*	25 in.	Width	9.5 in.	Depth**	24 in.
		63.5 cm		24.1 cm		61 cm
Weight:	38 lb/17	'.1 kg				

^{*}Height is with filter tubes inserted for use; **Depth is with filter drop bucket in place for use.

VK 808 Filter Changer

Specifications		
	Syringe Pump with Filter Changer and VK 8000	
Sampling Accuracy	± 0.3 mL (3%)	
Minimum Sample Interval	6 min.	
Sample Volume	1 - 14 mL	
Filter Type	Syringe ≥ 0.45 μm (Automation Certified)	

VK 8000 Sample Trays/Report Center Retrofit Kit



VK 8000 Sample Trays

We offer a variety of sample trays to work with many different tubes and vials. If you do not see your size below, call your Varian representative.



VK 8000 Sample Trays

VK 8000 Sample Trays

Item Description	Part Number
16 x 100 mm (~13 mL) open tube	17-1000
15 x 85 mm (~10 mL) open tube	17-1010
For 8 x 30 mm HPLC vials	17-1020
For 7 x 40 mm HPLC vials	17-1030
For 8 x 40 mm HPLC vials	17-1040
For 12 x 32 mm HPLC vials	17-1050
For 15 x 45 mm HPLC vials (VK 8020)	17-1060
For 15 x 45 mm HPLC vials (VK 8000)	17-1065
For 13 x 75 mm HPLC vials (VK 8000)	17-1070
For 13 x 100 mm HPLC vials (VK 8000)	17-1075
For 12 x 75 mm HPLC vials (VK 8000)	17-1080

VK 8000 Glass Sample Tubes

These disposable sample tubes are for use with VK 8000 sample trays (P/Ns 17–1000 and 17–1010). Tubes are sold in packs of 250.

VK 8000 Glass Sample Tubes

Item Description	Part Number
16 x 100 mm (13 mL), standard	17-5001
15 x 85 mm (10 mL)	17-5010

Report Center II Retrofit Kit

The retrofit kit is available for updating the VK 8000 from a thermal printer to a dot matrix printer (for permanent record keeping). This-RoHS-compliant printer is attached externally to your VK 8000.



Report Center II Printer

Report Center II Accessories

Item Description	Part Number
Report Center Printer II Retrofit	17-1400
Replacement Ribbons, pk. of 5 ribbons	12-9997
Plain Paper, 2.25 in. wide, pk. of 10 rolls	12-9995
Plain Paper, 2.25 in. wide, case of 100	12-9996

HPLC Vials



HPLC Vials

Disposable HPLC vials include polypropylene Snap Caps with PTFE / Silicone Septa (packaged separately).

HPLC Vials

Item Description	Part Number
12 x 32 mm (2 mL) clear glass with caps, pk. of 100	17-5020
15 x 45 mm (4 mL) clear glass with caps, pk. of 100	17-5030

Rinse Trays



Rinse Trays

This PVC tray fits over vessels in Varian six-, seven-, or eight-position dissolution apparatus (VK 7000 or VK 7010). Fill with water for easy flushing and rinsing of sampling lines between tests using the VK 8000 clean system function.

Rinse Trays

Item Description	Part Number
Rinse Tray for 6-position Benchsaver	17-1300
Rinse Tray for 8-position Easy Access	17-1310

Rinse Tray for V-Series

Due to the unique shape of the V-Series apparatus, the rinse tray is triangular. The tray holds eight cleaning reservoirs. Deionized water or clean media is placed in the reservoirs and the sampling cannulas are lowered into position to clean the lines.

Caps are included with the reservoirs to make transporting the rinse tray spill proof. The reservoirs are easily removed for emptying and cleaning.

Rinse Tray for V-Series

Item Description	Part Number
V-Series Cleaning Tray with Reservoirs	17-1320
Replacement Reservoirs with covers	17-1321

Did you know that when filtering, you should use an inert filter that does not cause adsorption of the active ingredient or contain extractable substances that would interfere with the analysis?

Calibration Tubes



Calibration Tubes

Calibration tubes are for use with the VK 8000 when using a Peristaltic Pump to verify the autocalibration. Tubes are prescored for volume verification.

Calibration Tubes

	Item Description	Part Number
Ca	alibration Tubes 10 mL (set of 8)	17-5040

Replacement Syringes for the VK 806 Syringe Pump

Replacement Syringes for the VK 806 Syringe Pump

Item Description	Part Number
Glass Syringe with threaded fitting, 10 mL	1003-0167

Media Rinse Reservoir



Media Rinse Reservoir

This replacement unit is for all VK 8000 sampling stations. The dual-chambered PVC reservoir is located in front of the autocalibration block The first chamber is used to rinse the needles and prevent cross contamination. The second chamber holds replacement media for withdrawal by the VK 8000 sample needles.

Media Rinse Reservoir

Item Description	Part Number
Media Rinse Chamber, VK 8000	17-1200

Automated Sampling Manifolds/Sampling Cannulas

65

Automated Sampling Manifolds



Automated Sampling Manifold

Automated sampling manifolds consist of a motor drive and manifold with type 316 stainless steel sampling and return cannulas. Upon command from the VK 8000 (or a PC), the motor drive lowers and then raises the cannulas into and out of the vessel. This minimizes the possibility of creating turbulence within the vessel. When used with VK 7000 and VK 7010 series instruments, the motor drive mounts internally. All automated manifolds are supplied with 6 feet of color-coded Teflon tubing and fittings.

Internal Motor Drive and Manifold

Item Description	Part Number
Benchsaver 3+3 (1L vessel)	17-3000
Easy Access 4+2 (1L vessel)	17-3005
Easy Access 4+3 (1L vessel)	17-3010
Easy Access 4+4 (1L vessel)	17-3015
Use with 200 mL vessels with mini paddles, 3+3	17-3030

Internal Motor Drive Only

Item Description	Part Number
Benchsaver 3+3	12-0200
Easy Access 4+2, 4+3, and 4+4	12-0205

Manifold Only

For use with internal motor drive (not included).

Item Description	Part Number
For use with Benchsaver, 3+3 (1L vessel)	17-3100
For use with Easy Access, 4+2 (1L vessel)	17-3102
For use with Easy Access, 4+3 (1L vessel)	17-3105
For use with Easy Access, 4+4 (1L vessel)	17-3107
For use with Benchsaver, 3+3 (200 mL vessel)	17-3115
For use with Easy Access, 4+2 (200 mL vessel)	17-3117
For use with Easy Access, 4+3 (200 mL vessel)	17-3118
For use with Easy Access, 4+4 (200 mL vessel)	17-3116
For use with UV Dissolution System, Easy Access, 4+3 and 4+4	17-3120

Sampling Cannulas

These cannulas are for use with the VK 8000 when used with an Apparatus 1 or 2. For replacement cannulas when working with a VK 8000 with Apparatus 3 or 7, see page 105.



Sampling Cannulas

Sample / Return Cannulas

The sample / return cannulas are fabricated of type 316 stainless steel. The 1/8 inch diameter includes a plastic sleeve for attachment of a cannula filter.

Item Description	Part Number
Cannula, 4.5 in.	17-3300
Cannula, 6.5 in.	17-3305
Cannula, 8.12 in., for 2L vessel	17-3307
Cannula, 10 in., for 4L vessel	17-3309
Cannula, 2.25 in.	17-3320

Return Cannulas



500 mL Cannula Extension

The return cannulas are fabricated of type 316 stainless steel.

500 mL Cannula Extension

Our standard sampling manifolds are designed to withdraw samples from 900 mL at the USP sampling point—halfway between the top of the paddle or basket and the top of the media.

The cannula extension is manufactured from type 316 stainless steel and is 1 1/8 inch in length. One end is fitted with a Teflon adapter that is press fit to the cannula. The Full Flow Filter attaches to the other end. When the extension is in place, the cannulas are in the correct location to sample from 500 mL within a 900 mL vessel. Some minor adjustment of

500 mL Cannula Extension

Item Description	Part Number
500 mL Cannula Extension	17-3306



Full Flow Filters®

Full Flow Filters are made of ultrahigh molecular weight polyethylene (UHMWPE) or polyvinylidene fluoride (PVDF) and are for use with 1/8 inch cannulas. The design of the Full Flow Filter optimizes the filter life by providing increased surface area. The filters are color coded to aid in identifying the correct pore size.

UHMWPE Filters

These filters are designed to fit on the ends of the sampling cannulas. The entire surface area is porous to allow excellent flow characteristics. The UHMWPE filters are color coded to distinguish the various pore sizes.



UHMWPE Filters

UHMW Filters

Item Description	Part Number
Blue, 10 µm, pk. of 100	17-4000
White, 35 μm, pk. of 100	17-4010
Red, 70 μm, pk. of 100	17-4020



PVDF Filters

For greater chemical resistance, we now offer filters constructed of new material: porous polyvinylidene fluoride (PVDF). The PVDF filter is a low protein-binding material which filters a greater variety of active drug substances. Some drugs bind to other filters or even react to them. The new PVDF offers a solution to these active drug substances which may absorb onto polyethylene fluoride materials. Filters are color coded to aid in identifying the correct pore size.

PVDF Filters

Item Description	Part Number
Green, 10 μm, PVDF, pk. of 100	17-4040
Yellow, 35 μm, PVDF, pk. of 100	17-4050

Conventional Filter Tips

Filter tips for 1/8 inch cannulas are made of polyethylene.



Conventional Filter Tips

Conventional Filter Tips

Item Description	Part Number
2 μm, pk. of 100	17-4100
5 μm, pk. of 100	17-4110
10 μm, pk. of 100	17-4120
20 μm, pk. of 100	17-4130
45 μm, pk.of 100	17-4140

Cannula Housing Filter for use with Varian 705-DS

These filters are specially designed to be easily removed from the 705-DS cannula housing. They are available in your choice of 35 or 70 μ m in ultrahigh molecular weight polyethylene (UHMWPE).

Cannula Housing Filter for Varian 705-DS

Item Description	Part Number
Cannula Housing Filter, 35 μm, UHMWPE, pk. of 100	17-4300
Cannula Housing Filter, 70 µm, UHMWPE, pk. of 100	17-4310

Automation Filters



Automation Filters

These specially designed automation filters are constructed to prevent compression on the membrane and allow flow. Glass fiber as well as other membrane types are available. Call Varian for more details. Filters are sold in packages of 200 and prepackaged in sleeves of 25 (these filters are ready for loading in the VK 808 Filter Changer).

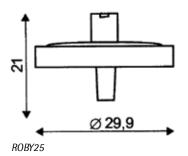
The filter housing is made from rigid polypropylene and is pressure resistant. They provide reproducible results and have been thoroughly tested in the VK 808 Filter Changer.

Whatman / S&S ROBY Automation Filters

- Pressure-resistant design
- Made from rigid polypropylene
- Provides reproducible results
- Available with membrane and glass fiber prefilter or glass fiber prefilter alone
- Low extractables depending on membrane type

ROBY25 Product Specifications

Specifications		
Filter diameter:	25 mm	
Effective filter area:	4.2 cm ²	
Recommended filtration volume:	≤100 mL	
Dead volume:	≤ 50 µL	
Maximum operating pressure:	5 bar	
Connections inlet:	Luer Lock inner core (female)	
Connections outlet:	Luer outer cone (male)	
Temperature resistance:	60 °C	
Housing material:	polypropylene	



Whatman / S&S ROBY Automation Filters

Item Description	Part Number
ROBY25/GF 92, 1/glass fiber, neutral, 1000 per pk.	17-4150
ROBY25/GF 92, 1/glass fiber, neutral, 200 per pk.	17-4151
ROBY25/0.45NL, 0.45/nylon, printed, 1000 per pk.	17-4152
ROBY25/0.45NL, 0.45/nylon, printed, 200 per pack.	17-4153
ROBY25/0.45NL - GF 92, 0.45/nylon-glass fiber, yellow, 1000 per pk.	17-4154
ROBY25/0.45NL - GF 92, 0.45/nylon-glass fiber, yellow, 200 per pk.	17-4155
ROBY25/0.45RC, 0.45/regenerated cellulose, printed, 1000 per pk.	17-4156
ROBY25/0.45RC, 0.45/regenerated cellulose, printed, 200 per pk.	17-4157
ROBY25/0.45RC-GF 92, 0.45/regenerated cellulose-glass fiber, brown, 1000 per pk.	17-4158
ROBY25/0.45RC-GF 92, 0.45/regenerated cellulose-glass fiber, brown, 200 per pk.	17-4159
ROBY25/0.45CA-GF 92, 0.45/cellulose acetate-glass fiber, green, 1000 per pk.	17-4160
ROBY25/0.45CA-GF 92, 0.45/cellulose acetate-glass fiber, green, 200 per pk.	17-4161
ROBY25/GF 55, ~0.7 glass fiber, brown, 1000 per pk.	17-4164
ROBY25/GF 55, ~0.7 glass fiber, 200 per pk.	17-4165



Automation Filter Validation Kit

Varian has prepared a Filter Validation Kit for use with the VK 808 Filter Changer. This kit is a sample pack that includes 25 each of eight different Schleicher & Schuell ROBY25 automation filters and a filter validation quide. The filter housing is made from rigid polypropylene and is pressure resistant. They provide reproducible results and have been thoroughly tested in the VK 808 Filter Changer. The filters are available in a variety of membranes and will be offered in packages of 200 or 1000.

Item Description	Part Number
Filter, 1.0 µm APFB glass fiber prefilter for processing and clarification of aqueous and organic solutions containing high particle levels	17-4200
Filter, 0.45 µm how protein binding PVDF membrane for processing and clarification of aqueous and mile organic solutions	17-4210
Filter, 0.45 µm nylon membrane for processing and clarification of aqueous and mile organic solutions	17-4220

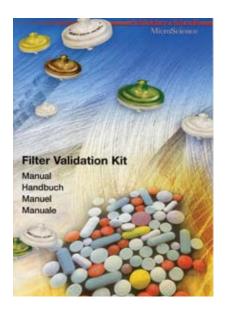
Filter Validation Kit

Selecting the right filter media is simple with the Filter Validation Kit. The kit contains eight different types of filters (the kit includes 25 of each different membrane type) from Whatman/Schleicher & Schuell MicroScience. Included with the kit is a filter selection guide and filter validation protocol to assist you in choosing the right membrane.

The filters are distinguished in three categories:

- 1. Glass fiber filter media (depth filter)
- 2. Membrane filter media (surface filter)
- 3. Membrane plus glass fiber prefilter

Follow the three test procedures included in the Filter Validation Kit and you'll determine the best filter for your application.



Automation Filters

NEW

Category	Filter Material	Product Name	Pore Size	Recommended Application
I	Glass fiber filter (GF) 92	Roby 25/ GF 92	1.7 μm	The standard for difficult-to-filter samples to retain coarse particles
I	Glass fiber filter (GF) 55	Roby 25/ GF 55	0.7 μm	The best filter for gelatinous capsules
II	Regenerated Cellulose Membrane (RC)	Roby 25/ 0.45 RC	0.45 μm	The best choice for HPLC application
Very low protein bin	Very low protein binding, better than PVDF - Very low extractables			
II	Cellulose Acetate Membrane (CA)	Roby 25/ 0.45 CA	0.45 μm	Extremely low protein binding, better than PVDF
II	Polyamide/Nylon Membrane (NL)	Roby 25/ 0.45 NL	0.45 μm	Robust membrane for applications where protein binding is not critical
III	Membrane plus Glass Fiber Pre filter	Roby 25/ 0.45 RC-GF 92 Roby 25/ 0.45 CA-GF 92 Roby 25/ 0.45 NL-GF 92 0.45	0.45 μm	When a membrane filter gets clogged and a glass fiber filter alone is not suitable

Filter Validation Kit

Item Description	Part Number
Filter Validation Kit	17-4195



Replacement Sample Tubing

This tubing is recommended for use with the Peristaltic Pump. Standard 0.066 inch outside diameter and 0.042 inch inside diameter color-coded Teflon tubing is available in six or eight individual 50 foot lengths. When changing the tubing, it is important to maintain the proper tubing lengths between components. Detailed instructions are included with the tubing packages.

Replacement Sample Tubing for Peristaltic Pumps

Item Description	Part Number
Teflon Tubing for 3x3 Benchsaver and VK 7025/7030, 6 lengths of 50 feet	17-6030
Teflon Tubing for 4x2 Easy Access and VK 7025/7030, 6 lengths of 50 feet	17-6031
Teflon Tubing for 4x4 Easy Access and VK 7025/7030, 8 lengths of 50 feet	17-6035

Adapters

Adapters connect Teflon tubing to Peristaltic Pump tubing.

Item Description	Part Number
Adapters, packs of 24	17-6050

Connectors

Nut and ferrule connectors allow easy connection of Teflon tubing.

Item Description	Part Number
Nut and ferrule connectors	17-6070



Color-coded Teflon Tubing

Replacement Tubing for the VK 8000 and UV Dissolution Systems

Varian offers sampling tubing for our VK 8000 autosampling and online UV Dissolution systems. The tubing is made from fluorinated ethylene propylene (FEP) which is softer and more flexible than tetrafluoroethylene (TFE). The added flexibility of the FEP tubing reduces the incidence of line crimping and sample flow blockage..

Replacement tubing for 4x4 instrument, with UV System, Peristaltic Pump and VK 7000 or VK 7010

Item Description	Part Number
Tubing Assembly, from pump to spectrophotometer	1005-1674
Tubing Assembly, from spectrophotometer to return cannual	1005-1784
Tubing Assembly, from sampling cannula to pump	1005-1785
Fitting, attaches to Peristaltic Pump	3090-0159

Replacement for UV System with VK 8000, Syringe Pump and VK 7000 or VK 7010

Item Description	Part Number
Tubing Assembly, from pump to autosampler	1005-1674
Tubing Assembly, from autosampler to return cannual	1005-1784
Tubing Assembly, from sampling cannula to pump	1005-1785

Replacement for UV System with VK 8000, Syringe Pump, Filter Changer and VK 7000 or VK 7010

Item Description	Part Number
Tubing Assembly, from pump to autosampler	1005-1674
Tubing Assembly, from Filter Changer to Syringe Pump	1005-1729
Tubing Assembly, from autosampler to return cannual	1005-1784
Tubing Assembly, from sampling cannula to pump	1005-1785

VK 8020 Sample Collector/Injector

VK 8020 Sample Collector and HPLC Auto-Injection Station

- Automatic sample collection and injection
- Compatibility with virtually any HPLC system
- Standard tray accommodates 15 x 45 mm (4 mL) vials, and other trays are available (see page 63 for other vial sizes)

To increase productivity, the VK 8020 automates both dissolution sample collection and HPLC injection.

Samples are pulled using the motorized sampling cannulas and deposited into an empty vial in the collection tray. Injections onto the LC column occur between sampling timepoints.

Sample collection always takes precedence over sample injections. During a sample point, the injector module goes into standby mode, returning to its task only at the end of the timepoint.

You can program injection intervals from 1 to 99 minutes or wait for the ready signal from the LC. It is possible to inject standards before or after, or bracket each group of samples. Standards and blanks are stored on two rows of the collection tray.

The VK 8020 can be used as a collector only, or as an HPLC auto-injector. You can independently program the number of standard injections to meet the USP system suitability requirements. The automated sampling cannula automatically lower and raise during the sampling cycle and the Peristaltic Pump transfers the samples from the vessels to the collector.

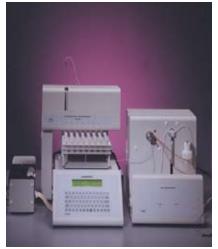
Should you wish to use our Syringe Pump and Filter Changer with the VK 8020, this configuration is possible with our Dissolution Workstation software (see page 72).

The VK 8020 modules:

- Base station including sipper assembly with needle
- Injector module with Rheodyne 7710 valve and 20 μl loop

VK 8020 HPLC Auto-injection Station

Specifications		
Sampling Module Injector Modu		Injector Module
Width:	15.3 in./39 cm	13.25 in./34 cm
Height:	16 in./41 cm	13.25 in./34 cm
Depth:	20.5 in./52 cm	18 in./46 cm
Weight:	72 lb/33 kg	40 lbs/18 kg



Pump, VK 8020 Sample Collector, and Auto-Injection Station



VK 8020 Sample Collector/Injector

VK 8020 Sample Collector and HPLC Auto-Injection Station with Peristaltic Pump

Item Description	Part Number
For use with VK 7000/7010, 4+4, 115V, 60 Hz	20-6300
For use with VK 7000/7010, 4+4, 230V, 50 Hz	20-6310

VK 8020 HPLC Auto-Injection Station with Syringe Pump

Item Description	Part Number	
For use with VK 7000/7010, 4+4, 115V	20-6580	
For use with VK 7000/7010, 4+4, 230V	20-6585	
For use with VK 7025/7030*, 8-position configuration, 115V	20-6540	
For use with VK 7025/7030*, 8-position configuration, 230V	20-6545	

VK 8020 Sample Collector and HPLC Auto-Injection Station with Syringe Pump & Filter Changer

Item Description	Part Number	
For use with VK 7000/7010, 4+4, 115V	20-6650	
For use with VK 7000/7010, 4+4, 230V	20-6655	
For use with VK 7025/7030*, 8-position configuration, 115V	20-6610	
For use with VK 7025/7030*, 8-position configuration, 230V	20-6615	

Injection Module Only For VK 8020

Item Description	Part Number
115V/230V dual-voltage	20-6200

Dissolution Workstation Software

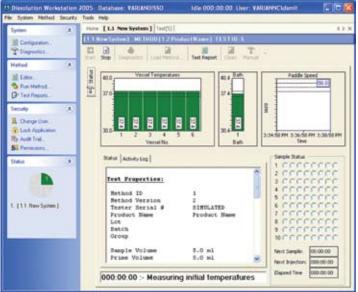




The Dissolution Workstation Software allows users to simultaneously control up to four systems of any configuration from a desktop PC. For example, a VK 8000 and a BIO-DIS can be on one bench and a VK 8000 and VK 7025 on another. From a single desktop PC, you can control both of these systems.

The Dissolution Workstation Software is the preferred solution for organizations that perform dissolution testing in an electronic records environment. The software implements the essential technical requirements of 21 CFR Part 11 in order to facilitate compliance. The Dissolution Workstation Software simplifies method management and system configuration for automated off-line dissolution testing. System configuration, method setup, and data capture is centralized in a relational database.

Access Control



Dissolution Workstation Software

The Dissolution Workstation Software leverages the security capabilities of the Windows® operating system and extensive use is made of user groups to restrict access to software features. These user groups are:

Access control is an important feature of the software. Each time the

VkDissoAuthorizer	Allows the user to sign final acceptance of the results
VkDissoDiagnostics	Allows the user to run diagnostic utilities on a configured system
VkDissoMethodMaint	Allows access to Method Creation and modification functions
VkDissoRunMethods	Allows the user to run any method on any system
VkDissoSystemConfig	Allows the user to change system configuration settings or to add new systems
VkModifyOthersMethod	Allows modification of methods owned by other users
VkModifyOthersSytstems	Allows modification of systems owned by other users

software is started, the user is prompted to logon and logon credentials are tested against the Windows security database before the user is able to gain access to the system. The user cannot access any features of the software for which the user is not a group member.

The software can be set to automatically lock after a defined period of time or be locked at any time by using the Lock Application function. This prevents unauthorized access to the system when the PC is unattended.

System Administration



Minimum PC Requirements for Dissolution Workstation Software:

Pentium 4

Windows XP

60 GB hard drive

1 GB memory

Serial Port (one per connected dissolution system) or 1 x USB port for USB to serial adapter

- 1 USB Port for Hardware Protection Dongle
- 1 Ethernet Port

Monitor capable of 1024 x 768 resolution

Dissolution Workstation Software

The Dissolution Workstation Software has the capability of automating dissolution tests using the following Varian instruments:

- VK 7000, VK 7010, VK 7025
- Apparatus 3 and 7
- Fraction Collector and HPLC Injector Module (VK 8000, VK 8020)
- Peristaltic Pump
- Syringe Pump
- Filter Changer

The software allows the configuration of multiple systems. System configuration entails selecting the equipment that will be physically deployed in your lab and setting the appropriate communication and other physical properties of the system. Serial numbers are stored for each system to allow tracking of physical system changes (e.g. paddle changes). Up to four systems can execute methods simultaneously on a single computer. No restrictions are placed on the number of configured systems in the database.

Since it is possible to use a centralized database, the software provides features that limit the execution of a system method to a specific workstation and can prevent changes to the system configuration by anyone else other than the "System Owner" and users that have the appropriate permissions.

Audit Trails

An important aspect of system configuration and method management is the audit trail. Whenever a system configuration or method is changed, a new version saved in the database. This allows the user to determine the differences between two or more versions of a system or method to determine what changes were made. These features satisfying the audit trail requirements of 21 CFR Part 11 Sec 11.10(e) for method and system management.

Method Execution

When a method is run on a particular dissolution system, the software records the method parameters used as well as temperature measurements and the times at which samples are drawn. The entire process is automatically recorded to the software database and the user is shown status information as the software progresses through each timepoint.

Test Reports

Once a method is complete, the results are available for review and electronic signature. The software maintains a complete history for all runs executed on the system and satisfies the technical requirements of 21 CFR Part 11. Data is physically stored in a protected database and can be exported as PDF files. A report viewer facility is incorporated into the software to allow printing and previewing of results generated by a run. Records are protected by limiting access to the database to individuals authorized to manage results and methods.

Electronic Signatures

Results can be electronically signed. The Dissolution Workstation Software allows multiple electronic signings of a set of results. Each signing is accomplished using the signature dialog box.



The user authenticity is determined by testing the user ID and passwo against the Windows security database. For 21 CFR Part 11 complian purposes, the software employs Windows features to ensure that:

- Access is limited to authorized individuals (11.10(d)).
- No two individuals have the same combination of identification code and password (11.300(a)). This is a fundamental feature of the Windows security database. Further, to ensure user identification when logon IDs are duplicated across Windows domains, the full Domain\UserID form of the user ID is used for all signature and audit trail events.
- Password issuances are periodically checked, recalled, or revised (11.300 (b)). No specific features of the Dissolution Workstation Software exist to ensure this. It is the responsibility of the system administrator to ensure that the password aging feature of the Windows operating system is properly set for each domain and local computer.
- Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes (11.300 (d)). An entry is made in the Windows system audit log when the account is disabled, and when the account is re-enabled. The end user is responsible for ensuring that the Windows Local Security Policy and Windows Domain Security Policy have been setup appropriately. The software can be set to automatically lock after a defined period of time or be locked at any time by using the Lock Application function. This prevents unauthorized access to the system when the PC is unattended.

The system can be unlocked by an authorized user. If a method is running, the method can only be stopped by a user with VkDissoRunMethods group membership. User logon is recorded to the workstation database.

Dissolution Workstation Software

Item Description	Part Number
Dissolution Workstation Software	11-0017

Varian UV Dissolution System

- Complete UV automation package
- IQ/OQ/PQ available for the system (dissolution apparatus, spectrophotometer, and software)
- Complete support from one vendor
- Easy testing, validation, and reporting
- Meets all current USP, JP, and EP requirements
- Designed to run on Windows XP

Varian provides you with the most innovative and flexible tablet dissolution systems on the market. This system provides you with a simple automated dissolution testing system using UV-Vis analysis.

Complete Dissolution System

The Varian UV Dissolution System includes a computer, monitor, printer, Cary 50 Spectrophotometer, and your choice of dissolution apparatus. The UV Dissolution System is available in single- or dual-apparatus configurations.

Cell-based or Fiber-Optic In Situ Measurement

This is the only dissolution software that integrates the capability to read UV data from either a flow cell or a fiber-optic probe. The advantage to you is there is only one software application to learn.

Varian in the only supplier of UV-based systems that manufactures the spectrophotometer, the dissolution apparatus, and the software. The end result is a truly integrated package backed by one supplier.

See page 83 for details on the Varian Fiber-Optic Solutions.

Self-operating System

The software allows you to preprogram a start time. When used in conjunction with the VK 7010 or VK 7025 paddle methods can be started automatically.

Single or Multicomponent Analysis

Our standard software is designed for single-component analysis. If you need multicomponent analysis capabilities, we offer an optional upgrade to the base software. The multivariate analysis software is The Unscrambler® from the Camo Software Inc. The Unscrambler includes such tools as PCA, Multivariate Curve Resolution (MCR), PLS regression, three-way PLS regression, clustering (K-Means), SIMCA, etc. We've integrated the appropriate methods to enable easy multicomponent analysis of a dosage form.

Measures Samples with High Background Correction

You can measure highly absorbing samples without dilution. The extended photometric range of the Cary instrument allows you to measure samples requiring high background correction that would normally require HPLC analysis.

Flow-through Sample Collection

The Cary 50 utilizes an 18-position multicell transport. The flow-through design maintains a constant volume in the vessels throughout the entire run by returning the sample solution back into the vessels, eliminating the need to calculate for volume lost. Cross contamination between vessels cannot occur as each vessel has a dedicated flow cell.

We also offer you the ability to collect a sample at each timepoint. When used with a VK 8000 Autosampler you can retain a sample from each timepoint. In the event you need to verify any results, you will have a sample to reference.

The 18-position cell holder allows two different path lengths to be configured together. Simply chose the set you wish to read. This makes it simple to switch between two different methods without replumbing your system.

Your Choice of Pumping System

We now offer you the choice of a multichannel peristaltic pump or an 8-position syringe pump. The peristaltic pump works great for most applications, but when you need even more chemical resistance, or if you want to use a 0.45 μ m membrane filter, the syringe pump is a great choice.

Xenon Lamp System

The Cary 50 uses just one light source, a xenon flash lamp. Since the source is only on when a measurement is taken, the lamp has a very long file time. Since no expensive deuteruim lamp is used, you will save thousands of dollars in replacement costs over the lifetime of the instrument.



Varian UV Dissolution System



Archiving Capability with in-line Analysis

Our new software allows you to incorporate a VK 8000 Autosampler into your system samples so that can be read and collected. Should you need to perform an investigation, you have an archived sample from each sample timepoint.

Variable Data Collection Rate

You can specify multiple regions in the test run, each of which has a different data collection rate. This allows you to collect more data when the absorbance is changing quickly and to have fewer data points in the more stable parts of the dissolution profile.

Secure Data Collection

Unlike more conventional systems that store data only at the end of a run, the UV Dissolution System stores data as it is acquired. Because data is being continually saved, even in the event of a power outage, your data to that point is secure.

Reporting Solution

A comprehensive report can be tailored for your specific reporting needs. Graphics showing time versus percent dissolved, time versus milligrams dissolved, and time versus absorbance can be included in a report, with each vessel indicated by a different color trace. Your dissolution reports can include your company logo or any bitmap you choose.

Audit trails are logged providing information about how the data was collected and calculated.

21 CFR Part 11 Compliant

Varian is committed to providing systems meeting this regulatory requirement for electronic records and signatures. We've developed the Varian 21 CFR Part 11 Assistant application enabling the establishment of required security functions. This important application provides tools to ensure your electronic records and signatures are compliant.

Once a system administrator has set up users, Varian 21 CFR Part 11 Assistant guides the system administrator through the required steps to set up the security features.

System Qualification

Varian offers a complete qualification guide of the entire system (spectrophotometer, dissolution apparatus, and dissolution system protocols). This guide is available to you as is the qualification service by one of our laboratory chemists. Order the appropriate catalog numbers for your configuration or call for details about our service capabilities.

Please note that the Varian UV Dissolution Software is an entirely new platform that stores data in a new format. As a result, data collected from previous cannot be read or analyzed, and previous software versions cannot be upgraded.



UV Dissolution dual-apparatus configuration

On-line Analysis

Cary® 50 Spectrophotometer

- Cary 50 Xenon lamp allows 80 data points per second
- Xenon lamp flashes only when acquiring a data point, unlike a diode array which exposes the sample to the whole wavelength range with each reading, causing degradation of photosensitive samples
- Cary 50 is unaffected by room light. It can be operated with the sample compartment opened or closed
- 18-position multicell transport easily handles either one or two dissolution apparatus. Because each vessel has its own flow cell, there is no cross contamination



Cary 50 Spectrophotometer

Software applications allow you to:

- Create and store custom methods, which include equipment parameters
- Create multi standard calibration curves
- Perform routine wavelength scanning measurements
- Measure the photometric value of samples at fixed wavelengths
- Run two different dissolution methods independently
- Check standards before and after test

Cary 50 Spectrophotometer

Item Description	Part Number
Cary 50 UV-VIS Spectrophotometer, 115V or 230V (requires PC to operate, and card and cable to connect PC and Spectrophotmeter)	11-1000
Cary 50 Card and Cable	11-1030
UV Dissolution Software	11-1054
Extended Sample Compartment	11-1010
Sample Compartment Tubing Coupler	11-1015
18-cell Multi-transport	11-1020
Cable Kit for connecting either 1 or 2 Varian dissolution apparatus	11-1035
Tubing Kit, replaces tubing between Peristaltic Pump and flow cells	11-1325

Dual Cell Tubing Kit

The Cary 50 makes it easy to interconnect two different cells within the 18-position multicell transport. This allows you to switch between two sets of cells (typically with different pathlengths) with no disassembling or reassembling of the tubing lines. Switching between methods requiring cells of different pathlengths is as easy as selecting the cells to be read using the UV Dissolution Software System. Only one dissolution apparatus can be used when the dual cell tubing is in place.

Dual Cell Tubing Kit

Item Description	Part Number
Dual Cell Tubing Kit, dual pathlength	11-1320

Quartz Flow Cells

Flow cells, or tablet dissolution cells, are specially designed and serialized for the Cary 50. Smaller pathlengths are available.

Quartz Flow Cells

Item Description	Part Number
Tablet Dissolution Cell, 10 mm, for Cary 50	11-1300
Tablet Dissolution Cell, 0.2 mm, for Cary 50	11-1301
Tablet Dissolution Cell, 0.5 mm, for Cary 50	11-1302
Tablet Dissolution Cell, 5 mm, for Cary 50	11-1305
Tablet Dissolution Cell, 2 mm, for Cary 50	11-1310
Tablet Dissolution Cell, 1 mm, for Cary 50	11-1315

Varian UV Dissolution System

The UV Dissolution System is a flexible equipment manager. It accommodates many different hardware tools that can be programmed based on your method requirements. The following guide is provided to assist you in selecting those items that are most appropriate for your dissolution testing needs. Use the following to help narrow your selection when ordering a UV Dissolution System:

Consideration 1: Flow Cell-based system versus in situ measurement (Fiber Optics).

The Cary 50 can be configured with either an 18-position multicell changer or a 16-position fiber-optic multiplexer. Both the multicell changer and the multiplexer can be used with one or two dissolution baths (the software allows you to select the number of dissolution baths to be used for that particular method).

Consideration 2: Multicell Changer: Peristaltic Pump or Syringe Pump:

If you choose a multicell changer system, then the samples will be withdrawn from the vessel and pumped to through the flow cells. We offer either a Peristaltic Pump or a Syringe Pump. The Syringe Pump option allows the VK 808 Filter Changer option to be incorporated.

Consideration 3: Multicell Changer: Archiving Samples

If you wish to archive a sample, this is possible with the multicell changer option. The VK 8000 Autosampler can be placed in-line to collect a sample during each measurement period. Failure investigation, if required, is much easier with a retained sample. The VK 8000 can be used with either the Peristaltic or Syringe Pump.

Consideration 4: Choice of Dissolution Apparatus

The UV Dissolution System is designed to work with all of the Varian models of dissolution equipment. We recommend either the VK 7000 Series (VK 7000 or VK 7010) or the V Series. It is possible to use the Varian 705–DS; however, this unit does necessitate the use of resident-dwelling probes. Other brands of dissolution apparatus can also be used. Contact you Varian representative for details.

Consideration 5: Pathlengths Required

When using a multicell changer we offer seven different flow cells of varying pathlength (0.2, 0.5, 1, 2, 5, 10, 20 mm). When ordering a fiber-optic multiplexer, order a set of cables with probes (six per dissolution apparatus) and the appropriate interchangeable tips (1, 2, 5, 10, 20 mm pathlength).



Fiber-Optic UV Dissolution System with VK 7000

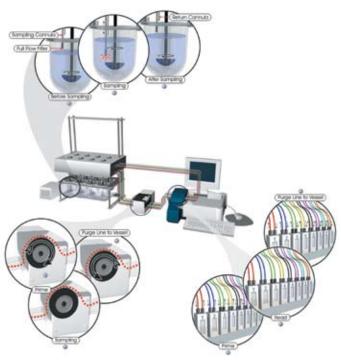
On-line Analysis



UV Dissolution Multicell (Flow Cell) System

When ordering the Multicell UV Dissolution System, you must select one from each of the following categories:

- Apparatus package: select either the VK 7000, VK 7010 or VK 7025 with desired pumping, filtering and sampling options
- Accessory kits: select either basket or paddle accessory components; additional kit required when ordering the VK 8000 Autosampler
- UV Dissolution Software package: select software with or without Cary 50TM UV-Vis Spectrophotometer and multicell changer, as well as PC, printer and monitor



UV Dissolution System, Spectrophotometer, Single Apparatus

UV Dissolution Multicell System with VK 7000 Dissolution Apparatus

Note software must be ordered separately, see pg. 79

Item Description	Part Number
VK 7000, Flow Cell System, Peristaltic Pump, 115V	11-1600E
VK 7000, Flow Cell System, Peristaltic Pump, 230V	11-1601E
VK 7000, Flow Cell System, VK 806 Syringe Pump, 115V	11-1607E
VK 7000, Flow Cell System, VK 806 Syringe Pump, 230V	11-1608E
VK 7000, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, 115V	11-1614E
VK 7000, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, 230V	11-1615E
VK 7000, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, VK 8000 Autosampler, 115V*	11-1621E
VK 7000, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, VK 8000 Autosampler, 230V*	11-1622E
VK 7000, Flow Cell System, Peristaltic Pump, VK 8000 Autosampler, 115V*	11-1628E
VK 7000, Flow Cell System, Peristaltic Pump, VK 8000 Autosampler, 230V*	11-1629E
VK 7000, Flow Cell System, VK 806 Syringe Pump, VK 8000 Autosampler, 115V*	11-1640E
VK 7000, Flow Cell System, VK 806 Syringe Pump, VK 8000 Autosampler, 230V*	11-1641E

^{*}Systems with a VK 8000 require an additional accessory kit; see below.

Accessory Kits for Multicell System with VK 7000

Item Description	Part Number
Accessory kit, 1L, stainless steel, 24 in. paddles	1001-1136
Accessory kit, 1L, Teflon, 24 in. paddles	1001-1137
Accessory kit, 1L, stainless steel basket, standard clip, 24 in. shaft	1001-1138
Accessory kit, 1L, stainless steel basket, 0-ring, 24 in. shaft	1001-1139

*Accessory Kits for Systems with VK 8000

Item Description	Part Number
Accessory kit, VK 8000, 6 or 8-valve, 16x100 mm vial tray	1001-1017
Accessory kit, VK 8000, 6 or 8-valve, 12x32 mm vial tray	1001-1018

Varian UV Dissolution Software

Please note the UV Dissolution Software requires the following:

- Pentium 4, 2.0 GHz processor (or higher)
- 512 MB RAM
- 40 GB Hard Drive
- CD-ROM
- Microsoft Windows XP Operating System, Service Pack 2
- Keyboard
- Mouse
- 17 in. Monitor capable of 1024 x 768 resolution
- 2 Serial Ports or 1 USB Port
- 2 Free PCI Card Slots

UV Dissolution Software for Multicell System

Item Description	Part Number
UV Dissolution Software, Cary 50, multicell changer, PC, printer, monitor, 115/230V	11-1118
UV Dissolution Software, Cary 50, multicell changer, 115/230V	11-1120
UV Dissolution Software for Multicell System (flow cells)	11-1054

UV Dissolution Multicell System with VK 7010 Dissolution Apparatus

Note software must be ordered separately, see left column.

Item Description	Part Number
VK 7010, Flow Cell System, Peristaltic Pump, 115V	11-1602E
VK 7010, Flow Cell System, Peristaltic Pump, 230V	11-1603E
VK 7010, Flow Cell System, VK 806 Syringe Pump, 115V	11-1609E
VK 7010, Flow Cell System, VK 806 Syringe Pump, 230V	11-1610E
VK 7010, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, 115V	11-1616E
VK 7010, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, 230V	11-1617E
VK 7010, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, VK 8000 Autosampler, 115V*	11-1623E
VK 7010, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, VK 8000 Autosampler, 230V*	11-1624E
VK 7010, Flow Cell System, Peristaltic Pump, VK 8000 Autosampler, 115V*	11-1630E
VK 7010, Flow Cell System, Peristaltic Pump, VK 8000 Autosampler, 230V*	11-1631E
VK 7010, Flow Cell System, VK 806 Syringe Pump, VK 8000 Autosampler, 115V*	11-1642E
VK 7010, Flow Cell System, VK 806 Syringe Pump, VK 8000 Autosampler, 230V*	11-1643E

^{*}Systems with a VK 8000 also require one of the additional kits on pg. 78.

Accessory Kits for Multicell System with VK 7010

Item Description	Part Number
Accessory kit, 1L, stainless steel, 24 in. paddles	1001-1140
Accessory kit, 1L, Teflon, 24 in. paddles	1001-1141
Accessory kit, 1L, stainless steel basket, standard clip, 24 in. shaft	1001-1142
Accessory kit, 1L, stainless steel basket, 0-ring, 24 in. shaft	1001-1143

On-line Analysis

UV Dissolution Multicell System with VK 7025 Dissolution Apparatus

Note software must be ordered separately, see pg. 79

Item Description	Part Number
VK 7025, Flow Cell System, Peristaltic Pump, 115V	11-1604E
VK 7025, Flow Cell System, Peristaltic Pump, 230V	11-1605E
VK 7025, Flow Cell System, VK 806 Syringe Pump, 115V	11-1611E
VK 7025, Flow Cell System, VK 806 Syringe Pump, 230V	11-1612E
VK 7025, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, 115V	11-1618E
VK 7025, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, 230V	11-1619E
VK 7025, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, VK 8000 Autosampler, 115V*	11-1625E
VK 7025, Flow Cell System, VK 806 Syringe Pump, VK 808 Filter Changer, VK 8000 Autosampler, 230V*	11-1626E
VK 7025, Flow Cell System, Peristaltic Pump, VK 8000 Autosampler, 115V*	11-1632E
VK 7025, Flow Cell System, Peristaltic Pump, VK 8000 Autosampler, 230V*	11-1633E
VK 7025, Flow Cell System, VK 806 Syringe Pump, VK 8000 Autosampler, 115V*	11-1644E
VK 7025, Flow Cell System, VK 806 Syringe Pump, VK 8000 Autosampler, 230V*	11-1645E

^{*}Systems with a VK 8000 also require one of the additional kits on pg. 78.

Accessory Kits for Multicell System with VK 7025

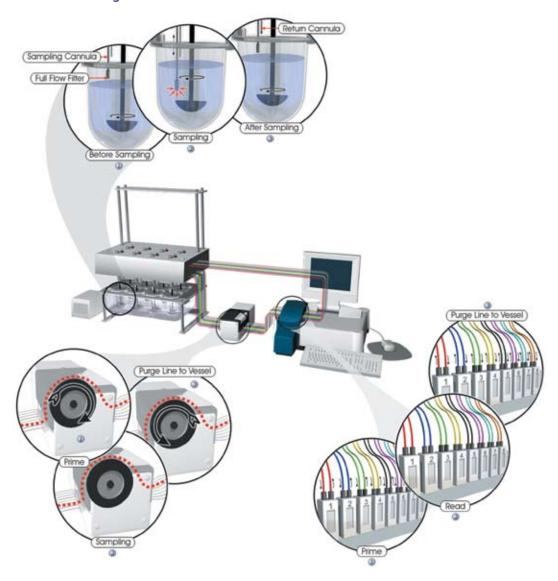
Item Description	Part Number
Accessory kit, 1L, stainless steel, 15 in. paddles	1001-1039
Accessory kit, 1L, Teflon, 15 in. paddles	1001-1040
Accessory kit, 1L, stainless steel basket, standard clip, 15 in. shaft	1001-1041
Accessory kit, 1L, stainless steel basket, 0-ring, 15 in. shaft	1001-1042

Did you know Varian qualification documents are available for purchase (see page 129)? Varian chemists are available to perform installation, operation, and performance qualifications on your equipment.



UV Dissolution System, Single-apparatus Configuration Utilizing Peristaltic Pump and Flow Cells

Media Flow Diagram

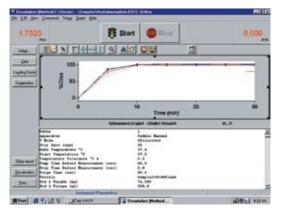


UV Dissolution System, Flow Cell System — Spectrophotometer, Dual-apparatus Configurations

The UV Dissolution System is also available in dual-apparatus configurations. This system allows you to run two dissolution apparatus with the same method at the same time.

A complete system consists of three components: the UV package, flow cells meeting your pathlength requirement, and two dissolution apparatus.

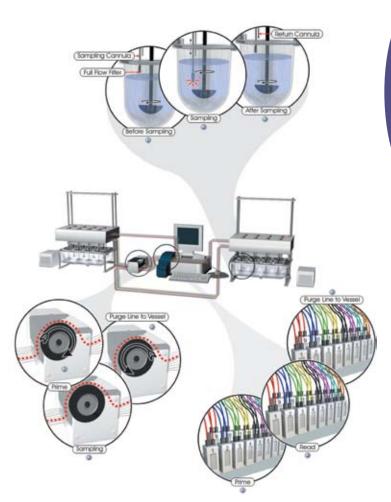
Contact your Varian representative for dual-apparatus configuration information.



UV Dissolution System Screen Display

UV Dissolution System, Dual-apparatus Configuration

Media Flow Diagram





Fiber Optics for VK 7000, VK 7010, VK 7025, and VK 7030



Fiber Optics for VK 7000, VK7010 and VK 7025

Fiber-Optic Dissolution Testing - Integrated Fiber-Optic Dissolution Solution

- Fiber-optic technology offers real-time (sample measurement) data acquisition
- Fully automated system allows walk-away performance
- Fewer moving parts. No moving liquid
- Single-source solution for equipment, qualification, and support
- Single- or multicomponent analysis

Complete Dissolution Solution

The fiber-optic system includes a Cary 50 Spectrophotometer with multiplexer, fiber-optic probes, computer, monitor, printer, and your choice of Varian dissolution apparatus. It is available in single- or dual-apparatus configurations. Instantaneous in situ analytical dissolution measurements employing the Cary 50 Fiber-Optic Spectrophotometer offers breakthrough performance with light from a Xenon pulse lamp carried to the vessel by specially designed optical fibers.

Advantages

- Completely automated on-line UV solution
- In-situ fiber-optic probes -- no liquid handling
- Entire spectral profiles
- Real-time data acquisition
- Complete qualification available for the system
- Simplified testing, validation and reporting

Hardware Features - Cary 50 Spectrophotometer

- 190-1100 nm wavelength range
- Photometric range ±3.3 Abs
- Pulsing Xenon lamp source, only on when measuring
- Dual-beam Multiplexer
- Channels light from source to individual vessels
- Supports either 8 or 12 fiber-optic probes for use with either one or two apparatus
- Completely integrated into the Cary 50

Fiber-Optic Probes

- Removable tips for easy cleaning
- Tips available: 2, 5, 10, 20 mm (or custom)
- Exchangeable tips are less expensive than other systems which require all new probes to change path lengths.
- Stainless steel body
- Transmission >35% (@ 500 nm)
- Small diameter minimizes hydrodynamic effects
- Can be removed from vessel when not taking measurements

Software Features

- User-friendly software controls the entire system
- Sample measurement can be made as quickly as every 30 seconds depending on scanning range.
- Provides a mathematical mechanism to correct results for excipient interferences and scattered light
- Gives step-by-step instructions for the user during the setup of the test
- Allows complete control of all dissolution apparatus functions for each method
- Audit trails are logged with all data, providing information about how the data was collected and/or calculated.

Single- or Multicomponent Analysis

Varian UV Dissolution System software is designed for single-component analysis. if you need multicomponent analysis capabilities, we offer an optional upgrade to the base software. The multi variable analysis software is The Unscrambler® from the Camo Software, Inc. The Unscrambler includes such tools as PCA, Multivariate Curve Resolution (MCR), PLS regression, 3-way PLS regression, clustering (K-Means), SIMCA, etc. We've integrated the appropriate methods to enable straightforward multicomponent analysis of a dosage form.

Camo Software Plug-In

In order to perform multicomponent analysis, two pieces of additional software are required: The Unscrambler and The Unscrambler Online Predictor (OLUP). Many companies may already have a license for the Unscrambler, in which case you only need to add the Predictor package.

Camo Software Plug-in

Item Description	Part Number
The Unscrambler Software, Multicomponent Analysis	11-0040
The Unscrambler Online Predictor Software	11-0045
The Unscrambler Online Classifier Software	11-0050

Data Report

- Automatically generated and built in real time to allow you to determine results of a test in progress
- Contains full spectrum for each vessel at each time point
- Can be tailored to your specific reporting needs including company logo
- Includes method parameters, raw data, percentage or mg dissolved calculations
- Results for corrected and uncorrected excipient interference also available

On-line Analysis

85

Fiber-Optic UV Dissolution System

When ordering the Fiber-Optic UV Dissolution System, you must select one from each of the following categories:

- Apparatus package; note probes and tips are ordered separately
- Accessory kits: select either basket or paddle accessory components
- UV Dissolution Software package: select software with or without Cary 50™ UV-Vis Spectrophotometer and 616-DS Fiber-Optic Multiplexer, as well as PC, printer and monitor



Fiber-Optic Probe Assembly with interchangeable tips



Fiber-Optic Probe Assembly (right) shown with AutoTemp Probe (left)

UV Dissolution Software for Fiber-Optic System

Item Description	Part Number
UV Dissolution Software, Cary 50, 616-DS Fiber-Optic Multiplexer, PC, printer, monitor, 115/230V	11-1076
UV Dissolution Software, Cary 50, 616-DS Fiber-Optic Multiplexer, 115/230V	11-1084
UV Dissolution Software for Fiber-Optic System	11-1092

Please note the UV Dissolution Software requirements on pg. 79.

Fiber-Optic Probes and Tips

Item Description	Part Number
Fiber-Optic Probe, 2 meters (tip not included), for use with VK 7000/7010	11-1425
Fiber-Optic Probe, 2 meters (tip not included), for use with V-Series	11-1426
Removable Tip (1 mm pathlength)	11-1429
Removable Tip (2 mm pathlength)	11-1430
Removable Tip (5 mm pathlength)	11-1435
Removable Tip (10 mm pathlength)	11-1440
Removable Tip (20 mm pathlength)	11-1445

Fiber-Optic UV Dissolution System with VK 7000 Dissolution Apparatus

Note software and fiber-optic tips and probes must be ordered separately, see pg 84.

Item Description	Part Number
VK 7000, Fiber-Optic System, 115V	11-1532E
VK 7000, Fiber-Optic System, 230V	11-1533E

Accessory Kits for Fiber Optic System with VK 7000

Item Description	Part Number
Accessory kit, 1L, 21 in. paddles	1001-1001
Accessory kit, 1L, Teflon, 21 in. paddles	1001-1002
Accessory kit, 1L, stainless steel basket, standard clip, 21 in. shaft	1001-1003
Accessory kit, 1L, stainless steel basket, O-ring, 21 in. shaft	1001-1004

Fiber-Optic UV Dissolution System with VK 7010 Dissolution Apparatus

Note software and fiber-optic tips and probes must be ordered separately, see pg 84.

Item Description	Part Number
VK 7010, Fiber-Optic System, 115V	11-1540E
VK 7010, Fiber-Optic System, 230V	11-1541E

Accessory Kits for Fiber Optic System with VK 7010

Item Description	Part Number
Accessory kit, 1L, 21 in. paddles	1001-1005
Accessory kit, 1L, Teflon, 21 in. paddles	1001-1006
Accessory kit, 1L, stainless steel basket, standard clip, 21 in. shaft	1001-1007
Accessory kit, 1L, stainless steel basket, 0-ring, 21 in. shaft	1001-1008

Fiber-Optic UV Dissolution System with VK 7025 Dissolution Apparatus

Note software and fiber-optic tips and probes must be ordered separately, see pg 84.

Item Description	Part Number
VK 7025, Fiber-Optic System, 115V	11-1588
VK 7025, Fiber-Optic System, 230V	11-1589
VK 7025, Fiber-Optic System, Automated Spindle Control (ASC), 115V	11-1590
VK 7025, Fiber-Optic System, Automated Spindle Control (ASC), 230V	11-1591

Accessory Kits for Fiber Optic System with VK 7025

Item Description	Part Number
Accessory kit, 1L, 15 in. paddles	1001-1039
Accessory kit, 1L, Teflon, 15 in. paddles	1001-1040
Accessory kit, 1L, stainless steel basket, standard clip, 15 in. shaft	1001-1041
Accessory kit, 1L, stainless steel basket, 0-ring, 15 in. shaft	1001-1042



LC Dissolution System

Varian LC Dissolution System brings together accurate dissolution sample collection with HPLC analysis, providing you with the opportunity to significantly increase your productivity. Samples are analyzed while your dissolution test is running, and you gain decision-making time by getting data earlier. Additionally, automated sampling and HPLC analysis allows for unattended testing, letting analysts spend time on other laboratory activities.

The LC Dissolution System enables you to:

- Obtain instant dissolution profile reports rather than creating timeconsuming reports from multiple HPLC chromatograms.
- Eliminate analysts' time and potential handling errors in sampling, filtering and transferring samples to HPLC equipment manually.
- Observe HPLC analysis of dissolution samples in real time.
- Save time by easily setting up, storing, retrieving and editing batch/lot information and methods for the dissolution apparatus using easy-tonavigate user interface screens.
- Customize final reports with data tables, dissolution profiles and statistical evaluation and comparison tools.

Contact your Varian representative to learn more.



LC Dissolution System with Modular LC

Cross-Platform Integration 8



Automated Compatible Systems

Varian dissolution apparatus are ideal for use in automated systems. There are a number of analytical instrument systems designed for use with Varian apparatus. Many analytical instrument companies and third party software providers' products are compatible with Varian's products. The mention of their products in this catalog is not intended to be an explicit or implied endorsement, sponsorship, or other association by these companies with Varian or its affiliated businesses.

Agilent ChemStation®

- Varian Dissolution Systems can be easily integrated with ChemStation™ software, allowing complete control of Varian apparatus and sampling equipment
- Optimize communication between Varian dissolution systems and Agilent's 8453 Diode Array Spectrophotometer with ChemStation Dissolution software
- Only with these drivers do you get a system that stops the paddle and media rotation before delivering the dosage form
- Only with the Varian sampling pumps are the sample lines emptied between timepoints
- Fully functioning single- and multiapparatus system drivers are available

Optimize Communication Between Varian and Agilent Dissolution Components

The ChemStation software drivers from Varian enable intelligent communication between Varian dissolution systems and the Agilent ChemStation dissolution software. The drivers integrate full control of the dissolution apparatus VK 7000, VK 7010, VK 7025, and VK 7030 including sampling manifolds or cannulas, in-vessel temperature measurement, and dosage delivery mechanism into the ChemStation software. They also enable control of the Varian Peristaltic Pump or the VK 806 Syringe Pump with optional VK 808 Filter Changer in single apparatus systems. Use of the Varian bidirectional peristaltic pump allows the filters to be backflushed and the sampling tubes emptied after each measurement cycle. Both single- and multiapparatus drivers are available. In a single apparatus configuration, eight flow cells (six for dissolution samples, two for analytical solutions, e.g. control standard and blank) are utilized, each with a dedicated line. At each timepoint, the sample solutions are simultaneously circulated through the cells and then returned to the appropriate vessel. Using the Varian Peristaltic Pump or VK 806 Syringe Pump, the sample lines are emptied between readings. The multiapparatus system drivers can control up to four apparatus and pull each sample sequentially. Each dissolution apparatus utilizes a single flow cell in the multicell transport; the six samples and two analytical solutions are sequentially pulled through a switching valve and the flow cell, read, and discarded. A report containing all test parameters and data can be automatically generated at the conclusion of the test.

Sequential Automated Testing for Multi-bath Systems

The Varian ChemStation Multi-bath driver enables compliance with USP guidelines by delivering dosage forms into nonrotating media and providing the least hydrodynamic disturbance during sampling.

AutoSpindle Control and Individual Cannula Control

The V-Series apparatus feature optional AutoSpindle Control (ASC). These electronically controlled clutch mechanisms allow each spindle to be operated independently. In addition, the V-Series apparatus feature individually controlled sampling cannulas. This enables independent control of each cannula for staggered sampling. The sampling depth is also controlled according to the volume of medium in the vessels and the apparatus used.

Why Is This Important?

The USP suggests that dissolution medium is not rotating when dosage forms are delivered into the vessel. The USP requires that the dosage form be allowed to sink to the bottom of the vessel before rotation is started. The Varian ChemStation software drivers, when configured with the V-Series apparatus and the ASC option, make it possible to meet USP requirements by controlling each spindle individually. Rotation of each spindle begins after the dosage for the particular vessel is introduced, thus making automated staggered starts possible. At each timepoint the sampling cannulas are sequentially lowered into each vessel, the sampling depth being programmed according to the apparatus (e.g. paddles or baskets) and media volume. Each cannula is only immersed in the dissolution medium for the time required to take each sample thus minimizing any hydrodynamic disturbance.

Both the single- and multiapparatus drivers include a driver qualification quide and cables for connection to the ChemStation PC.

For more information on Agilent compatible automated dissolution testing drivers, contact your Varian representative.

For use with Varian Peristaltic Pump

Item Description	Part Number
Software Drivers for single-apparatus configuration	11-0013
Software Drivers for multiapparatus configuration	11-0014

For use with Varian Syringe Pump and Filter Changer

Item Description	Part Number
Software Drivers for single-apparatus configuration	11-0016



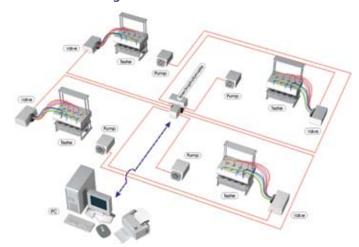
Agilent Single Apparatus Configuration with Varian Bidirectional Pump

Media Flow Diagram



Agilent Multiapparatus Configuration

Media Flow Diagram



Cross-Platform Integration



Caliper Life Sciences MultiDose® G3

Caliper Life Sciences developed an advanced workstation for fully automated USP Apparatus 2 dissolution testing. The MultiDose G3 Automated Dissolution Workstation runs up to 8 batches (48 samples) without intervention, using the same method or different methods. The system can perform single-point dissolution tests or multiple point dissolution profiles. All activities of the system are documented in an electronic audit trail. The system is fully USP compliant. The MultiDose G3 performs a typical automated dissolution sequence in the following way:

- Preheat and degas the medium
- Dispense the requested volume of medium into each vessel with gravimetric confirmation
- Verify and record the temperature in all six vessels
- Automatically introduce the dosage unit to start the test
- Remove and filter samples at prescribed time intervals)
- Replace the volume of medium removed at user's option
- Perform on-line UV measurements or collect samples
- Empty vessels, then wash them in place
- Start again until all methods have been executed

MultiDose G3 software capabilities include the capability to utilize a network of shared database and client versions. It also utilizes easy-to-configure reports and LIMS output. The MultiDose G3 is fully validated upon installation; IQ, OQ and PQ protocols executed and final report generated. Also, the new MultiDose G3 software package now makes the unit fully 21 CFR Part 11 compliant.



Caliper Life Sciences MultiDose G3 with VK 7000-series Dissolution Apparatus

VK 7000 for use with MultiDose G3

Item Description	Part Number
VK 7000, 4x4, 115V	10-6615
VK 7000, 4x4, 230V	10-6620

VK 7000 for use with MultiDose G3

Product Specifications

 Recommended bench space: 60.95 cm (24 in.) not including for PC controller, dissolution apparatus, or sample output devices, such as sample collector or UV-Vis spectrophotometer

Caliper Life Sciences MultiDose G3 Plus



The MultiDose G3 Plus, in conjunction with an "automation ready" VK 7000 dissolution apparatus, can run up to eight batches of samples unattended. The system preheats and conditions the dissolution media, fills each vessel with the appropriate volume of media, verifies temperature, starts the dissolution test, removes sample aliquots at the user-defined time intervals, then empties and cleans each vessel before starting another test. When configured for Apparatus 1, the system removes the spent basket and replaces it with a new basket containing the dosage unit for the next analysis. When configured for Apparatus 2 with capsule sinkers, the system is capable of retrieving the sinker at the end of the run. The system can also act as a standard MultiDose System for ordinary Apparatus 2 dissolution tests. Dissolution samples are either stored for off-line analysis or can be analyzed on-line with an appropriate multicell UV-Vis spectrophotometer. All operations of the system are documented in an electronic audit trail.

MultiDose G3 Plus software capabilities include the capability to utilize a network of shared database and client versions. It also utilizes easy-to-configure reports and LIMS output.

The new MultiDose G3 Plus software package now makes the unit fully 21 CFR Part 11 compliant.

VK 7000 for use with the MultiDose G3 Plus

Item Description	Part Number
VK 7000, Easy Access, 4+2, 115V, 60 Hz	10-6800
VK 7000, Easy Access, 4+2, 230V, 50 Hz	10-6810

VK 7000 for use with MultiDose G3 Plus

Product Specifications

 Recommended bench space: Linear array: 210.82 cm (83 in.); Non-Linear Array: 144.78 cm (57 in.) not including space for PC controller, dissolution apparatus, or sample output devices, such as sample collector or UV-Vis spectrophotometer



MultidosePlus System for use with Paddles and Baskets

Waters Corporation



The VK 7000, VK 7010, VK 7025, and VK 7030 are fully compatible with the Waters Alliance and Empower Systems for automated sampling using programming capabilities built into Varian dissolution apparatus. Unlike other dissolution apparatus, Varian apparatus do not require the use of resident dwelling probes. All operating parameters can be initiated by the transfer station, including the dropping of tablets and recording individual vessel temperature measurements and sampling timepoints (dosage dropping and vessel temperature measurement are standard features of the VK 7025 and VK 7030). Up to two apparatus can be connected to one LC. To accommodate the Waters sampling probes, we offer customized sampling manifolds and cannula housings. These can be fitted to any VK 7000 or VK 7010.

For Varian dissolution apparatus equipped with Dosage Delivery Module (DDM), you can automate the start of the test (measuring and recording the temperature) as well as dropping the dosage form when used with Apparatus 2 (paddles).

Note that tubing and sampling cannulas are supplied by Waters. Manifolds require the use of a motorized drive. Your VK 7000 may or may not have this already installed (this feature is standard on the VK 7010, VK 7025, and VK 7030).

Call your Varian representative if you have questions.

Waters Corporation

Item Description	Part Number
Manifold for Benchsaver testers (3+3 configuration)	17-3130
Manifold for Easy Access models (4+2, 4+3 or 4+4 configurations)	17-3132

USP Apparatus 3 BIO-DIS III Accessories

;

USP Apparatus 3 BIO-DIS III™ Standard 7-tube System



RIO DIS III

The BIO-DIS III is designed to meet current USP and EP specifications. It is ideal for dissolution profiling of extended release dosage forms. Different media can be placed into each of the six rows. This allows a method to incorporate pH changes simulating the conditions found within the GI tract.

BIO-DIS III uses a reciprocating motion to "dip" the inner sample tube into media. Per the USP, the stoke length is 10 cm. At the designated time, the entire row of inner sample tubes raises and moves to the next row of media.

The BIO-DIS III is fully programmable in each row for functions such as dip speed, time in each row, hold dip time as well as drain time. It is capable of running unattended for periods of up to six days and can store up to 15 programs. There are seven sample tubes which automatically traverse up to six rows of corresponding outer media tubes filled with different media. Custom units with more rows are available. Virtually any solid dosage form can be accommodated. Mesh screens retain the samples in the inner sample tubes as they move through the medium. With accessories, the appropriate media volume can vary; 100 mL, 300 mL (USP), or 1000 mL.

The BIO-DIS III is shipped complete with all the necessary accessories for working with the 300 mL outer vessels. Temperature is controlled using the VK 750D Heater/Circulator. A built-in Report Center II Printer records the operating parameters during the test method.

Automated sampling is easily integrated to the BIO-DIS III. See page 98.

The standard 7-tube system includes the following items:

- Three 14-position outer media tube vessel carriers
- Seven inner sample tubes with upper and lower caps
- One sample kit of polypropylene and stainless steel screens
- 42 USP outer media tubes, 300 mL
- One external heater/circulator

BIO-DIS III

Item Description	Part Number
BIO-DIS III Extended Release Tester 115V, 60 Hz	25-1000
BIO-DIS III Extended Release Tester 230V, 50 Hz	25-1100

Dissolution Basket Adapter for BIO-DIS III

This adapter, manufactured from type 316 stainless steel, allows use of a dissolution basket on the BIO-DIS III. The basket must be order separately (see pages 30–33 for baskets).

Basket Adapter

Item Description	Part Number
BIO-DIS III Dissolution Basket Adapter, DuraFit, basket not included	27-2400
BIO-DIS III Dissolution Basket Adapter with clip assembly, basket not included	27-2401



20 mesh Basket with BIO-DIS III Adapter P/N 27-2401



Automated Sampling for Apparatus 3 (BIO-DIS III)

The sample collection process can be easily automated with the use of the VK 8000. See page 98 for more details.



USP Apparatus 3 BIO-DIS III USP Apparatus 3 BIO-DIS III

BIO-DIS III Conversion Kits

The BIO-DIS III can be configured in many different ways. Standard conversion kits are available to lower the vessel volume to 300 mL or increase the volume to 1L. In addition, a second row of sample tube holders can be added for greater capacity. Please note adding additional rows decreases the number of media changes that can be performed. For example: the 14-position kit for 100 or 300 mL outer media tubes can run two tests simultaneously in one BIO-DIS III apparatus. The three-position conversion kit is for converting the BIO-DIS III to use with 1000 mL vessels. Special vessel carriers and water baths are also available to accommodate up to 24 rows of outer tubes.

Order one of the following BIO-DIS III conversion kits for each BIO-DIS III (P/N 25-1000 or 25-1100, see page 90).



300 mL, 7 x 2 Layout

BIO-DIS III Conversion Kits

Item Description	Part Number
100 mL Conversion Kit	27-6100
1L Conversion Kit	27-6105
Double Row Dip 300 mL	27-6200
Double Row Dip 1L	27-6202
Double Row Dip 1L / 300 mL	27-6204

BIO-DIS III Retrofits

BIO-DIS III retrofits are for previously purchased units. Retrofits must be performed by a Varian representative.

BIO-DIS III Retrofit

Item Description	Part Number
Double Row Dip 300 mL Retrofit	27-6201
Double Row Dip 1L Retrofit	27-6203
Double Row Dip 1L / 300 mL Retrofit	27-6205



Double Row Dip 1L

Custom BIO-DIS III

If you are interested in a new BIO-DIS configured in one of the above formats, contact your Varian representative. We can customize a unit to suit your needs.



Double Row Dip 300 mL Conversion

USP Apparatus 3 BIO-DIS III Accessories



Accessories for BIO-DIS III



Accessories

Inner Sample Tubes (A)

Inner sample tubes have threaded glass ends.

Item Description	Part Number
0.984 in. inside diameter, 1.102 in. outside diameter for standard 300 mL outer media tubes	27-5000
0.654 in. inside diameter, 0.748 in. outside diameter for 100 mL outer media tube	27-5010

Outer Media Tubes (B)

Outer media tubes are manufactured of borosilicate glass. The part numbers listed below are for tubes sold individually.

Item Description	Part Number
300 mL, standard (B)	27-5100
100 mL, requires vessel carrier P/N 27-6005	27-5110
1000 mL, flat bottom requires vessel carrier P/N 27-6010	27-5120

BIO-DIS III Upper Cap (C)

Upper caps are for use with the inner sample tubes.

Item Description	Part Number
300 mL, USP, for use with P/N 27-5000	27-1000
100 mL, for use with P/N 27-5010	27-1010

BIO-DIS III Lower Cap (D)

Lower caps are for use with the inner sample tubes.

Item Description	Part Number
300 mL, USP, for use with P/N 27-5000	27-1020
100 mL, for use with P/N 27-5010	27-1030
Varian Type for P/N 27-5000, (wider diameter improves mixing action within the vessel)	27-1050

BIO-DIS III Sample and Return Probes (E)

The BIO-DIS III can be used in conjunction with the VK 8000. For automated sampling, sample and return cannulas are fitted into the evaporation caps. BIO-DIS sample and return probes are constructed of type 316 stainless steel.

Item Description	Part Number
BIO-DIS Sample and Return Probes, 5.5 in.	27-6500
BIO-DIS Return Probes, 2.75 in.	27-6520

BIO-DIS III Evaporation Caps (F)

The evaporation cap is for use with the outer media tube.

Item Description	Part Number
For 300 mL USP outer media tube	27-1500
For 100 mL outer media tube	27-1510
For 300 mL USP outer media tube, tinted	27-1520

BIO-DIS III Vessel Carriers for Outer Media Tubes

Vessel Carriers

(Not pictured.)

Item Description	Part Number
300 mL, 7 x 2 layout, set of 3	27-6000
100 mL, 7 x 2 layout, set of 3	27-6005
1000 mL, 1 x 3 layout, set of 3	27-6010

See page 93 for information on screens (G).

BIO-DIS III Replacement Screens

Replacement Polypropylene Screens, 1.25 inch diameter for 300 mL Inner Sample Tubes

Item Description	Part Number
20 mesh, 840 μm	27-2000
40 mesh, 405 μm	27-2005
56 mesh, 250 μm	27-2007
78 mesh, 177 μm	27-2010
100 mesh, 150 μm	27-2015

Polypropylene Screens, 0.75 inch diameter for 100 mL Inner Sample Tubes

Item Description	Part Number
20 mesh, 840 μm	27-2200
40 mesh, 405 μm	27-2205
78 mesh, 177 μm	27-2210
100 mesh, 150 μm	27-2215



USP Apparatus 3 BIO-DIS III Accessories

Stainless Steel Screens, 1.25 inch diameter for 300 mL Inner Sample Tubes

Item Description	Part Number
10 mesh, 1905 μm	27-2099
20 mesh, 864 μm	27-2100
30 mesh, 533 μm	27-2103
40 mesh, 381 μm	27-2105
100 mesh, 140 μm	27-2110
200 mesh, 74 μm	27-2115
300 mesh, 46 μm	27-2120
400 mesh, 38 μm	27-2125

Stainless Steel Screens, 0.75 inch diameter for 100 mL Inner Sample Tubes

Item Description	Part Number
8 mesh, 2591 μm	27-2300
10 mesh, 1905 μm	27-2305
20 mesh, 864 μm	27-2310
40 mesh, 381 μm	27-2315
60 mesh, 229 μm	27-2320

BIO-DIS Compatibility Table

Part Number	Holder	Outer Vessel			
		50 mL	100 mL	300 mL (USP)	1000 mL
		Apparatus 3			
		27-5130, 27-5135, 27-5160	27-5110	27-5100, 27-5111, 27-5112	27-5120
27-5000	Inner tube (300 mL)	-		√	V
27-5010	Inner tube (100 mL)	-	V	√	√
	Standard dissolution basket	-	NR	√	√
	•		Appar	atus 7	
27-5000	Inner tube (300 mL)	-	-	V	V
27-5010	Inner tube (100 mL)	-	V	√	√
	Standard dissolution basket	-	NR	√	√
27-8620, 27-8621	Mini dissolution basket	√	√	√	√
27-8622	Basket assembly, titanium	V	V	√	√
27-3000, 27-3002	Pointed acrylic rod / kit	√	V	√	V
27-3001	Transdermal patch holder kit	-	-	√	√
27-8005	1.6 cm ² reciprocating disk	V	V	√	V
27-8010	2.5 cm ² reciprocating disk	-	-	√	V
27-8015	5.0 cm ² reciprocating disk	-	-	V	V
27-8020	7.0 cm ² reciprocating disk	-	-	V	V
27-8025	10.0 cm ² reciprocating disk	NR	NR	NR	V
27-6540	Replacement stent holder	V	V	V	V
27-6541	Stent holder - 8 mm (horizontal)	V	V	V	$\sqrt{}$
27-6542	Stent holder - 18 mm (vertical)	V	V	√	V
27-6543	Stent holder - 30 mm (vertical)	V	V	V	V
27-0100	Spring holder - 1.45 in L x 0.58 in ID x 0.031 in wire ID	NR	NR	V	V
27-0101	Spring holder - 1.40 in L x 0.31 in ID x 0.040 in wire ID	√*	√*	√*	V
27-0102	Spring holder - 0.96 in L x 0.33 in ID x 0.031 in wire ID	√ ∗	V *	√*	V
27-0103	Spring holder - 0.60 in L x 0.25 in ID x 0.040 in wire ID	√*	√ *	√*	V
27-0104	Spring holder - 1 in L x 0.50 in ID x 0.031 in wire diam.	V	V	V	V
27-8035	Angled disk, 1.98 in	-	-	-	V
27-8036	Angled disk, 1.42 in	-	-	√	V

NR - not recommended; * - based on dimension measurements only; shaded box - accessory will not fit outer vessel



Standard 7-tube System

Apparatus 7

Item Description	Part Number
Apparatus 7, 6-row system, 115V, 60 Hz	25-2000
Apparatus 7, 6-row system, 230V, 50 Hz	25-2100

Modified Apparatus 7 Reciprocating Holder 12-tube/12-row System

The 12-row system utilizes the same housing as the standard USP Apparatus 3 and 50 mL outer media tubes. The dosage form is placed in an inverted basket. Other dosage forms can be tested using this apparatus. We can customize a holder for your application. Contact us for details.

A custom 12-valve VK 8000 is designed to automatically sample from this system. See pages98 for more details on the VK 8000 Sampling Stations.

Modified Apparatus 7

Item Description	Part Number
Modified Apparatus 7 12-row System 115V, 60 Hz	25-2500
Modified Apparatus 7 12-row System 230V, 50 Hz	25-2600

Note that the USP Apparatus 3 (BIO-DIS) and USP Apparatus 7 configurations are not interchangeable.

Varian 400-DS Dissolution Apparatus

Varian recently released a new Apparatus 7 device specifically designed for small volumes. The Varian 400-DS is capable of performing dissolution in 5 or 10 mL tube. The unit utilizes a patented magnetic drive which allows the vessel to be sealed, thereby minimizing evaporative loss. The instrument features include capability to sample and replace up to four different media in a single method. For more information, visit our web site or contact your Varian representative.



Modified 12-row System



Varian 400-DS Dissolution Apparatus

Accessories for USP Apparatus 7

Reciprocating Disks

This standard USP Apparatus 7 sample holder, the reciprocating disk, is manufactured of type 316 stainless steel with an O-ring to hold the transdermal system in place.

Reciprocating Disks for Apparatus 7

Item Description	Part Number
1.6 cm², 1.428 cm diameter	27-8005
2.5 cm², 1.778 cm diameter	27-8010
5.0 cm², 2.692 cm diameter	27-8015
7.0 cm², 3.175 cm diameter	27-8020
10.0 cm², 5.029 cm diameter	27-8025

Pointed Rod Kit

This standard Apparatus 7 sample holder is manufactured of acrylic.

Item Description	Part Number
Pointed Acrylic Rod Kit for Apparatus 7	27-3000
Replacement Acrylic Rod	27-3002

Angled Disk Kit

The angled disk holder is used for transdermal patches. Manufactured from 316 stainless steel.

Item Description	Part Number
Angled Disk Holder, 1.98 inch	27-8035
Angled Disk, 1.42 inch	27-8036

Cylinder

This standard Apparatus 7 sample holder, the cylinder, is used for transdermal patches.

Item Description	Part Number	
Cylinder (Transdermal Kit)	27-3001	

Stent Holder for Apparatus 7

These stent holders are specifically designed for cardiac and carotid stents. Both horizontal and vertical holders are available. Please call for custom holders.

Item Description	Part Number
Stent Holder, 8 mm horizontal	27-6541
Stent Holder, 18 mm vertical	27-6542
Stent Holder, 30 mm vertical	27-6543
Stent Holder, replacement	27-6540

Mini Basket and Shaft

To order the mini basket and shaft for use with the Apparatus 7, order P/N 27-8600 and order the desired basket based on mesh size (either P/N 27-8620 or 27-8621).

Item Description	Part Number
Mini Basket Shaft	27-8600
Mini Basket, 40 mesh (for use with 27-8600)	27-8620
Mini Basket, 50 mesh (for use with 27-8600)	27-8621

USP Apparatus 7 Accessories



Reciprocating Holder with O-ring

Outer Media Tubes

Outer media tubes are manufactured of borosilicate glass. The part numbers listed below are sold individually.

Outer Media Tubes

Item Description	Part Number
300 mL, standard, for use with 7 x 2 layout standard vessel carrier P/N 27-6000	27-5100
100 mL, requires vessel carrier P/N 27-6005	27-5110
100 mL with 100 mL calibration line, requires vessel carrier P/N 27-6005	27-5111
100 mL with 50 mL calibration line, requires vessel carrier P/N 27-6005	27-5112
1000 mL, requires vessel carrier P/N 27-6010	27-5120
50 mL for 12-valve Apparatus 7, requires vessel carrier P/N 27-6050	27-5130
50 mL for 12-valve Apparatus 7 (class B), requires vessel carrier P/N 27-6050	27-5135
50 mL for 12-valve Apparatus 7, amber, requires vessel carrier P/N 27-6050	27-5160
Graduated, requires vessel carrier P/N 27-6000	27-5170

Vessel Carriers for Outer Media Tubes

Vessel Carriers

Item Description	Part Number
300 mL, 7 x 2 layout, set of 3	27-6000
100 mL, 7 x 2 layout, set of 3	27-6005
1000 mL, 1 x 3 layout, set of 3	27-6010
50 mL, 6 x 7 layout	27-6050

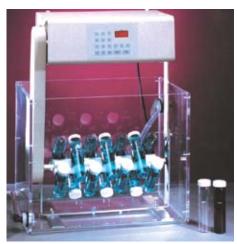
Evaporation Shield

Evaporation shields are used on both the BIO-DIS III and Apparatus 7. They are used to minimize the evaporative loss in those tubes in which the dipping has yet to occur as well as those already used. The front and back covers are not interchangeable.

Evaporation Shield

Item Description	Part Number
Evaporation Shield, curtain, front, vinyl, BIO-DIS III	4040-0380
Evaporation Shield, curtain, rear, vinyl, BIO-DIS III	1300-0628
Evaporation Shield, curtain, front, Teflon, BIO-DIS III	4040-0354
Evaporation Shield, curtain, back, Teflon, BIO-DIS III	4040-0355

Rotating Bottle Apparatus.



Rotating Bottle Apparatus

The Rotating Bottle Apparatus meets National Formulary (NF) XIV specifications and is designed for release rate testing of tablets or pellets. Bottles are clipped into a rotating shaft which is immersed in a water bath. The speed of rotation can be programmed. The manual changing of media during a test simulates a dosage passing through a pH gradient. Sealed bottles prevent evaporative loss. A variety of bottle and vial sizes can be used with this system. This apparatus is suitable for use in testing of implants

Rotating Bottle Apparatus

Item Description	Part Number
115V, 60 Hz with VK 750D Heater/Circulator	30-1000
230V, 50 Hz with VK 750D Heater/Circulator	30-1100
115V, 60 Hz without heater/circulator	30-1200
230V, 50 Hz without heater/circulator	30-1300

Replacement Caps and Bottle for Rotating Bottle Apparatus

Item Description	Part Number
Rotating Bottle Cap with Viton liner	32-1101
Rotating Bottle Decanter Cap with screen	32-1121
Viton Liner for 100 mL bottle	32-1201
Screen for Decanter Bottle P/N 32-1121	32-1221
Rotating Bottle and Cap for 100 mL, Rotating bottle	32-5001
Rotating Bottle only, 100 mL, amber	32-5521
Rotating Bottle only, 100 mL, clear	32-5530

Rotating Bottle Apparatus



Bottle Conversion Kit for 200 mL Bottles

This conversion kit adapts the Rotating Bottle Apparatus from 100 mL to 200 mL.

Conversion kits and clips are available for both larger and smaller bottles. Call your Varian representative for more information.

The Rotating Bottle Conversion Kit includes:

- 4 Delrin spacers with hardware
- 14 clips, 200 mL type
- 20 amber test bottles, 200 mL
- 5 decant caps

Rotating Bottle Conversion Kit

Item Description	Part Number
Kit with 200 mL bottles, amber	32-0110
Kit with 16 x 100 mm tubes (4 in. extensions on center shaft)	32-0120

Rotating Bottle Apparatus Accessories

Varian Rotating Bottle Apparatus Replacement Bottles/Caps/Screens/Liners

Varian's Rotating Bottle Apparatus caps for 100 mL bottles have been redesigned. The original cap design (P/Ns 32-1100 and 32-1120) can only be used with the original bottle design (P/Ns 32-5020, 32-5020, 32-5510, and 32-5520) as well as the original screen design (P/N 32-1220) and the original liner design (P/N 32-1200). The original caps are no longer available for sale.

If you have the original cap design and only want to purchase replacement bottles, you must order P/N 32-5510 or 32-5520. Otherwise, it is necessary to buy both new caps and new bottles. The new caps (P/N 32-1121) require the new screens (P/N 32-1221) and the new caps (P/N 32-1101) require the new liners (P/N 32-1201). See the following table to verify which part numbers are used together. Part numbers marked NLM are no longer made and are not available for sale.

Rotating Bottle Apparatus Accessories: Original-to-New Design Cross Reference

Bottles		Caps		Screens		Lin	ers
Original Design	New Design	Original Design	New Design	Original Design	New Design	Original Design	New Design
32-5000 (NLM)	32-5001	32-1100 (NLM)	32-1101			32-1200 (NLM)	32-1201
32-3000 (NLIVI)	32-3001	32-1120 (NLM)	32-1121	32-1220 (NLM)	32-1221		
32-5020 (NLM)	32-5021	32-1100 (NLM)	32-1101			32-1200 (NLM)	32-1201
32-3020 (INLIVI)	32-3021	32-1120 (NLM)	32-1121	32-1220 (NLM)	32-1221		
32-5510 (NLM)	32-1125	32-1100 (NLM)	32-1101			32-1200 (NLM)	32-1201
32-33 IU (INLIVI)	32-1123	32-1120 (NLM)	32-1121	32-1220 (NLM)	32-1221		
32-5520 (NLM)	32-5530	32-1100 (NLM)	32-1101			32-1200 (NLM)	32-1201
32-3320 (INLIVI)	32-3330	32-1120 (NLM)	32-1121	32-1220 (NLM)	32-1221		
32-5030	32-5521	32-1105				32-1205	
32-3030	32-3321	32-1125		32-1225			

NLM= No Longen Manufactured order the New Design replacement.

Accessories for Rotating Bottle Apparatus

Bottles

Item Description	Part Number
200 mL Amber Bottle with cap (for 200 mL conversion only)	32-5030
100 mL Amber Bottle without cap, new design	32-5521
100 mL Clear Bottle without cap, new design	32-5530

Caps

Item Description	Part Number
Cap with Viton liner for 100 mL bottle	32-1101
Cap with Viton liner for 200 mL bottle	32-1105
Bottle Decant Cap with 40 mesh screen for 100 mL bottle (Note: this cap is used for the straining of beads between media changes.)	32-1121
Bottle Decant Cap with 40 mesh screen for 200 mL bottle	32-1125

Screens and Liners

Item Description	Part Number
Viton Liner for 100 mL bottle, new design	32-1201
Viton Liner for 200 mL bottle	32-1205
40 mesh Screen only for 100 mL decant cap, new design	32-1221
40 mesh Screen only for 200 mL decant cap	32-1225

Replacement Bottle Clips

Item Description	Part Number
Replacement Bottle Clips for 100 mL bottle, P/N 32-5000	32-1300
Replacement Bottle Clips for 16 x 100 mm tubes	32-1301
Replacement Bottle Clips for 28 x 98 mm (40 mL) tubes	32-1302
Replacement Bottle Clips for 200 mL bottle, P/N 32-5030	32-1305

VK 8020 Sample Collector and HPLC Auto-Injections

99

VK 8000 Dissolution Sampling Station

- Modular design
- Operates as an integrated system for fully automated sampling
- Patented autocalibration
- Septum piercing capability—eliminates evaporative loss
- Retains up to 15 programs—including all pertinent dissolution apparatus parameters (when used with Varian dissolution apparatus)



The VK 8000 automates the tedious task of manually pulling samples. The sampling station can be configured with new dissolution apparatus or retrofitted to older models. It is flexible enough to sample up to ten timepoints on a single tray (or twenty when two programs are linked). Offered with a choice of Peristaltic or Syringe Pumps, it can even incorporate a filter changing option.

The VK 8000 integrates with either conventional dissolution apparatus (Apparatus 1, 2, 5, and 6 – see page 54 for information on the VK 8000 for use with Apparatus 1 and 2) as well as with Apparatus 3 and 7 (reciprocating instruments). The system includes the VK 8000 base station, and either a Peristaltic Pump or Syringe Pump. The sampling cannula on the evaporation blocks which are attached to the reciprocating shafts.

VK 8000 Base Station

Dimensions and Weight						
Size:	Height	16 in.	Width	16 in.	Depth	20 in.
		40.6 cm		40.6 cm		50.8 cm
Weight:	72 lb/32.4 kg					



Septum Piercing

Automatic Calibration

The patented autocalibration block is used in conjunction with the Peristaltic Pump to ensure accurate volume replacement. Calibration is as easy as pressing the calibration key. The volume removed is based on the time each individual valve is left open. The accuracy is independent of volume differences in the various tubing connections.

Septum Piercing Capability

Because the VK 8000 can pierce septa, you do not have to worry about evaporation distorting your results. The unique two-barrel needle design eliminates overpressurizing of the vial during filling. Overpressurized vials lead to reproducibility problems in autosamplers.

Simplified Control

The VK 8000 controls the operation of the Varian dissolution apparatus. All operating parameters, including those of the dissolution apparatus, can be entered using the VK 8000 keypad.

Sealed Switch-type Keypad

A fully functional keypad has been incorporated into the VK 8000 for the entry of methods and information. The control keys along the bottom row provide programming, calibration and self-cleaning functions in addition to manual control.

Automatic Documentation

The Report Center II Printer lets you print everything from system calibration verification to comprehensive test data even when the unit is unattended. Print full batch information downloaded from the dissolution apparatus—including unit ID number; operating temperature; water bath temperature; elapsed time; test length; DPM; sampling timepoints; and depending on the model and configuration of the apparatus, and dosage delivery time.



Autocalibration Blocks



VK 8000 Keypad



VK 8000 Configurations for use with Apparatus 3 & 7

VK 8000 with Peristaltic Pump



Peristaltic Pump

The VK 8000 can be configured with a specially designed Peristaltic Pump. The bidirectional Peristaltic Pump is specifically designed to be used in dissolution (even allowing the use of surfactants without excessive foaming). By reversing directions, the lines can be purged while at the same time back-flushing either in line or cannula tip filters. When used in conjunction with the patented autocalibration block, you are assured of accurate volume removal and replacement. We are able to achieve accurate volume removal using a Peristaltic Pump because the amount withdrawn is based on the time the sample valve is open to dispense. This time constant is different for each sampling line. In this manner, we are able to accurately withdraw to \pm 0.5 mL.

- Set color-coded Teflon tubing
- Set of six or eight PEEK body sampling valves with needles for piercing vial septa
- 80-position sample tray (8 x 10) for 16 mm sample tubes (tubes included) or HPLC autosampler vials (vials not included). We offer a variety of trays to accommodate different vials (see page 62 for further ordering information). Please specify type and size of tray.
- Bidirectional Peristaltic Pump with transistor-transistor logic (TTL) actuated auto-reverse function
- Report Center II Printer
- Accessory kit (includes pack of Peristaltic Pump tubing and starter packs of Full Flow Filters, 10, 35, and 70 µm pore sizes (50 each)

VK 8000 for use with Apparatus 3 & 7 (with Peristaltic Pump)

Item Description	Part Number
8-valve for use with Apparatus 3 or Apparatus 7, 115V	15-1410
8-valve for use with Apparatus 3 or Apparatus 7, 230V	15-1420
12-valve for use with 12 x 12 Apparatus 7 with Peristaltic Pump, 115V	15-1441
12-valve for use with 12 x 12 Apparatus 7 with Peristaltic Pump, 230V	15-1442
12-valve for use with Alza Release Station with Peristaltic Pump, 115V (custom)	15-1443
12-valve for use with Alza Release Station with Peristactic Pump, 230V (custom)	15-1444

Please note that the 12-row system is only available with the Peristaltic Pump.

VK 8000 with Syringe Pump



VK 806 Syringe Pump

Remove your samples using a Syringe Pump for even greater accuracy and reproducibility. The Syringe Pump is also ideal when you need a totally inert sampling system. Your sample will only come in contact with the cannula, Teflon tubing, the glass syringe, and the PEEK valves. If your methods call for additional back pressure associated with filtering down to 0.45 μm , we recommend you consider this option.

The Filter Changer requires the greater pressure generation of the Syringe Pump. If you plan to add this capability to your system, we suggest the Syringe Pump version, which can be later upgraded to integrate the Filter Changer (see page 102).

VK 8000 for use with Apparatus 3 (with Syringe Pump)

Item Description	Part Number
8-valve for use with Apparatus 3 or Apparatus 7, 115V	15-7155
8-valve for use with Apparatus 3 or Apparatus 7, 230V	15-7165

VK 8000 Configurations for use with Apparatus 3 & 7



VK 8000 with Filter Changer and Syringe Pump

- Filters and collects samples automatically
- Changes filters (down to 0.45 µm membrane filter) automatically between sample timepoints
- Program all elements from the VK 8000 base unit

Next Step in Automation

The combination of the VK 8000 with the Filter Changer and Syringe Pump allows you to take the next step in automating your dissolution testing. It provides a level of automation that was previously only found in full robotic systems.

The coordination of these three Varian elements allows you to run long dissolution tests with multiple timepoints unattended while guaranteeing precise sample volumes. In addition, you do not have to manually filter each individual sample prior to analysis. The samples collected on the VK 8000 will be taken at the correct time and will be ready for immediate analysis once acquired.

The Syringe Pump draws samples from a standard dissolution apparatus (Varian or another manufacturer) and ensures precise sample volumes.

Each sample is passed through a 25 mm membrane filter before being stored in a collection tube or vial on the VK 8000 base unit. Varian has designed special automation-ready filters (see page 106).

The VK 8000 controls the Filter Changer to change the filters between each sample timepoint.



VK 8000 with Filter Changer and Syringe Pump

VK 8000 with Filter Changer and Syringe Pump

Item Description	Part Number
8-valve for use with Apparatus 3 or Apparatus 7, 115V	15-2410
8-valve for use with Apparatus 3 or Apparatus 7, 230V	15-2420



VK 8000 for use with Apparatus 3 & 7

Peristaltic Pump

- Flexible—can be configured for 6, 7, 8, 12, 14, 16 channels
- Bidirectional
- Low gear ratio—allows use with surfactants



Peristaltic Pump

The Peristaltic Pump has a 16-channel maximum capacity for sample transfer in all Varian dissolution sampling systems and an 8-roller design for smooth flow. There is bidirectional TTL actuated operation for pumping and purging. The flow rate is 25 mL/min. (nominal). Part numbers listed below include 0.110 in. inside diameter Marprene tubing and adjustable pump cartridges.

Peristaltic Pump

Dimensions and Weight						
Size:	Height	5.5 in.	Width*	6 in.	Depth	18 in.
		13.97 cm		15.2 cm		45.72 cm
Weight:	19 lb/9	kg				

^{*} With cartridge and tubing connectors

Peristaltic Pump

Item Description	Part Number
6 cartridges, 115V, 60 Hz	17-2000
6 cartridges, 230V, 50 Hz	17-2100
8 cartridges, 115V, 60 Hz	17-2200
8 cartridges, 230V, 50 Hz	17-2300
16 cartridges, 115V, 60 Hz	17-2600
16 cartridges, 230V, 50 Hz	17-2700

Did you know surfactants are substances that lower the resistance between immiscible liquids? Surfactants fall into three categories:

- 1. Detergents
- 2. Wetting agents
- 3. Emulsifiers

Peristaltic Pump Cartridge

Individual replacement cartridge for Peristaltic Pumps with adjustable tensioning arm (P/N 17-2000 through P/N 17-2700)



Peristaltic Pump Cartridges (8)

Peristaltic Pump Cartridge

Item Description	Part Number
Peristaltic Pump Replacement Cartridge	17-6020

Peristaltic Cartridge Tubing

Peristaltic Pump cartridge tubing is available in durable and chemicalresistant Neoprene, conventional silicone, and Viton. All types are coded purple and white with a 0.110 in. inside diameter. Packs of eight.

Peristaltic Pump Tubing

Item Description	Part Number
Peristaltic Pump Tubing, silicone	17-6010
Peristaltic Pump Tubing, Viton	17-6005
Peristaltic Pump Tubing, Neoprene	17-6000

VK 8000 for use with Apparatus 3 & 7

103

VK 806 Syringe Pump



VK 806 Syringe Pump

- Precise delivery
- Available with 10 mL syringes
- Uses Teflon tubing and PEEK valves
- Great when you require inert sampling

The Syringe Pump draws samples from a Varian dissolution apparatus and ensures precise sample volumes. Due to the accuracy of the Syringe Pump, the autocalibration block, which is used with the Peristaltic Pump, is not required.

The Filter Changer requires the greater pressure generation of the Syringe Pump. If you plan to add this capability to your system, we suggest you consider the Syringe Pump. See page 62 for information on this combination of accessories.

When using the Syringe Pump we recommend Teflon tubing with an inside diameter of 0.03 inch. This tubing is supplied with all new sampling cannulas ordered with Syringe Pumps. If you are retrofitting an existing VK 8000, tubing is available in six or eight individual 50 foot color-coded lengths. When changing the tubing, it is important to maintain the proper tubing lengths between components. Detailed instructions are included with the tubing packages.

The following part numbers are for upgrading your existing VK 8000 with Peristaltic Pump to a VK 8000 with Syringe Pump.

VK 806 Syringe Pump

Dimensions and Weight						
Size:	Height	10.75 in.	Width	9.5 in.	Depth	6 in.
		27.31 cm		24.13 cm		5 cm
Weight:	14 lb/6	kg				

VK 806 Syringe Pump

Specifications						
	Syringe Pump and VK 8000 Syringe Pump with Fil Changer and VK 800					
Sampling Accuracy	± 0.2 mL (2%)	± 0.3 mL (3%)				
Minimum Sample Interval	5 min.	6 min.				
Sample Volume	1 - 14 mL	1 - 14 mL				
Filter Type	Full Flow Cannula UHMWPE	Syringe \geq 0.45 μ m (Automation Certified)				

Syringe Pump for VK 8000 Upgrade

Item Description	Part Number
Syringe Pump Upgrade for 8-channel 115V, 60 Hz	15-5100
Syringe Pump Upgrade for 6-channel 115V, 60 Hz	15-5101
Syringe Pump Upgrade for 8-channel, 230V, 50 Hz	15-5110
Syringe Pump Upgrade for 6-channel, 230V, 50 Hz	15-5111



VK 8000 for use with Apparatus 3 & 7

VK 808 Filter Changer

- Automatic filter changing between each sample timepoint
- Special 25 mm filters designed for automation
- Variety of membrane materials available
- Pore sizes down to 0.45 μm

The Filter Changer is designed to be used in conjunction with the VK 8000. This unit can easily be added to an existing autosampler (a Syringe Pump is required).

The Filter Changer is designed to filter six, seven or eight lines simultaneously and can store up to 200 filters at a time. The filters come prepackaged in tubes of 25 for easy loading. See page 106 for automation filters.

When used with the VK 8000, all of the parameters are set using the VK 8000 keypad. The sequence of events is as follows:

- The Filter Changer is in line between the Syringe Pump and the VK 8000.
- A multichannel Syringe Pump pulls media from each vessel.
- A series of pulls is required to fill the lines of the VK 8000.
- Once the lines are full, the valves in the VK 8000 open and the Syringe Pump fills the tubes or vials in the sample tray with filtered sample.
- The valves in the VK 8000 close and the remaining media in the line is pushed from the lines.
- Then the filters are ejected from the lines and new filters are rotated into position.

You are assured of the proper sample volume being withdrawn due to the accuracy of the Syringe Pump. These syringes have an accuracy of \pm 3% when used with the Filter Changer and \pm 2% when used without the Filter Changer.

You can order the Filter Changer to retrofit existing VK 8000s. For these systems a new ROM chip is installed in the VK 8000 and the unit is retrofitted with a Syringe Pump to replace the existing Peristaltic Pump.

When ordering, please specify the serial number of your existing VK 8000.

VK 808 Filter Changer

Dimensions and Weight							
Size:	Height*	25 in. 63.5 cm	Width	9.5 in. 24.1 cm	Depth**	24 in. 61 cm	
Weight:	38 lb/17	'.1 kg					

*Height is with filter tubes inserted for use; **Depth is with filter drop bucket in place for use.

VK 808 Filter Changer

Specifications				
	Syringe Pump with Filter Changer and VK 8000			
Sampling Accuracy	± 0.3 mL (3%)			
Minimum Sample Interval	6 min.			
Sample Volume	1 - 14 mL			
Filter Type	Syringe \geq 0.45 μ m (Automation Certified)			



The following part numbers are for upgrading your existing VK 8000 with Peristaltic Pump to a VK 8000 with Syringe Pump and Filter Changer.

Filter Changer with Syringe Pump for VK 8000

Upgrade includes all the necessary accessories required, including the new ROM chip and sampling cannulas, filter catch basin, Teflon tubing, and cables.

Item Description	Part Number
Filter Changer and Syringe Pump Upgrade for 8-channel, 115V, 60 Hz	15-5000
Filter Changer and Syringe Pump Upgrade for 8-channel, 230V, 50 Hz	15-5010

The following part numbers are for upgrading your existing VK 8000 with Syringe Pump to include a Filter Changer.

Filter Changer for VK 8000 with Syringe Pump Upgrade

Includes all the necessary accessories required, including the new ROM chip and sampling cannulas, filter catch basin, Teflon tubing, and cables.

Item Description	Part Number
Filter Changer Upgrade for 8-channel, 115V	15-5002
Filter Changer Upgrade for 6-channel, 115V	15-5004
Filter Changer Upgrade for 8-channel, 230V	15-5006
Filter Changer Upgrade for 6-channel, 230V	15-5008

VK 8000 for use with Apparatus 3 & 7



VK 8000 Sample Trays

We offer sampling trays for a variety of tubes and vials. Call your Varian representative if you require a size not shown.



VK 8000 Sample Trays

VK 8000 Sample Trays

Item Description	Part Number
16 x 100 mm (~13 mL) open tube	17-1000
15 x 85 mm (~10 mL) open tube	17-1010
For 8 x 30 mm HPLC vials	17-1020
For 7 x 40 mm HPLC vials	17-1030
For 8 x 40 mm HPLC vials	17-1040
For 12 x 32 mm HPLC vials	17-1050
For 15 x 45 mm HPLC vials (VK 8020)	17-1060
For 15 x 45 mm HPLC vials (VK 8000)	17-1065
For 13 x 75 mm HPLC vials (VK 8000)	17-1070
For 13 x 100 mm HPLC vials (VK 8000)	17-1075
For 12 x 75 mm HPLC vials (VK 8000)	17-1080

VK 8000 Glass Sample Tubes

These disposable sample tubes are for use with VK 8000 sample trays (P/Ns 17-1000 and 17-1010). Tubes are sold in packs of 250.

VK 8000 Glass Sample Tubes

Item Description	Part Number
16 x 100 mm (13 mL), standard	17-5001
15 x 85 mm (10 mL)	17-5010

Report Center II Retrofit Kit

The retrofit kit is available for updating the VK 8000 from a thermal printer to a dot matrix printer (for permanent record keeping). ThisRoHS-compliant printer is attached externally to your VK 8000.



Report Center II Printer Kit

Report Center II Printer Accessories

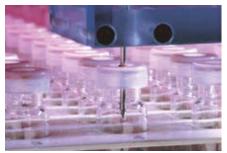
Item Description	Part Number
Report Center II Retrofit, VK 8000	17-1400
Replacement Ribbons, pk. of 5 ribbons	12-9997
Plain Paper, 2.25 in. wide, pk. of 10 rolls	12-9995
Plain Paper, 2.25 in. wide, case of 100	12-9996



VK 8000 for use with Apparatus 3 & 7 Accessories

HPLC Vials

Disposable HPLC vials include Snap Caps with PTFE/Silicone Septa (packaged separately).



HPLC Vials

HPLC Vials

Item Description	Part Number
12 x 32 mm (2 mL) clear glass with caps, pk. of 100	17-5020
15 x 45 mm (4 mL) clear glass with caps, pk. of 100	17-5030

Replacement Cannulas

These cannulas are for use with the VK 8000 when used with an Apparatus 3 or Apparatus 7. For replacement cannulas when working with a VK 8000 with Apparatus 1 or 2, see page 65.

Replacement Cannulas

Item Description	Part Number
Sample Probe, 5.5 in., for use with standard Apparatus 3 or Apparatus 7	27-6500
Return Probe, 2.75 in., for use with standard Apparatus 3 or Apparatus 7	27-6520
Sampling Cannula for use with 12-valve Apparatus 7	27-6521
Return Cannula for use with 12-valve Apparatus 7	27-6522

In-line filters for Apparatus 3 and 7

Varian recommends the use of in-line filters prior to the start of each run. These filters prevent obstructions from reaching the valves of the sampling system.

The 5 μm filters that are recommended are manufactured from acrylic copolymer (P/N 3081-0004).

Calibration Tubes

Calibration tubes are for use with the VK 8000 for verification of volume dispensed. Tubes are prescored to contain 10 mL.



Calibration Tubes

Item Description	Part Number
Calibration Tubes 10 mL (set of 8)	17-5040

Media Rinse Reservoir

This replacement unit is for all VK 8000 sampling stations. The dual-chambered PVC reservoir is located in front of the autocalibration block. The first chamber is used to rinse the needles and prevent contamination. The second chamber holds replacement media for withdrawal by the VK 8000 sample needles.



Media Rinse Reservoir

Media Rinse Reservoir

Item Description	Part Number
Media Rinse Chamber, VK 8000	17-1200

VK 8000 for use with Apparatus 3 & 7 Accessories



Automation Filters



Automation filters

These specially designed automation filters are constructed to prevent compression on the membrane and allow flow. Glass fiber as well as other membrane types are available. Call Varian for more details. Filters are sold in packs of 200 and prepackaged in sleeves of 25 (these filters are ready for loading in the Filter Changer).

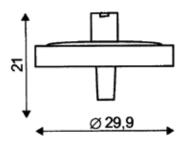
The filter housing is made from rigid polypropylene and is pressure resistant. They provide reproducible results and have been thoroughly tested in the VK 808 Filter Changer. The filters are available in a variety of membranes and will be offered in packages of 200 or 1000. Please see the following list for reorder information.

Whatman / S&S ROBY Automation Filters

- Pressure-resistant design
- Made from rigid polypropylene
- Provides reproducible results
- Available with membrane and glass fiber prefilter or glass fiber prefilter alone
- Low extractables depending on membrane type

ROBY25 Product Specifications

Product Specifications		
Filter diameter:	25 mm	
Effective filter area:	4.2 cm ²	
Recommended filtration volume:	≤100 mL	
Dead volume:	≤ 50 µL	
Max. operating pressure:	5 bar	
Connections inlet: Luer Lock inner core (female)		
Connections outlet:	Luer outer cone (male)	
Temperature resistance:	60 °C	
Housing material:	polypropylene	



ROBY Filter

Whatman / S&S ROBY Automation Filters

Item Description	Part Number
<u> </u>	
ROBY25/GF 92, 1/glass fiber, neutral, 1000 per pk.	17-4150
ROBY25/GF 92, 1/glass fiber, neutral, 200 per pk.	17-4151
ROBY25/0.45NL, 0.45/nylon, printed, 1000 per pk.	17-4152
ROBY25/0.45NL, 0.45/nylon, printed, 200 per pk.	17-4153
ROBY25/0.45NL - GF 92, 0.45/nylon-glass fiber, yellow, 1000 per pk.	17-4154
ROBY25/0.45NL - GF 92, 0.45/nylon-glass fiber, yellow, 200 per pk.	17-4155
ROBY25/0.45RC, 0.45/regenerated cellulose, printed, 1000 per pk.	17-4156
ROBY25/0.45RC, 0.45/regenerated cellulose, printed, 200 per pk.	17-4157
ROBY25/0.45RC-GF 92, 0.45/regenerated cellulose-glass fiber, brown, 1000 per pk.	17-4158
ROBY25/0.45RC-GF 92, 0.45/regenerated cellulose-glass fiber, brown, 200 per pk.	17-4159
ROBY25/0.45CA-GF 92, 0.45/cellulose acetate-glass fiber, green, 1000 per pk.	17-4160
ROBY25/0.45CA-GF 92, 0.45/cellulose acetate-glass fiber, green, 200 per pk.	17-4161
ROBY25/GF 55, ~0.7 glass fiber, brown, 1000 per pk.	17-4164
ROBY25/GF 55, ~0.7 glass fiber, brown, 200 per pk.	17-4165



Automation Filter Validation Kit

Varian has prepared a Filter Validation Kit for use with the VK 808 Filter Changer. This kit is a sample pack that includes 25 each of eight different Schleicher & Schuell ROBY25 automation filters and a filter validation guide. The filter housing is made from rigid polypropylene and is pressure resistant. They provide reproducible results and have been thoroughly tested in the VK 808 Filter Changer. The filters are available in a variety of membranes and will be offered in packages of 200 or 1000.

Item Description	Part Number
Filter, 1.0 µm APFB glass fiber prefilter for processing and clarification of aqueous and organic solutions containing high particle levels	17-4200
Filter, 0.45 µm how protein binding PVDF membrane for processing and clarification of aqueous and mile organic solutions	17-4210
Filter, 0.45 µm nylon membrane for processing and clarification of aqueous and mile organic solutions	17-4220



NEW

VK 8000 for use with Apparatus 3 & 7 Accessories

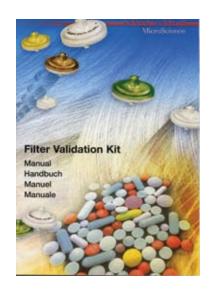
Filter Validation Kit

Selecting the right filter media is simple with the Filter Validation Kit. The kit contains eight different types of filters (the kit includes 25 of each different membrane type) from Whatman/ Schleicher & Schuell MicroScience. Included with the kit is a filter selection guide and filter validation protocol to assist you in choosing the right membrane.

The filters are distinguished in three categories:

- 1. Glass fiber filter media (depth filter)
- 2. Membrane filter media (surface filter)
- 3. Membrane plus glass fiber prefilter

Follow the three test procedures included in the Filter Validation Kit and you'll determine the best filter for your application.



Automation Filters

Category	Filter Material	Product Name	Pore Size	Recommended Application
I	Glass fiber filter GF 92	Roby 25/ GF 92	1.7 μm	The standard for difficult-to-filter samples to retain coarse particles
I	Glass fiber filter GF 55	Roby 25/ GF 55	0.7 μm	The best filter for gelatinous capsules
II	Regenerated Cellulose Membrane (GC)	Roby 25/ 0.45 RC	0.45 μm	The best choice for HPLC application
Very low protein binding, better than PVDF - Very low extractables				
II	Cellulose Acetate Membrane (CA)	Roby 25/ 0.45 CA	0.45 μm	Extremely low protein binding, better than PVDF
II	Polyamide/Nylon Membrane (NL)	Roby 25/ 0.45 NL	0.45 μm	Robust membrane for applications where protein binding is not critical
III	Membrane plus Glass Fiber Prefilter	Roby 25/ 0.45 RC-GF 92 Roby 25/ 0.45 CA-GF 92 Roby 25/ 0.45 NL-GF 92 0.45	0.45 μm	When a membrane filter gets clogged and a glass fiber filter alone is not suitable

Sample Filter Validation Kit

Item Description	Part Number
Filter Validation Kit	17-4195



Replacement Sample Tubing

For use with Peristaltic Pump Configurations

This tubing is recommended for use with the Peristaltic Pump. Standard 0.066 inch outside diameter and 0.042 inch inside diameter color-coded Teflon tubing is available in six or eight individual 50 foot lengths. When changing the tubing, it is important to maintain the proper tubing lengths between components. Detailed instructions are included with the tubing packs.

For use with Syringe Pump Configurations

This color-coded Teflon tubing is recommended for use with the Syringe Pump. Standard 0.063 inch outside diameter and 0.03 inch inside diameter tubing is available in six or eight individual 50 foot lengths. When changing the tubing it is important to maintain the proper tubing lengths between components. Detailed instructions are included with the tubing packs.

Replacement Sample Tubing

Item Description	Part Number
Teflon Tubing, 6 lengths of 50 feet	17-6030
Teflon Tubing, 8 lengths of 50 feet	17-6035



VK 8020 Sample Collector and HPLC Auto-Injections

VK 8020 Sample Collector and HPLC Auto-Injection Station



- Automatic sample collection and injection
- Compatibility with virtually any HPLC system
- Standard tray accommodates 15 x 44 mm vials—other trays available
- The VK 8020 can only be used with either the VK 7010, VK 7025, VK 7030 and 705-DS in conjunction with the Dissolution Workstation (see page 72 for details on the Dissolution Workstation)

To increase productivity, the VK 8020 automates both dissolution sample collection and HPLC injection.

Samples are pulled using the motorized sampling cannulas and deposited into empty vial in the collection tray. Between each sampling timepoint, as many injections as possible are made prior to the next pull.

Sample collection always takes precedence over sample injections. During a sample point, the injector module goes into standby mode, returning to its task only at the end of the timepoint.

You can program injection intervals from one to 99 minutes or wait for the ready signal from the LC. It is possible to inject standards before or after, or bracket each group of samples.

The VK 8020 can be used as a collector only or as an HPLC auto-injector. You can independently program the number of standard injections to meet the USP system suitability requirements. The automated sampling cannula automatically lower and raise during the sampling cycle and the Peristaltic Pump transfers the samples from the vessels to the collector.

Should you wish to use our Syringe Pump and Filter Changer with the VK 8020, this configuration is possible with our Dissolution Workstation software (see page 72).

Consists of two modules:

- Base station including sipper assembly with needle.
- Injector module with Rheodyne 7710 valve and 20 μl loop.

VK 8020 Sample Collector and HPLC Auto-Injection Station

Specifications			
	Sampling Module Injector Module		
Width:	15.3 in./39 cm	13.25 in./34 cm	
Height:	16 in./41 cm	13.25 in./34 cm	
Depth:	20.5 in./52 cm	18 in./46 cm	
Weight:	72 lb/33 kg	40 lbs/18 kg	

VK 8020 HPLC Auto-Injection Station

Item Description	Part Number
VK 8020, injection module only	20-6200
VK 8020, 4x4, for HPLC, Peristaltic Pump, for VK 7000/7010, 115V	20-6300
VK 8020, 4x4, for HPLC, Peristaltic Pump, for VK 7000/7010, 230V	20-6310
VK 8020, Peristaltic Pump, for VK 7025, 115V	20-6510
VK 8020, Peristaltic Pump, for VK 7025, 230V	20-6515
VK 8020, for HPLC, 8-valve, VK 806 Syringe Pump, for VK 7025, 115V	20-6540
VK 8020, for HPLC, 8-valve, VK 806 Syringe Pump, for VK 7025, 230V	20-6545
VK 8020, for HPLC, VK 806 Syringe Pump, for VK 7000/7010, 115V	20-6580
VK 8020, for HPLC, VK 806 Syringe Pump, for VK 7000/7010, 230V	20-6585
VK 8020, 8-valve, VK 806 Syringe Pump, VK 808 Filter Changer, for VK 7025, 115V	20-6610
VK 8020, 8-valve, VK 806 Syringe Pump, VK 808 Filter Changer, for VK 7025, 230V	20-6615
VK 8020, 4x4, for HPLC, VK 806 Syringe Pump, VK 808 Filter Changer, for VK 7000/7010, 115V	20-6650
VK 8020, 4x4, for HPLC, VK 806 Syringe Pump, VK 808 Filter Changer, for VK 7000/7010, 230V	20-6655

^{*} Please note that in order for the VK 8020 to work with the Apparatus 3/Apparatus 7, it is necessary to run the system from the Dissolution Workstation Software (see page 72 for ordering information for the Dissolution Workstation Software).

Accessory Kits for VK 8020

Item Description	Part Number
Accessory kit, VK 8000, 6 or 8-valve, 16x100 mm vial tray	1001-1017
Accessory kit, VK 8000, 6 or 8-valve, 12x32 mm vial tray	1001-1018

VK 100 Accessories

USP Tablet Disintegration Testing Systems

VK 100 Automated Disintegration Apparatus

- Meets all current USP specifications
- Includes integrated drive system, water bath, and heater/circulator
- Microprocessor controlled
- Three-basket models can be independently programmed
- Compact, bench-saving design

The VK 100 is available in two models: single basket and three basket. Both are fully programmable. Simply enter the time duration of the test. The baskets are automatically lifted from the beaker at the end of the test in the pass/fail mode. The three-basket model has individual digital time displays for each basket so three different tests can be performed simultaneously. The water bath temperature continuously displays on the front panel. Both models include accessories. The optional printer can be factory installed or retrofitted at a later date and used for calculating and recording test results. A RS-232 communication port is located on the rear of the VK 100 system.

VK 100 systems ship complete with accessories required for performing the standard USP test: Six-tube basket rack assembly(ies) with 80 mm tube length; 10 mesh, 1905 μm stainless steel screen(s); disintegration beaker(s); and fluted disk(s). Other configurations are available and should be ordered separately.

Accessories for the VK 100 can be found on pages 111 - 115.

VK 100

Specifications						
Dip Speed	30 DPM	l ± 1 DPM				
Stroke Length:	5.5 cm ± 0.1 cm					
	Environment					
Bath Temperature Range:	' I Ambient + 5 % to 60 %					
	Dimensions and Weight					
Size:	Height 20 in. Width 17 in. Depth 24 in. 52.1 cm 43.18 cm 60.96 cm				24 in. 60.96 cm	
Weight:	28 lb/12	2.7 kg				

VK 100 Automated Disintegration Apparatus

Item Description	Part Number
Single-basket system, 115V, 60 Hz	35-4000
Single-basket system, 230V, 50 Hz	35-4100
Three-basket system, 115V, 60 Hz	35-4200
Three-basket system, 230V, 50 Hz	35-4300

Item Description	Part Number
Retrofit Report Center Printer option, 115V, 60 Hz	37-0150
Retrofit Report Center Printer option, 230V, 50 Hz	37-0155
Retrofit printer option for VK 100 CE 115/230V	37-0200
Bath Temperature Probe	67-0300



Single-basket VK 100



Three-basket VK 100

VK 100 Disintegration Testing

Basket Hangers

Basket Hangers

The basket hangers are made of stainless steel. The assembly is notched for holding USP disintegration baskets. These basket hangers are for use with the Standard Disintegration Apparatus (single-basket, three-basket, six-basket, or 12-basket systems).

Basket Hangers

Item Description	Part Number
Basket Hanger, 1-unit	37-1000
Basket Hanger, 3-unit	37-1005
Basket Hanger, 6-unit	37-1015

Basket Suspension Rod

The basket suspension rod is made of type 316 stainless steel. It has an adjustable clip for easy setup.

Basket Suspension Rod

Item Description	Part Number
Suspension Rod for Standard Disintegration Apparatus	37-1040

Disintegration Accessories



VK Verified

- Individual certificate
- Critical dimensions measured
- Results are traceable

Varian offers several individually verified disintegration accessories shown below. For

a nominal charge, each of the accessories listed is measured to ensure conformance. A certificate is included to provide the actual measured values, the type of measuring device used, and its traceability.

Should you require verification of another component—give us a call!

Basket Rack Assembly

Item Description	Part Number
Basket Rack Assembly for VK 100, 6-tube, 10 mesh, 1905 μm stainless steel screen, fits VK 100, includes individual certificate	37-3001V
Basket, 6-tube, 10 mesh, 1905 µm stainless steel screen for standard disintegration unit, includes individual certificate	37-2001V



Basket Hange



Basket Suspension Rod



Standard 6-tube Basket for Automated Unit

Basket Rack Assemblies

Standard 6-tube

The standard 6-tube basket rack assembly is designed to meet or exceed current USP specifications. This assembly has 10 mesh type 316 stainless steel screens and 80 mm length tubes. The tubes have a 25 mm outside diameter.

Standard 6-tube with 10 mesh, 1905 μm Stainless Steel Screen

Item Description	Part Number
For use with Standard Disintegration Apparatus	37-2001
For use with Automated Disintegration Tester, VK 100	37-3001

Special 6-tube Assembly

The special 6-tube assembly uses 20 mesh screens made of type 316 stainless steel. The tubes are 80 mm in length and have a 25 mm outside diameter.

Special 6-tube with 20 mesh, 864 μm Stainless Steel Screen

Item Description	Part Number
For use with Standard Disintegration Apparatus	37-2010
For use with Automated Disintegration Apparatus, VK 100	37-3010

Nylon 6-tube Assembly

The Nylon 6-tube basket assembly is designed to meet current USP specifications. All components are Nylon except the 10 mesh type 316 stainless steel screen. The tubes are 80 mm in length and have a 25 mm outside diameter.

Nylon 6-tube Basket, with 10 mesh, 1905 µm Stainless Steel Screen

Item Description	Part Number
For use with Standard Disintegration Apparatus	37-2020
For use with Automated Disintegration Apparatus, VK 100	37-3020



Standard 6-tube Basket for Automated Unit



Nylon 6-tube Basket for Automated Unit

VK 100 Accessories

3-tube Basket for Bolus and Large Tablets

The 3-tube basket for bolus and large tablets has 10 mesh type 316 stainless steel screens. The tubes are 80 mm in length and have a 38 mm outside diameter.

3-tube Basket with 10 mesh, 1905 µm Stainless Steel Screen

Item Description	Part Number
For use with Standard Disintegration Apparatus	37-2030
For use with Automated Disintegration Apparatus, VK 100	37-3030

Single-tube Basket for Bolus and Large Tablets

The single-tube basket for bolus and large tablets has a 10 mesh type 316 stainless steel screen. The tube is 92 mm in length and has a 44 mm outside diameter.

Single-tube Basket, with 10 mesh, 1905 µm Stainless Steel Screen

Item Description	Part Number
For use with Standard Disintegration Apparatus	37-2040
For use with Automated Disintegration Apparatus, VK 100	37-3040

6-tube Basket Assembly with 40 mesh screens and 40 mesh cover

This basket assembly is designed to meet current USP specifications. It includes a basket and special 6-hole stainless steel cover with 40 mesh stainless steel screen. The tubes are 80 mm in length and have a 25 mm outside diameter.

6-tube Basket, with 40 mesh Stainless Steel Screen

Item Description	Part Number
For use with Standard Disintegration Apparatus	37-2050
For use with Automated Disintegration Apparatus, VK 100	37-3050



3-tube Basket for Automated Unit



Single-tube Basket for Standard Unit



6-tube Basket for Standard Unit

Basket Rack Assembly Accessories

Covers for Basket Assemblies

Covers are designed to meet current USP specifications. One stainless steel cover is required per basket assembly. These covers fit both the standard and automated (VK 100) Apparatus basket assemblies.



Stainless Steel Cover with Stainless Steel Screen

Item Description	Part Number
UPS 10 mesh, 1905 μm for 6-tube basket	37-2100
(screen type) (A)	37 2100
10 mesh, 1905 μm for 3-tube basket	37-2105
(3-hole type) (B)	37-2103
40 mesh for 6-tube basket (six-hole type) (C)	37-2110

Replacement Screens for Basket Assembly

Replacement screens fit both standard and automated (VK 100) apparatus basket assemblies. Screens are sold in sets of six.

Stainless Steel Screen

Item Description	Part Number
USP 10 mesh, 1905 µm for 6-tube basket	37-2200
20 mesh, 864 μm for 6-tube basket	37-2205
40 mesh for 6-tube basket	37-2210

Replacement Glass Tubes

Replacement tubes fit both standard and automated (VK 100) apparatus basket assemblies.

Replacement Glass Tubes

Item Description	Part Number
USP-type Tube for 6-tube basket rack	37-5000
80 mm length, 25 mm outside diameter, set of 6	37-3000
Tube for 3-tube basket rack 80 mm	37-5005
length, 38 mm outside diameter, set of 3	37-3003
Tube for single-tube basket rack 92 mm	37-5010
length, 44 mm outside diameter	37-3010

Depth Gauge

This depth gauge is designed to verify that the disintegration baskets do not dip lower than within 25 mm of the bottom of the disintegration water bath.

Depth Gauge

Item Description	Part Number
Depth gauge, 25 mm	37-9000

Plastic Disks

Plastic disks fit both standard and automated (VK 100) apparatus basket assemblies.



Plastic Disks

Item Description	Part Number
USP Fluted Disks for 6-tube assembly, set of 6	37-4000
Disks for 3-tube assembly, set of	37-4010
Disks for single-tube assembly	37-4020

Plunger Assemblies

Plunger assemblies fit both standard and automated (VK 100) apparatus basket assemblies.



Plunger Assemblies

Item Description	Part Number
Type for 6-tube assembly	37-4100
Special type for 3-tube assembly	37-4110
Canadian type for 6-tube assembly	37-4120



Disintegration Beakers

Disintegration beakers are for use with disintegration basket assemblies. These beakers come with either a flared top or USP flat top and a 900 mL mark.

Disintegration Beakers

Item Description	Part Number
Flared-top Beaker for standard disintegration	37-5200
apparatus only	37 3200
USP Flat-top Beaker fits all Varian disintegration	
apparatus (standard disintegration and VK 100). Meets	37-5305
current USP requirements	

Beaker Platforms

The beaker platform is made to use with the Standard Disintegration Apparatus. It is made of stainless steel and has rubber feet to keep it in place. The platform raises beakers 2.5 inches from the bottom of the water bath.

Beaker Platform

Item Description	Part Number
Platform for 19 x 12 x 8 in. (40 x 30.5 x 20 cm) water bath, for use with P/N 60-2000	62-1000
Platform for 24 x 12 x 8 in. (61 x 30.5 x 20 cm) water bath, for use with P/N 60-2100	62-1005
Platform for 42 x 12 x 8 in. (107 x 30.5 20 cm) water bath, for use with P/N 60-2300	62-1010

Ethafoam® Cushions

The Ethafoam cushion is a 1/2 inch thick cushion for use with fabricated transparent water baths like those used with the Standard Disintegration Apparatus. The cushion isolates the water bath from the bench top and protects the acrylic. For larger water baths, two cushions may be required.

Ethafoam Cushions

Item Description	Part Number
Ethafoam Cushion 24 x 12 x 1/2 in., (61 x 30.5 x 1.3 cm)	62-1100
Ethafoam Cushion 19 x 12 x 1/2 in., (48 x 30.5 x 1.3 cm)	62-1110
Ethafoam Cushion 12 x 15 x 1 in., (30.5 x 38 x 2.5 cm)	62-1120



Platform (A) and Ethafoam Cushion (B)

VK 200 Hardness Testing

VK 200 Tablet Hardness Tester



The VK 200 combines the accuracy and precision of a microprocessor-controlled instrument at an economical price. Operation is straightforward, the top-loading design makes tablet insertion quick and convenient, and the jaws automatically adjust for tablet size. Quick, easy calibration is accomplished in the laboratory in minutes. The VK 200 has an exceptionally small footprint—perfect for the most crowded bench top. Its rugged design is perfect for on-line testing in production areas.

Each VK 200 is shipped complete with a standard jaw plate, fragment safety shield, trim pot tool, and tablet fragment brush. The VK 200 operates at a constant speed of under 3.5 mm/sec. A RS-232 communication port is located on the rear of the VK 200 system.

VK 200 Tablet Hardness Tester

Specifications						
Range:	0.4 to 3	5 kiloponds	(also ava	ilable from	0.4 to 50) kp)
Thickness:	With optional thickness gauge					
Resolution	0.001 in./ 0.01 mm					
Jaw Configurations:	Standard jaws accommodate tablets up to 1.375 in. diameter					
Dimensions and Weight						
Size:	Height	6 in. 15.24 cm	Width	11 in. 27.94 cm	Depth	7 in. 17.78 cm
Weight:	22 lb/9.	98 kg				

VK 200 Tablet Hardness Tester

Item Description	Part Number
VK 200, 115V, 60 Hz, kp/SC	40-2000
VK 200, 115V, 60 Hz, kp/newton	40-2010
VK 200, 115V, 60 Hz, SC/newton	40-2011
VK 200, 115V, 60 Hz equipped with a ROM chip for measuring thickness and diameter (thickness gauge included)	40-2012
VK 200, 230V, 50 Hz, kp/SC	40-2100
VK 200, 230V, 50 Hz, kp/newton	40-2110
VK 200, 230V, 50 Hz, SC/newton	40-2111
VK 200, 230V, 50 Hz equipped with a ROM chip for measuring thickness and diameter (thickness gauge included)	40-2112
VK 200, 115V, 60 Hz, 50 kp version	40-2200
VK 200, 230V, 50 Hz, 50 kp version	40-2300

Report Center Printer Options with Statistics



RoHS-compliant Printers

This standalone printer records hardness values, width and thickness (if equipped), as well as a statistical summary of each run. The printer does comply with RoHS standards

RoHS-compliant Printer

Item Description	Part Number
Report Center Printer option, VK 200, RoHS, 115V/230V	42-0120
Report Center Printer retrofit option, VK 200, RoHS, 115V/230V	42-0160
Report Center Printer retrofit option, VK 200, 50 kp, RoHS, 115V/230V	42-0162
Report Center Printer retrofit option, VK 200, kp/n, RoHS, 115V/230V	42-0164
Report Center Printer retrofit option, VK 200, SC/n, RoHS, 115V/230V	42-0166

Force Conversion Chart

- 1 kilopond=9.807 newton
- 1 pound=0.45359 kilopond
- 1 kilopond=2.2046 pound
- 1 StrongCobb=0.714 kilopond

VK 200 Accessories

Tablet Thickness Gauge



This option allows you to measures the tablet thickness in millimeters or inches. The tablet thickness gauge is factory installed in new units. Return existing units to Varian for retrofitting.

Tablet Thickness Gauge

Item Description	Part Number
Thickness Gauge Option, factory installed	42-0300
Thickness Gauge Option, retrofit	42-0350
Battery for Thickness Gauge	42-0355

Manual Tablet Thickness Gauges

The manual tablet thickness gauge measures tablet thickness with precise results as close as 0.001 inches or 0.01 mm. Both gauges have a range of 0 to 12.7 mm / (0 to 0.5 inches).

Manual Tablet Thickness Gauge

Item Description	Part Number
Gauge consisting of a dial indicator with revolution counter and rigid frame with handle	42-6105
Digital Gauge	42-6110

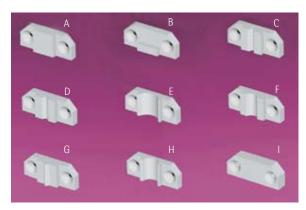
Calibration Fixture

The calibration fixture easily mounts on a bench top and locks the VK 200 in position during the calibration procedure.

Jaw Plates Calibration Fixture

İ	Item Description	Part Number
	VK 200 Calibration Fixture	42-2000

Removable interchangeable jaw plates allow you to adapt your VK 200 to almost any size or shape tablet.



Jaw Plates

Item Description	Part Number
Standard jaw (A)	42-1000
Shelf type (B)	42-1005
1/8 in. x 60 degree groove (C)	42-1010
1/16 in. radius <i>(D)</i>	42-1015
1/4 in. radius <i>(E)</i>	42-1020
1/8 in. radius <i>(F)</i>	42-1025
Bolus type (G)	42-1030
3/16 in. radius (H)	42-1035
Flat face (I)	42-1040
Hard Jaw Plate (adjustable for making height adjustments)	42-1050

Kilopond (kp) is the force of one kilogram (kg) at an acceleration of 1g. Often used in hardness testing along with the StrongCobb (SC) unit.



Trim Pot Tool

The trim pot tool is used to adjust the VK 200 during calibration.

Trim Pot Tool

Item Description	Part Number
Trim Pot Tool	42-2005

Calibration Weight Hanger

The calibration weight hanger easily attaches to the VK 200 to hold slotted weights in position during the calibration procedure.

Calibration Weight Hanger

Item Description	Part Number
Calibration Weight Hanger	42-2020

Tablet Fragment Safety Shield

The tablet fragment safety shield is mounted over the jaw plate and guards the operator from potentially harmful tablet fragments as the tablet is being crushed.

Tablet Fragment Shield

Item Description	Part Number
Tablet Fragment Shield	42-2010

Tablet Fragment Brush

Use the tablet fragment brush to remove tablet fragments between tests.

Tablet Fragment Brush

Item Description	Part Number
Tablet Fragment Brush	42-2030

Calibration Weights

All weights are slotted for use with the calibration weight hanger included in the VK 200 accessory kit.

Calibration Weights

Weights including certificates.

Item Description	Part Number
200 grams	42-1200
500 grams	42-1205
1 kilogram	42-1210
2 kilograms	42-1215
5 kilograms	42-1220
10 kilograms	42-1225
20 kilograms	42-1230



Trim Pot Tool



Calibration Weight Hanger



Tablet Fragment Shield



Tablet Fragment Brush



Calibration Weight

Friability Testers

Friability testers are designed to meet current USP specifications.

These testers are capable of replicating the punishment that tablets and capsules can be subjected to during various phases of manufacturing, distribution and handling. Possible edging, crumbling, chipping or breakup of tablets can be spotted before shipment. The unique two-chamber patented design of the Varian Type drum permits the testing of two different products or batches simultaneously in a single drum, and meets current USP specifications. Roche and Abrasion drums are also available. All models include a USP compliance certificate. The optional printer can be factory installed or retrofitted at a later date and used for calculating and recording test results.

The microprocessor-controlled friability testers allow the programming of a specific time interval or a set number of rotations. The LED display indicates either the elapsed time or the revolution count depending on the method chosen. The programming also allows the initial weight to be entered, which is used in determining the actual percent loss.

Single- and Dual-drum Friability Testers

Dimensions and Weight				
Size:	Height (w/drums) 13.5 in.	Width (w/single drum)	12.75 in. 32.38 cm	Depth (w/drums) 12.25 in.
	34.30 cm	Width (w/dual- drums)	16.12 in. 40.94 cm	31.11 cm
Weight:	33 lb/15 kg			

Single-drum Friability Testers

The Friability Tester is available in a single-drum model. Single-drum friability testers accept one drum on the left side of the instrument. There are a variety of drum configurations available. Depending on the type of drum (see page 120 for drum options), up to two different products or batches can be tested simultaneously.



Single-drum Friability Tester

Single-drum Friability Tester

Item Description	Part Number
Friability Tester, 115V, 60 Hz with Varian drum (tests two batches in the same drum)	45-1000
Friability Tester, 115V, 60 Hz with Roche drum	45-1200
Friability Tester, 230V, 50 Hz with Varian drum (tests two batches in the same drum)	45-1300
Friability Tester, 230V, 50 Hz with Roche drum	45-1400

Dual-drum Friability Testers

The Friability Tester is available in a dual-drum model. Dual-drum friability testers offer greater capacity for a nominal price increase over the single-drum version. Depending on the type of drum (see page 120 for drum options), up to four different products or batches can be tested simultaneously.



Dual-drum Friability Tester

Dual-drum Friability Tester

Item Description	Part Number
Friability Tester, 115V, 60 Hz with Varian drums (tests two batches in the same drum)	45-2000
Friability Tester, 115V, 60 Hz with Roche drums	45-2100
Friability Tester, 230V, 50 Hz with Varian drums (tests two batches in the same drum)	45-2200
Friability Tester, 230V, 50 Hz with Roche drums	45-2300

Optional Report Center Dot Matrix Printers

This standalone printer maintains documentation of data, start time, and length of test in either counts or time. The keypad can be used as a calculator to document percent loss for friability results.

Optional Dot Matrix Printer

Item Description	Part Number
Report Center Printer option, Friability Tester, RoHS, 115V/230V	47-0120
Report Center Printer retrofit option, Friability Tester, RoHS, 115V/230V	47-0153

Friability Accessories 121

Friability Accessories

VK Verified



To assure the accuracy of your friability testing equipment, we offer VK Verified friability drums. For a nominal charge, each of the drums listed is individually measured to ensure conformance. A certificate is included to provide a detailed list of USP specifications the actual measured values, the type of measuring device used, and its traceability.

Varian-Type Drums

Item Description	Part Number
Clockwise rotation, standard	47-1000
Counterclockwise rotation, standard	47-1005
Clockwise rotation, includes individual certificate	47-1000V
Counterclockwise rotation, includes individual certificate	47-1005V

Varian-Type Drums

Two arched bridges save time by allowing two tests in one drum. This drum is designed to meet current USP specifications.

Roche-Type Drums

This drum has a single arch which allows for one test per drum. This drum is designed to meet current USP specifications.

Item Description	Part Number
Clockwise rotation, standard	47-1010
Counterclockwise rotation, standard	47-1015
Clockwise rotation, includes individual certificate	47-1010V
Counterclockwise rotation, includes individual certificate	47-1015V

Abrasion Drums

The abrasion drum is a universal type for more rigorous testing of tablet and coating integrity. Use for either clockwise or counterclockwise rotation.

Abrasion Drums

Item Description	Part Number
Abrasion Drum	47-1020

10 Degree Lift

USP states to use a wedge "if the tablet size or shape causes irregular tumbling." The lift tilts the instrument so that its axis forms a 10 degree angle with the bench top and prevents binding and irregular tumbling of tablets in the drum.

10 Degree Lift

Item Description	Part Number
10 Degree Lift	47-1030



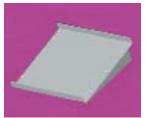
Varian-Type Drum



Roche-Type Drum



Abrasion Drum



10 Degree Lift

Tapped Density Testers — USP & ASTM

USP Tapped Density Models

Varian's USP Tapped Density Testers are designed to meet current USP specifications for tapped density testing. The USP drop height is 14 ± 2 mm and the unit taps at 300 taps per minute. These testers offer a standardized and repeatable method of measuring the tapped or packed volumes of powders as well as granulated or flaked materials. The unique simultaneous tapping and rotary motion assures that the material being tested is packed evenly throughout the cylinder and that its surface is level for direct reading of the graduated cylinder.



Single-platform Tapped Density Tester

- Cylinders are available from 10 mL up to 500 mL (see page 122 for sizes)
- Platforms are interchangeable
- Optional Report Center Printer for calculating and recording test results

USP Single- and Dual-platform

Specifications						
Dimensions and Weight						
Size:	Height	9.75 in.	width	12 in.	depth	11 in.
		24.77 cm		30.48 cm		27.94 cm
Weight:	33 lb/14	1.97 kg				

USP Single-platform Tapped Density Testers

The microprocessor-controlled unit has a single platform. The parameters are set from the key pad including: number of taps, time, date, and initial and final readings.

USP Single-platform Tapped Density Tester

Item Description	Part Number
USP Tapped Density Tester, 115V, 60 Hz, 100 mL platform	50-1000
USP Tapped Density Tester, 230V, 50 Hz, 100 mL platform	50-1100
USP Tapped Density Tester, 230V, 50 Hz, 250 mL platform	50-1800

USP Dual-platform Tapped Density Testers

The Dual-platform Tapped Density Tester takes up no more space than the single-platform tester. The two platforms operate from the same motor so testing must be started and stopped at the same time. The Dual-platform Tapped Density Tester can be ordered with the optional Report Center Printer which can be factory installed or added at a later date.



Dual-platform Tapped Density Tester

USP Dual-platform Tapped Density Tester

Item Description	Part Number
Dual Tapped Density Tester, 115V, 60 Hz, 100 mL platform	50-1200
Dual Tapped Density Tester, 230V, 50 Hz, 100 mL platform	50-1300
Dual Tapped Density Tester, 115V, 60 Hz, 250 mL platform	50-1850
Dual Tapped Density Tester, 230V, 50 Hz, 250 mL platform	50-1851

The sound associated with the operation of this instrument may distract those working in the area. We recommend the Acoustic Cabinet to minimize the noise associated with this test (see page 121).

ASTM Tapped Density Models

These Tapped Density Testers comply with ASTM standards which require a 250 tap per minute speed, no platform rotation and a 1/8 inch (or 3 mm drop). There are 2 ASTM specifications involving tapped density. D4164-03 is for testing catalyst particles and requires a 250 mL cylinder and platform. B527-06 involves metallic powders and compounds. These use a 25 or 100 mL cylinder and platform. Specify the cylinder size you require when you order.

ASTM Single-platform Tapped Density Tester

Item Description	Part Number
ASTM Tapped Density Tester, 115V, 60 Hz	50-2000
ASTM Tapped Density Tester, 230V, 50 Hz	50-2100

ASTM Dual-platform Tapped Density Tester

Item Description	Part Number
ASTM Dual Tapped Density Tester, 115V, 60 Hz	50-2200
ASTM Dual Tapped Density Tester, 230V, 50 Hz	50-2300

Optional Report Center Printers

This report center dot matrix printer can be ordered with the USP or ASTM Tapped Density tester or retrofitted at a later date. It will provide a printout of the time and date of the test, as well as calculate and document the data for determining the tapped volume.

Optional Report Center Printer

Item Description	Part Number
Report Center Printer option, Tapped Density Tester, RoHS, 115V/230V	52-0120
Report Center Printer retrofit option, Tapped Density Tester, RoHS, 115V/230V	52-0153



Tapped Density Accessories

Tapped Density Accessories

Acoustic Cabinet

The acoustic cabinet encloses the tapped density tester for sound control. In this cabinet, the noise level of the tapped density tester is 67 decibels. There is a Plexiglas door for clear observation of the test.

Acoustic Cabinet

Specifications						
Dimensions and Weight						
Size:	Height	33.75 in.	Width	19.5 in.	Depth	17.5 in.
		85.73 cm		49.53 cm		44.45 cm
Weight:	60 lb/2	7.2 kg				

Acoustic Cabinet

Item Description	Part Number
Acoustic Cabinet for all models	52-2010

Graduated Cylinders

These cylinders have a graduated, metric scale and a hexagonal base. The funnel top is easy to fill. All graduated cylinders conform to Class B standards.

Graduated Cylinder

Item Description	Part Number
Graduated Cylinder, 10 mL funnel top	52-5000
Graduated Cylinder, 100 mL funnel top	52-5010
Graduated Cylinder, 250 mL funnel top	52-5020
Graduated Cylinder, 25 mL standard top	52-5040
Graduated Cylinder, 50 mL standard top	52-5050
Graduated Cylinder, 500 mL standard top	52-5060

Tapped Density Cylinder Platforms

Tapped density cylinder platforms are self-locking with Delrin lift bushings for hexagonal base cylinders.

USP Platforms

Item Description	Part Number
USP Tapped Density Platform, 10 mL, 14 mm drop	52-1000
USP Tapped Density Platform, 25 mL and 50 mL, 14 mm drop	52-1010
USP Tapped Density Platform, 100 mL, 14 mm drop	52-1020
USP Tapped Density Platform, 250 mL, 14 mm drop	52-1030
USP Tapped Density Platform, 500 mL, 14 mm drop	52-1040



Acoustic Cabinet



Graduated Cylinders

ASTM Platforms

Item Description	Part Number
ASTM Tapped Density Platform, 10 mL, 3 mm drop	52-1050
ASTM Tapped Density Platform, 25 mL and 50 mL, 3 mm drop	52-1060
ASTM Tapped Density Platform, 100 mL, 3 mm drop	52-1070
ASTM Tapped Density Platform, 250 mL, 3 mm drop	52-1080
ASTM Tapped Density Platform, 500 mL, 3 mm drop	52-1090



Water Baths for Dissolution and Disintegration

Molded Water Bath Conversion Kits

Molded Water Bath Conversion Kits

These water baths are molded of PETG, a high-performance polymer with better chemical and heat stability than plain acrylic. This is a seamless water bath with rounded corners making cleaning easier. It is clear, allowing an unobstructed view of the vessels.

The water bath is suspended by four clamps under the vessel table minimizing evaporation from the water bath. This water bath can be used with VK 600, VK 6000, VK 6010, VK 700, VK 7000, and VK 7010 Dissolution Apparatus.

Item DescriptionPart NumberFor 3+3 configuration dissolution apparatus
(19 x 12 x 8 in.)60-1000For 4+2 and 4+4 configuration dissolution apparatus
(24 x 12 x 8 in.)60-1100

For 4+2 and 4+4 configuration dissolution apparatus (24 x 12 x 8 in.) Dual-bath kit, for two 3+3 configuration dissolution apparatus Dual-bath kit, for two 4+4 configuration dissolution apparatus Replacement Water Bath, for 3+3 configuration dissolution apparatus (19 x 12 x 8 in.), drain and clamps not included Replacement Water Bath, for 4+2 and 4+4 configuration dissolution apparatus (24 x 12 x 8 in.), drain and clamps 60-1500

Standard Disintegration Water Baths

not included

The disintegration water bath is a molded water bath (same as pictured above) with a supporting stand. Includes bracket for mounting immersion circulator.

Standard Disintegration Water Bath

Item Description	Part Number
Water Bath for single- and three-basket Standard Disintegration Apparatus	37-6010
Water Bath for six-basket Standard Disintegration Apparatus	37-6000



Molded Water Bath

Water Baths 1235

Fabricated Acrylic Water Baths

Acrylic water baths have a 3-piece construction with solvent-welded seams.



Fabricated Acrylic Water Bath

Item Description	Part Number
Water Bath for one- to three-basket Standard Disintegration Apparatus (19 x 12 x 8 in.)	60-2000
Water Bath for six-basket Standard Disintegration Apparatus (24 x 12 x 8 in.)	60-2100
Water Bath for VK 100 Disintegration Apparatus	60-2120
Water Bath for Rotating Bottle Apparatus, for use with immersion circulators (24 x 12 x 12 in.)	60-2200
Water Bath for 12-basket Standard Disintegration Apparatus or 12-spindle dissolution apparatus (42 x 12 x 8 in.)	60-2300
Water Bath for BIO-DIS III Extended Release Apparatus (23 x 21 x 8 in.)	60-2400
Water Bath for BIO-DIS I & BIO-DIS II Extended Release Apparatus	60-2410
Water Bath for Rotating Bottle Apparatus and 2L and 4L dissolution apparatus	60-2500
Water Bath for 2L dissolution apparatus, 8-vessel models (24.5 x 12.7 x 15.3 in.)	60-2600

Acrylic Water Baths with Immersion Heater/Circulator

Acrylic water baths have a three-piece construction with solvent welded seams. The immersion heater/circulator is mounted to the water bath and circulates constant temperature liquids. See page 126 for more information.



Acrylic Water Bath with Immersion Heater/Circulator

Item Description	Part Number
Water Bath, 19 x 12 x 8 in., with immersion heater/circulator, 115V, 60 Hz	60-3000
Water Bath, 19 x 12 x 8 in., with immersion heater/circulator, 230V, 50 Hz	60-3100
Water Bath, 24 x 12 x 8 in., with immersion heater/circulator, 115V, 60 Hz	60-3200
Water Bath for Rotating Bottle Apparatus, for use with immersion heater/circulator (24 x 12 x 12 in.)	60-3400
Water Bath, 42 x 12 x 8 inch, with immersion heater/ circulator, 115V, 60 Hz	60-3600



External Heater/Circulator/Temperature Probe

VK 750D External Heater/Circulator

This bench top, all purpose, precision heater/circulator is designed expressly for use with some models of Varian dissolution testing instrumentation. It monitors water bath temperature directly using a remote thermistor which is placed in the water bath. RS-232 serial ports offer digital control and communication. The VK 750D also has a front panel keypad with easy-to-read digital display of the temperature to within 0.1 °C and heaters for rapid achievement of set temperature.

For information on Immersion Heater/Circulators see page 126.



VK 750D External Heater/Circulator

Specifications						
Accuracy:	± 0.1 °C					
Internal Volume:	Internal Volume: <1 liter					
Circulation Capacity: ~10 liters/minute						
Environment						
Temperature Range: Ambient to 75 °C						
Dimensions and Weight						
Size:	Height	8.25 in. 20.96 cm	Width	15.25 in. 38.74 cm	Depth	7.25 in. 18.42 cm

VK 750D External Heater/Circulator for use with VK 7000, VK 7010, Apparatus 3, and Apparatus 7

Item Description	Part Number
VK 750D Heater/Circulator 115V, 60 Hz	65-3000
VK 750D Heater/Circulator 230V, 50 Hz	65-3100

Replacement Heater/Circulator for use with VK 7020 and VK 7025

Replacement Heater/Circulator for use with VK 7020 and VK 7025

Item Description	Part Number
Replacement Heater/Circulator, 115V	65-3800
Replacement Heater/Circulator, 230V	65-3810

Universal "Tankless" Heater/Circulator for use with Varian 705-DS

The small, space-saving design utilizes a unique heating sleeve to rapidly heat the circulating water. The unit monitors the incoming temperature and selectively applies heat to control the temperature to ± 0.1 °C



Universal "Tankless" Heater/Circulator for use with 705-DS

Item Description	Part Number
Universal "Tankless" Heater/Circulator, 115V	65-3820
Universal "Tankless" Heater/Circulator, 230V	65-3830

Temperature Probe

The replacement temperature probe can be used with the VK 750D Heater/Circulator as well as the VK 650A, and is designed fo use with VK 6010, VK 700, VK 7000, VK 7010, and V-Series Dissolution Apparatus.



Temperature Probe

Item Description	Part Number
Thermistor Probe	67-0300

Immersion Heater/Circulators/Ethafoam Cushions



Immersion Heater/Circulators



The immersion heater/circulator can be mounted to the water bath and used with Varian standard disintegration testing instrumentation. This compact immersion heater/circulator circulates constant temperature liquids. A shield of stainless steel protects the function of elements such as the heater, hydraulic thermo-regulator and pump against damage. The immersion heater/circulator has a digital controller for accurate repeatability of temperature settings. This unit is supplied with the original manufacturer's warranty.

Features include:

- Digital display with push button temperature selection
- Temperature range: to 100 ± 0.05 °F (38 ± 0.05 °C)
- Pump capacity: ~12 liters/minute
- Adjustable over-temperature cutoff

Immersion Heater/Circulation

Item Description	Part Number
Immersion Heater/Circulator, 115V, 60 Hz	65-2000
Immersion Heater/Circulator, 230V, 50 Hz	65-2100

Ethafoam® Cushions

The Ethafoam cushion, 1/2 inch thick, is for use with fabricated transparent water baths. It isolates the water bath from the bench top and protects the acrylic. For longer water baths, two cushions may be required.



Ethafoam Cushions

Item Description	Part Number
Ethafoam Cushion, 24 x 12 x 1/2 in. (61 x 30.5 x 1.3 cm)	62-1100
Ethafoam Cushion, 19 x 12 x 1/2 in. (48 x 30.5 x 1.3 cm)	62-1110
Ethafoam Cushion, 12 x 15 x 1 in. (30.5 x 38 x 2.5 cm)	62-1120



Water Bath Replacement Parts and Supplies

Water Bath Replacement Parts and Supplies

Drain Valve

The drain valve has a two-way on/off valve for filling and emptying the molded water bath.

Drain Valve

Item Description	Part Number
Drain Valve	62-9000

Bulkhead Fitting

The bulkhead fitting is a polypropylene assembly with 3/8 inch NPT and two neoprene gaskets.

Bulkhead Fitting

Item Description	Part Number
Bulkhead Fitting	62-9010

Flow Deflector

The flow deflector eliminates vibration and assures even distribution of heated water on return to the water bath. It attaches to the return bulkhead fitting on the inside wall of the water bath.

Flow Deflector

Item Description	Part Number
Flow Deflector	62-9020

Barbed-angle Tubing Adapter

The barbed-angle tubing adapter accepts 1/2 inch inner diameter tubing. The plastic tubing is attached to the barbed-angel tubing adapters with the tubing clamps to allow water to flow from the water bath to the heater/circulator and back into the water bath.

Barbed Angle Tubing Adapter

Item Description	Part Number
Barbed Angle Tubing Adapter	62-9025

Tubing Clamps

Stainless steel tubing clamps are used with 3/8 inch diameter laboratory tubing.

Tubing Clamps

Item Description	Part Number
Tubing Clamps, set of 4	62-9040

Plastic Tubing

This laboratory-grade PVC tubing has a 3/4 inch outside diameter and 1/2 inch inside diameter and is available as a 50 foot coil.

Plastic Tubing

Item Description	Part Number
Plastic Tubing	62-9030



Drain Valve



Bulkhead Fitting



Flow Deflector (Bulkhead Fitting and Tubing Adapter not included)



Barbed Angle Tubing Adapter (Bulkhead Fitting not included)



Tubing Clamps



Plastic Tubing



Hotline: Questions? We're To Help!

If you or anyone from your staff are experiencing problems with your dissolution testing, call us toll-free at 888.826.5351. One of our experienced chemists will be glad to assist you.

We can also be reached via e-mail at dissolution.hotline@varianinc.com

Varian's Laboratory Services can help troubleshoot calibration issues, suggest alternative methodology, assist in equipment programming, or simply refer you to published articles on a number of dissolution-related topics.

With over 100 years of combined laboratory experience, we are here to

Some sample questions from the Hotline include:

- How are the suspension cups used?
- Can you advise me how to perform the USP suitability test for the mini basket setup?
- Which type of membrane or patch comes with the Enhancer Cell of 4 cm²? Is the membrane included with the purchase of the Enhancer Cell system?
- Will you forward me information on the maintenance program for the Tapped Density Apparatus?

IR NEWS

Immediate Release Newsletter: Your monthly source for current dissolution-related information. Produced by dissolution scientists for dissolutions scientists, this electronic newsletter's purpose is simple: To put the source of dissolution-related information into your hands. The newsletter provides abstracts which will help you find the information you need to keep up to date in this highly regulated, constantly changing pharmaceutical environment. Our scientists scour the literature to keep you up to date. This is a free service from Varian - sign up today! Each edition includes a feature topic and other Special Delivery dissolution topics, as well as occasional regulatory updates in the Regulatory Corner.

This electronic newsletter is easy opt in and easy opt out for your convenience. E-mail ir_news@varianinc.com for more information. Don't miss out on important industry news!



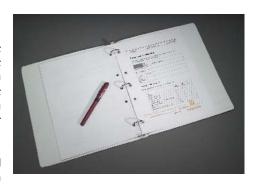
Equipment specifications

IQ/OQ/PQ

At Varian, we understand in the importance of equipment qualification. Varian has developed extensive and comprehensive guides with complete IQ QQ (installation and operational qualifications) and where applicable, PQ (performance qualification) procedures. Each document guides the performer through a step-by-step procedure, with complete documentation throughout, to ensure you are able to utilize your investment with full confidence in your results. These documents are sold as a site license, with a nominal charge for additional qualification guides for instruments of that model in your lab or department.

This document is designed so that you can do it yourself. Or if you prefer, a trained and certified technician from Varian Laboratory Services can do it for you. Call your Varian representative for a no-obligation quote. In order to ensure you receive the correct qualification guide for your instrument,

please specify the model and serial number of the instruments being qualified. Additional copies can be reordered at a later date for a nominal printing charge.



Qualification Guides

Item Description	Part Number
Cary 50 / UV Dissolution System Qualification Guide	70-4920
Fiber-Optic Qualification Guide	70-4935
VK 100 Disintegration Apparatus Qualification Guide	70-4940
Cary 50 Calibration Guide	70-4960
VK 8020 Qualification Guide	70-5300
Apparatus 3 Performance Qualification Guide	70-5505
Rotating Bottle Apparatus Qualification Guide	70-5550
Alza Qualification Guide (custom)	70-5700
VK 8000 for use with Alza Qualification Guide (custom)	70-5710
VK 8000 for use with HVSP Qualification Guide (custom)	70-5720
VK 700 Qualification Guide	70-5900
Friability Tester Qualification Guide	70-6300
Agilent 8453 for use with VK 7000 Series Qualification Guide	70-6500
Agilent 8453 Multibath for use with VK 7000 Series Qualification Guide	70-6550
Tapped Density Tester Qualification Guide	70-6600
Dissolution Apparatus Performance Qualification Guide	70-6900
VK 905 Washing Station Qualification Guide	70-6901
VK 905 Washing Station Cleaning Verification Guide	70-6903
VK 7010 AutoTemp Re-verification Test	70-6907
QAll C Qualification Guide	70-6908
Dissolution Workstation Qualification Guide	70-6951
VK 8000 with Peristaltic Pump (for Dissolution Apparatus) IQ	76-1000
VK 8000 with Peristaltic Pump (for Dissolution Apparatus) OQ	76-1001
VK 8000 with Syringe Pump (for Dissolution Apparatus) IQ	76-1040
VK 8000 with Syringe Pump (for Dissolution Apparatus) 00	76-1041
VK 8000 with Peristaltic Pump (for Dissolution Apparatus) $I\Omega/O\Omega$	76-1003
VK 8000 with Syringe Pump (for Dissolution Apparatus) $I\Omega/O\Omega$	76-1043
VK 8000 with Peristaltic Pump (for Apparatus 3/ Apparatus 7) IQ	76-1060
VK 8000 with Peristaltic Pump (for Apparatus 3/ Apparatus 7) OQ	76-1061

Item Description	Part Number
VK 8000 with Syringe Pump (for Apparatus 3/Apparatus 7) IQ	76-1080
VK 8000 with Syringe Pump (for Apparatus 3/Apparatus 7) 00	76-1081
VK 8000 with Peristaltic Pump (for Apparatus 3/ Apparatus 7) IQ/OQ	76-1063
VK 8000 with Syringe Pump (for Apparatus 3/Apparatus 7) IQ/OQ	76-1083
VK 7000/7010 IQ	76-2000
VK 7000/7010 OQ	76-2001
VK 7000/7010 IQ/OQ	76-2003
VK 7000/7010 Qualification Guide	76-2006
Total Solution with VK 7000/7010 Qualification Guide	76-2008
Total Solution with Dual VK 7000/7010 Qualification Guide	76-2009
VK 7020/7020S/7025 IQ	76-2100
VK 7020/7020S/7025 OQ	76-2101
VK 7020/7020S/7025 IQ/OQ	76-2103
VK 7020/7020S/7025 Qualification Guide	76-2106
Total Solution with VK 7020/7020S/7025 Qualification Guide	76-2108
Total Solution with Dual VK 7020/7020S/7025 Qualification Guide	76-2109
VK 7030 IQ	76-2200
VK 7030 OQ	76-2201
VK 7030 IQ/OQ	76-2203
VK 7030 Qualification Guide	76-2206
Total Solution with VK 7030 Qualification Guide	76-2208
Total Solution with Dual VK 7030 Qualification Guide	76-2209
Apparatus 3/Apparatus 7 IQ	76-3000
Apparatus 3/Apparatus 7 OQ	76-3001
Apparatus 3/Apparatus 7 IQ /OQ	76-3003
Apparatus 3 Qualification Guide	76-3006
Varian 705-DS IQ	76-3010
Varian 705-DS 0Q	76-3011
Varian 705-DS IQ/OQ	76-3013
Varian 705-DS Qualification Guide	76-3014
Varian UV Dissolution Qualification Guide (fiber optic)	76-3015
Varian UV Dissolution Qualification Guide (multicell)	76-3016

Laboratory Services



Your Lab Partner™ in Dissolution Testing

Providing technical support and assistance to clients throughout the pharmaceutical industry is the major theme behind Varian's Laboratory Services. Pharmaceutical manufacturing laboratories, contract laboratories and universities benefit from the knowledge and expertise provided by our dissolution experts at our headquarters and in the field. Our Laboratory Services team is made up of experienced analytical chemists with many years of combined pharmaceutical experience in the field of dissolution. Our chemists are strategically placed throughout the US and Europe. This reduces travel time and costs to out customers. Our field-based chemists are supported by our staff in Cary, NC, USA. The following are some of the services we provide.

IQ/OQ/PQ

- Providing the proper documentation for equipment is essential in the pharmaceutical industry; and Varian's Laboratory Services provides that documentation with various qualification guides, installation and operational qualifications (IQ, OQ) for all our products
- After completion of the installation and operation qualification, the performance qualification is executed on all Varian systems ensuring the equipment meets the specifications listed
- Our Laboratory Services staff can also provide performance qualifications (PQ) for all brands of dissolution apparatus

Application Support

- Varian Laboratory Services can help you choose the right piece of equipment for your method
- We also provide support for novel dosage forms

Technical Support

- Contact Laboratory Services for all of your dissolution apparatus questions, from automated sampling to UV analysis
- Laboratory Services can also help you in your quest to develop a method that conforms to USP and evaluate a product



Qualification Advantages

- Varian provides a complete documentation package to meet all cGMP requirements
- Varian's experienced chemists are specifically trained to perform dissolution qualification on Apparatus 1, 2, and 3
- Allow your analysts and metrology group to focus on more meaningful projects
- Cost effective
- Reduce the possibility of failure and subsequent failure investigation
- We offer the most modern equipment for physical parameter verification
- You receive hard-copy documentation of the data
- Preventative maintenance programs are available to keep your instruments in good working order

Training Advantages

- Varian's experienced staff of chemists teach courses customized to your particular need or level of expertise
- Educational Services—With courses ranging from Fundamentals of Dissolution to Advanced Dissolution Theory, Varian has trained over 4500 people worldwide. Other courses include Method Development and Validation as well as IVIVC
- Training courses can be provided on site
- Varian's training services can supplement your in-house training programs and reduce your trainers' workload
- Varian offers up-to-date, comprehensive training material
- Certificates are provided upon successful completion of training
- Standardized training ensures reproducible technique
- Varian can make you aware of factors that contribute to calibration and testing failures
- Labcast—Varian provides training and conferencing live using interactive video from our studio in Cary, NC. This communication format allows us to quickly disseminate information and at the same time encourage dialog.

Educational Services

Varian's Seminar Series is specifically designed to provide the latest in theory, techniques, and hands-on experience for those involved in dissolution testing. Our instructors include Varian chemists and prominent scientists from around the world. Varian brings the latest techniques and procedures directly to your facility.



For a complete list of seminar dates and locations, please visit our Web site at www.varianinc.com to request a schedule and registration form. These courses are offered throughout the US and internationally, and the seminars can be brought to your site via video conferencing.

Program Coordinator

Seminar Coordinator Varian. Inc.

E-mail: dissolution.education@varianinc.com

Ordering information for the Dissolution Seminar Series is available on page 134.

Fundamentals of Dissolution Workshop

About the Course

The Fundamentals of Dissolution Workshop is a comprehensive two-day course designed for new and emerging dissolution analysts. The course places emphasis on basic dissolution fundamentals and theory, along with focused discussions on current compendial dissolution testing apparatus, USP physical parameter requirements and the current USP calibration procedure. Hands-on workshops provide participants with experience preparing for and executing a dissolution test.

This course will most benefit the novice dissolution analyst and those in quality control and assurance, calibration, and metrology. This course also serves as a refresher for those individuals with limited or intermediate dissolution experience.

Topics Covered

- Evolution of dissolution testing
- Dissolution fundamentals and theory
- Compendial dissolution testing
- Calibration of USP Apparatus 1 and 2
- Critical physical parameters
- Compendial extended release
- Methods of sample analysis
- Dissolution technique
- · Regulatory issues

The hands-on workshops include dissolution apparatus familiarization, performing the dissolution test, and physical suitability testing.

Upon successful completion of this course the attendee should be able to:

- Describe basic principles of dissolution theory and compendial Apparatus
 1 through 7
- Perform proper dissolution techniques to conform with USP guidelines
- List critical physical parameters associated with Apparatus 1 and 2
- Describe essentials in USP calibration of Apparatus 1 and 2, as well as regulatory issues associated with dissolution and GMP guidelines



Educational Services



Advanced Dissolution: Principals and Theory

About the Course

Advanced Dissolution: Principals and Theory is a two-day program designed for the intermediate dissolution analyst, as well as those involved in drug metabolism, drug disposition, pharmacokinetics, and analytical methods development. The participant will learn dissolution theory and participate in focused discussion on current practices with the compendial devices, USP Apparatus 1–7, and nonofficial dissolution techniques. Special attention is devoted to the development of meaningful *in vitro / in vivo* correlation, design and development of dissolution methods, and the use of dissolution data in bioavailability / bioequivalence assessments. Handson laboratory sessions put theory into practice.

Topics Covered

- Dissolution theory: how and why
- Dissolution testing devices: the tools of the trade
- Compendial and regulatory agencies
- Dissolution method development
- Dissolution dosage forms: conventional and modified
- Dissolution in new product development (NDA)
- Predicting bioequivalence from dissolution (ANDA)
- Maintenance and calibration of USP apparatus
- In vitro / in vivo correlations

This course will most benefit individuals in analytical methods development, quality control and assurance, formulations, stability, pharmacy and phamacology, pharmacokinetics, and regulatory affairs.

Upon successful completion of this course the attendee should be able to:

- Name USP Apparatus 1 through 7
- Describe dissolution theory and principal
- Outline method development
- Compute and interpret data
- Define dissolution and bioavailability
- Categorize basic principals of in vitro / in vivo correlation

Correlating Dissolution and Bioavailability: Understanding IVIVC

About the Course

Correlating Dissolution and Bioavailability: Understanding IVIVC is a comprehensive, two-day program designed for advanced dissolution analysts. *In vitro* dissolution tests seem to be the most reliable predictors of *in vitro* availability. While the bioavailability of drug substances and drug products in humans can provide evidence of a potential relationship between dissolution and physiological availability, it is often impractical to perform extensive and expensive human testing.

The goal of the course is to learn how to assess and develop methods of correlating *in vitro and in vivo* performance parameters.

Topics Covered

- Fundamentals of correlation
- Bioavailability assessment
- Dissolution and bioavailability
- Basics of in vitro / in vivo correlation
- Characterization of dissolution data
- IVIVC parameters

This course is designed for individuals involved with analytical methods development and validation, quality control, quality assurance, formulations, stability, pharmacology, pharmacokinetics, and regulatory affairs.

Upon successful completion of this course the attendee should be able to:

- · Discuss relevant aspects of dissolution and bioavailability
- Describe essentials of bioavailability assessment regarding various dosage forms
- Outline fundamentals of interpretation of dissolution profiling and data
- Explain regulatory perspective of IVIVC and SUPAC guidelines
- Characterize dissolution data
- Reduce, analyze, and interpret IVIVC data

In Vitro Dissolution of Ointments, Creams, and Transdermals Workshop

About the Course

The In Vitro Dissolution of Ointments, Creams, and Transdermals Workshop is a comprehensive, two-day course designed for academic researchers and industry scientists with interests in evaluating drug release from topical preparations. The goal of the course is for the participant to learn the application of current dissolution testing techniques and equipment in the evaluation of drug release from semisolids and transdermal drug delivery systems (both immediate and controlled release). Discussion includes the use of this technology in product development and quality control.

This course is designed for individuals involved in the development, manufacturing, or quality control of topical products.

Topics Covered

- Compendial testing Apparatus 5, 6, and 7
- Method validation
- Non-compendial testing
- Aspects of membrane selection
- Proposed calibration methodology
- SUPAC guidance
- Use of the Enhancer Cell and Franz Cell
- Method development
- World community regulatory requirements

The hands-on workshop includes:

- Use of the Enhancer Cell and Franz Cell
- · Data analysis
- Method development
- Demonstration of Apparatus 5, 6, and 7

Upon successful completion of this course the attendee should be able to:

- Describe basics of compendial dissolution testing with USP Apparatus 5, 6, and 7
- Outline uses and restrictions of non-compendial testing and apparatus
- Explain uses of the Enhancer Cell and Franz Cell
- Describe ointment, cream, and transdermal method development and validation techniques
- Describe SUPAC guidelines for topicals
- Explain regulatory requirements with perspective on the world community

Dissolution and Bioequivalence of Generic Pharmaceuticals

About the Course

Dissolution and Bioequivalence of Generic Pharmaceuticals is a two-day program designed for the advanced dissolution analyst, as well as those involved in drug metabolism, drug disposition, generics, pharmacokinetics, and analytical methods development. Participants learn how to demonstrate bioavailability and bioequivalence of pharmaceutical formulations without designing and executing time consuming and expensive clinical trials in humans.

Two pharmaceutical formulations are considered bioequilivent (BE) when their respective rate and extent of bioavailability (BA) following administration of a unit dose under standard clinical experimental conditions are substantially similar. In vitro testing is an ideal surrogate for predicting BA or BE of pharmaceutical formulations. This intensive two-day course presents the fundamental considerations necessary to understand BA or BE and the utility of in vitro dissolution testing in the prediction of BA or BE.

This course is designed for individuals involved with research and development, quality control/quality assurance, and pharmacokinetics.

Topics Covered

- Biopharmaceutics Classification System (BCS)
- Dissolution method development for generic formulationst
- Characterization/computation of dissolution parameters

f1 and f2 equations

- IVIVC relevant to generics
- Computation of PK parameters for BA/BE
- Worldwide regulatory requirements for demonstration of BE, design of a clinical protocol

Upon successful completion of this course the attendee should be able to:

- Understand BCS and dissolution testing
- Develop dissolution test method development for generic formulations
- Use f1 and f2 expressions in generic drug development
- Comprehend IVIVC relevant to generic pharmaceuticals
- Compute PK parameters for BA and BE
- Design basic clinical protocol

Educational Services

135

Dissolution Method Development and Validation

About the Course

Dissolution Method Development and Validation is an intensive two-day course for experienced R&D, method development, or QC chemists interested in the development and validation of discriminating in vitro dissolution methods. This course will provide an interactive approach to the selection of a discriminating method, including discussion of biorelevant media and test conditions and an examination of appropriate testing equipment. New advancements in noncompendial apparatus and automated equipment (including Fiber Optics) in regards to innovative method development are also explored. The Biopharmaceutics Classification System will be an integral part of the method development aspects. Accompanying these topics are presentations of regulatory guidelines for concise method validation and instructional exercises designed to enhance the student's learning experience. Participants will be encouraged to share their method development experiences and problems.

This course is designed for individuals involved with research and development, quality control/quality assurance, and pharmacokinetics.

Topics Covered

- Overview of in vitro method dissolution
- Goals for dissolution method development
- Selection of test conditions
- Discrimination challenges
- · Specification setting
- Test method generation
- Validation of the dissolution method
- Method transfer

Upon successful completion of this course the attendee should be able to:

- Develop a dissolution method according to current regulatory quidelines
- Assess the discriminatory power of your dissolution method
- Determine sources of error associated with the proposed method
- Perform thorough validation of all manual and automated methods
- Explore all aspects of method transfer

Seminar Ordering Information

Refer to the Varian Web site for a complete schedule of the Varian Dissolution Seminar Series at www.varianinc.com.

Seminar Ordering Information

Item Description	Part Number
Fundamentals of Dissolution, 2-day seminar	70-7100
Advanced Dissolution: Principals and Theory, 2-day seminar	70-7000
Correlating Dissolution and Bioavailability: Understanding IVIVC, 2-day seminar	70-7500
In Vitro Dissolution of Ointments, Creams, and Transdermals, 2-day seminar	70-7300
Dissolution and Bioequivalence of Generic Pharmaceuticals, 2-day seminar	70-7107
Dissolution Method Development and Validation, 2-day seminar	70-7105

Varian also offers on-site seminars to bring the latest techniques and procedures directly to your facility.

On-site Seminar Ordering Information

Item Description	Part Number
On-site Fundamentals of Dissolution, 2-day seminar	70-7101
On-site Advanced Dissolution: Principals and Theory, 2-day seminar	70-7104
On-site Correlating Dissolution and Bioavailability: Understanding IVIVC, 2-day seminar	70-7109
On-site <i>In Vitro</i> Dissolution of Ointments, Creams, and Transdermals, 2-day seminar	Contact us
On-site Dissolution and Bioequivalence of Generic Pharmaceuticals, 2-day seminar	70-7106
Dissolution Method Development and Validation, 2-day seminar	70-7108



Labcast®: Live from the Varian Global Broadcast Studio Cary, NC

What is Labcast?

In simple terms, Labcast is a way for Varian to communicate through video conferencing equipment with other capable sites around the world. Video broadcasting from our studios in Cary allows instantaneous conferencing, training and services to all points of the globe. Varian trainers can televisit your office to meet with you and your employees and explore the latest methods and techniques for effective dissolution testing. Keep your lab personnel abreast of new practices with ongoing education programs and even link with other locations for standardized training sessions. All this without leaving home.



Calibration of Apparatus 1 and Apparatus 2

60-minute module

Varian's Laboratory Services has prepared a one-hour refresher course on the proper way (per USP) to calibrate Apparatus 1 and 2. A great deal of controversy exists over whether the calibration process is an indication of the status of the dissolution bath, the calibrators, the analyst or the entire system. The reality is that they all come into play. This course is intended to show how all the constituents should function in order to properly qualify a dissolution bath.

About the Course

The seminar addresses the following topics:

- Historical perspective of dissolution calibration
- Checklist of required physical parameters
- Review of essential preparation
- Review of the proper execution of the Prednisone and Salicylic Acid calibration procedure
- Review of common sources of calibration failure
- Question and answer period

Aberrant Data Investigation

90-minute module

Lack of proper failure investigation and documentation generally leads the list of problems in FDA observations of analytical laboratories. Many standard operating procedures for handling out-of-specification data do not properly deal with dissolution data. Join Laboratory Services for a live seminar on the proper procedures for properly investigating and documenting out-of-specification dissolution test results in your lab.

About the Course

The seminar addresses the following topics:

- Detailed procedures for properly investigating and documenting out-ofspecification results
- Ideas about how rudimentary investigations may uncover calculation or standard preparation errors before performing a Stage 2 test
- Discussion on how proper investigation and reporting can limit the possibility that an analyst will repeat an error in a second test
- Review of actual FDA observations
- Question and answer session

Apparatus 3

60-minute module

The reciprocating cylinder became an official method in the USP XXII, Fifth Supplement. It is also known as the BIO-DIS (USA). Given the increasing introduction of modified and extended release products, this valuable tool is growing in usage. This one-hour presentation covers the historical development as well as the principles of the operation. This interactive seminar is designed for anyone unfamiliar with Apparatus 3 and interested in learning how the instrument operates.

About the Course

The seminar addresses the following topics:

- Evolution of Apparatus 3 from the Rotating Bottle method (NF XIV)
- Principles of operation
- Demonstration of Apparatus 3
- When to consider Apparatus 3 in method development
- Calibration requirements
- Automation of the sampling process
- Options / accessories for unique dosage forms
- Question and answer session



Varian, Inc's Laboast Studio

Dissolution 1-on-1



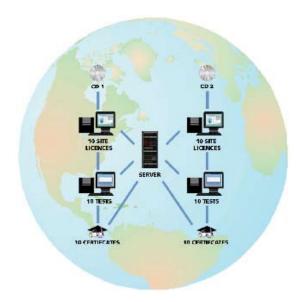
Dissolution 1-on-1: The Core Curriculum You Complete From Home

You won't need an apple for the teacher with these lessons. We've compiled everything there is to know about dissolution—from Apparatus 1 and 2 to calibration; automated testing to regulatory issues – and packaged it on a single CD that makes it easy to learn outside a classroom setting. This interactive course is designed to be taken individually so scientists and technicians can learn at their own pace. When students have completed the course and pass the test, they receive a certificate of completion.

Adapted from the highly successful Varian seminar entitled "Fundamentals of Dissolution", the comprehensive CD includes much of the material from the two-day course. The Dissolution 1-on-1 CD makes it possible to learn at your own pace right from your computer. Training can be accomplished on-site in a standardized format that ensures consistency for your entire organization.

Mastery of the material is assured via a comprehensive exam completed online after studying the CD. Test results are communicated back to the student and the designated administrator.

As the dissolution test continues to gain in prominence within the pharmaceutical industry, standardized testing will be key to knowing that scientists around the world are similarly trained. Document that your scientists and technicians are following the major pharmacopoeias with this CD today!



The Syllabus

This CD-based dissolution training program is organized into four main sections. The introduction explains what happens to medicines in the body and illustrates why dissolution testing is so important. This first section also covers the theories behind dissolution, explains the various types of dissolution rates, and provides an overview of the apparatus used for collecting data of specific types. The evolution of dissolution testing section includes key people and events from the test's inception to the present day.

The second section of the CD delves into the specifics of Apparatus 1 and 2. Compendial descriptions provide in-depth information about paddles and baskets. Critical physical parameters, an operation checklist, and instructions for executing the dissolution test and performing calculations are also included. Guidelines for analyzing the success of tests, making noncompendial modifications, and performing preventative maintenance round out this second section.

Calibration of USP Apparatus 1 and 2 is covered in section three. Learn when and how to perform physical and chemical calibration and filter validation. Failure investigation is an important and detailed topic in this section.

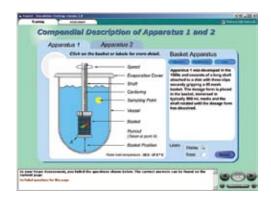
Automated dissolution testing permits far more efficient and precise testing than manual methods and also requires training. The concept of automated testing is explored in the supplemental section of the CD. Here, scientists and technicians will discover the advantages and disadvantages of automated testing, and learn how to set up and run automated systems. Sampling and sample handling, analysis and data reduction, cleanup and changeover are explained as well. The future of automated dissolution is also examined as is fiber optic UV spectroscopy.

When it comes to regulatory issues, the reference material section of this CD provides a comprehensive listing of FDA 483 observations and standard operating procedures. Helpful links to additional sources of dissolution-related information are also provided.

How to Purchase

Don't miss this chance to learn everything about dissolution, from A to Z. Order this powerful and convenient one-on-one presentation today by calling 1.800.229.1108 in the U.S. or 1.919.677.1108 outside the U.S.

Visit www.varianinc.com for more information.



CD-based Dissolution Training Program: Site license with 10 users

The Varian CD-based interactive dissolution training program allows users to learn the fundamentals of dissolution at their own pace. Once the training module has been completed, students simply log on to the assessment center to take an on-line test. Upon successful completion, participants will receive a training certificate verifying that they have completed the course. The site license CD with 10 users is valid for one year past the date of registration. Additional CDs with users in sets of 10 are available under the same site license if purchased at the same time.

Additional users can be added to the site licensed CD in increments of five. Please note: access to the Internet is required in order to access the program and complete the test.

Second CD with 10 users

The second CD with 10 users for an existing site license. The CD is valid through the date of the site license.

Third CD with 10 users

The third CD with 10 users for an existing site license is valid through the date of the site license.

Five additional users on site-licensed CD

Five additional users can be placed on the site-licensed Varian dissolution training program CD. Multiple sets of five users can be added to the site license CD.

CD Ordering Information

Item Description	Part Number
Dissolution Training Program CD, site license for 10 users	70-7110
Second Dissolution Training Program CD for 10 users	70-7111
Third Dissolution Training Program CD for 10 users	70-7112
Five additional users on site-licensed CD	70-7113



Site License Training



Example On-Line Test



What is the DDG?

The DDG Dissolution Discussion Group® is a free online, independent forum providing you an opportunity to anonymously discuss issues which challenge the industry and affect the day-to-day task of developing, performing and validating dissolution tests and related chemical analyses—completely free of regulatory burdens. There are DDG chapter meetings held, too, where members meet face-to-face to discuss the latest dissolution topics.

Members are fellow analysts from QC, stability, R&D, and academia. The DDG is the most practical solution for inside views on current topics. The issues discussed, suggestions shared, and problems solved are based on knowledge that can only come from first-hand experience.

To learn more about the DDG, including its mission, by-laws, goals, and purpose, visit the DDG Web site at www.dissolution.com. While you're there, engage in real-time discussions and learn more about dissolution questions, suggestions, and techniques, or find out about future DDG meetings, and read informative updates from previous meetings.

See what you've been missing!

Imagine you being able to view the contents of the entire DDG Web site on CD. View this unique source of shared knowledge off-line at any time — no internet connection is necessary. Discover what other pharmaceutical scientists are saying about issues challenging the industry today!

- Browse thousands of posts on the bulletin board for hundreds of threaded discussions by hundreds of Dissolution Discussion Group members
- Find any topic using a keyword search. Your keywords are highlighted within the returned documents for easy recovery
- Learn about the DDG mission, by-laws, and meeting information
- Access DDG meeting notes for recent years
- View regulatory news and FDA 483 citations
- Tease your brain with the DDG crossword puzzle

