

RESTEK

Dissolution Test Systems



RIGGTEK Brochure



Product Portfolio 2019







www.QLA-LLC.com

RIGGTEK is offering a wide product range for the Dissolution Test and combines innovative instruments from RIGGTEK like the famous "DissoPrep" Media Delivery Station with the worldwide common products from DISTEK like the patended "bathless heating" model "DISTEK 2500 Select" and the high quality dissolution accessories from QLA for all dissolution brands.

DissoPrep X8

Dissolution Media Preparation and Delivery Station.







RIGGTEK GmbH
Dissolution Test Systems

The RIGGTEK "DissoPrep X8" Media Preparation and Delivery Station is the result of 20 years of experience with the gravimetric working principle. It ensures very precise dosing with extremely high degassing efficiency and best reproducibility. The system offers great flexibility, optional mobile use, easy operation, high network connectivity and easy operation with the innovative "Browser-Interface", which also allows 21CFR compliant usage.

PREPARATION ACCORDING USP METHOD / USP COMPLIANT

The DissoPrep is filtering, warming, mixing, degassing and dispensing media directly into the vessels according to the recommended process of the USP.

GRAVIMETRIC MIXING AND DOSING

The gravimetric working principle ensures a very high mixing and dispensing accuracy directly into the vessels, even better than the recommended 1% by the USP – even if foaming media is used.

REPRODUCIBLE RESULTS

The working principle of the DissoPrep ensures, that each method performed produces the same results regarding dispensed volume and degassing every time. Results can not be manipulated by users.

HIGH DEGASSING EFFICIENCY

Because the DissoPrep is using no fluidic pump, but withdraws and dispenses media by vacuum or pressure, the degassing under vacuum starts during withdrawing the media. Additionally the combination of heating and high vacuum ensures reproducible degassing with better than 5ppm of residual oxygen.

TIMESAVING

While you are preparing your dissolution test, the DPX is creating one batch of media (8 or 15 liter). The filling of each vessel can be done one after the other within a few seconds only.

COMPLETE DOCUMENTATION / CFR COMPLIANCE

The DissoPrep delivers a complete documentation. With the standard Browser-Interface – controlled with every Web-Browser – a CFR-compliance can be ensured incl. electronic signature.

Sampilio X8

Dissolution Autosampler





RIGGTEK GmbH Dissolution Test Systems

The RIGGTEK "Sampilio X8" Dissolution Autosampler is the result of listening to the needs of our customers. It works with patented small volume diaphragm pumps, which ensure high precision, low cross-contamination and short sampling intervals. The system offers a small footprint in your laboratory, high network connectivity and easy operation with the innovative "Browser-Interface", which also allows 21CFR compliant usage.

- COMPAREABLE TO MANUAL SAMPLING The patented pumps ensure a "first-in-firstout" working principle. In combination with the low internal dead volume the sampling is
 - absolutely comparable to a manual sampling with a syringe.
- LOWEST CROSS CONTAMINATION Low internal dead volume, inert parts and less internal "bottle necks" like connections ensure the lowest possible cross contamination for reproducible and accurate results.
- SHORT SAMPLING INTERVALS Short sampling times ensure more precise results and a better quality control of the dissolution process. The Sampilio X8 achieves sampling intervals down to 2min, because of the low internal dead volume and efficient dispensing process.

EASY OPERATION

The Sampilio X8 is ready to use within a few minutes due to the easy, step-by-step menu. The handling of the racks is done within seconds. For more detailed things, like administration of users, creation of reports, etc. the innovative Browser-Interface is used.

EASY CLEANING AND MAINTENANCE

Cleaning of Autosamplers can be time consuming. The Sampilio X8 uses standard test tubes, which can easily be replaced after each test. The automated cleaning process and the minimum of internal connections with a low dead volume ensure very easy cleaning as well as low maintanance.

FLEXIBLE FOR FUTURE TASKS

The individual bidirectional pumps for each line, the high performance CPU and all kinds of electronic connectors ensure flexibility for future tasks and demands.







RIGGTEK GmbH
Dissolution Test Systems

The RIGGTEK "easyDISS" Dissolution Tester is a basic dissolution tester with reliable, easy to use technology. The high quality production ensures the highest standards of performance and reliability. It is USP-compliant, available with 6 or 8 positions and all accessories like USP Apparatus 1,2,5, rotating cylinders, immersion cell, small volume kits or intrinsic kit. This ensures great flexibility and efficiency in your lab.

- 6 OR 8 POSITIONS

 The easyDISS is available with 6 or 8 positions
- MANY ACCESSORIES
 Various accessories are available for the easyDISS like USP Apparatus 1,2,5, rotating cylinders, intrinsic kit, immersion cell, auto-tablet drop-kit, amber vessels and covers or Teflon coating.
- EASY VESSEL CENTERING
 An easy changeable vessel-ring ensures a strong and reproducible vessel fixing in each position.
- BASKETS

 Due to screw fittings baskets, paddles, rotating cylinders can be switched within seconds.

QUICK CHANGE OF PADDLES AND

- LASER NUMBERING AND CERTIFICATION
 All parts like shafts, vessels, paddles, baskets, etc.
 are serialized by laser-numbering and delivered
 with certificates of conformance. Certificates of
 Analysis are available on demand. This ensures
 easy performance of the EMC (Enhanced
 Mechanical Calibration Qualification Test).
- DOCUMENTATION AND CONNECTION Reports can be printed and easily administrated via the Browser Interface with a connection to the Autosampler Sampilio X8. The Sampilio is also able to control the easyDiss to perform a simultaneous start of your Dissolution Test. Moreover the whole method can be reported into one common report.

DISTEK 2500 Select

Bathless Dissolution Tester







The Distek Model 2500 Select Bathless Dissolution System is the culmination of three generations of patented bathless technology with extremely short media heating times and dramatically smaller energy use. The system offers great flexibility and configurability. It can be configured as USP Apparatus 1, 2, 5 and 6 plus intrinsic dissolution. The extensive users, method and reporting storage capabilities are enabled by a brilliant touch screen. Patent pending wireless temperature sensors continuously monitor and display the in-vessel temperature for each vessel. Unparalleled control of the instrument plus automatic storage of component serial numbers and automatic qualification reminders make the Model 2500 Select robust and reliable enough for QC applications yet flexible enough for R&D use.

BATHLESS HEATING

Eliminates the water bath and all associated maintenance. Heater jackets raise media temperatures from ambient to 37°C in less than 15 minutes, using considerably less energy in the process. Bathless design also allows high temperature operation up to 99°C.

WIRELESS IN-SHAFT TEMPERATURE SENSORS

"Patent Pending" wireless temperature sensors control and monitor the temperature.

- Continuously monitor, display and record the in-vessel temperature for each vessel
- Ensure and document temperature compliance throughout the entire dissolution test
- Eliminate additional labor to measure actual temperature
 in vessels

SERIALIZED COMPONENT TRACKING

Enter and track all serialized components including; paddles, baskets, basket adapters, shafts and vessels.

COLOR TOUCH SCREEN DISPLAY

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the dissolution test.

ELECTRONIC QUALIFICATION GUIDANCE

Settable automatic electronic instrument requalification reminders eliminate missed validation dates and ensures continuous instrument uptime.

QUICK CHANGE PADDLES AND BASKETS

Interchangeable stirring elements coupled with the automatic height adjustment provide a fast transition between Apparatus 1 and 2 without having to remove the shaft.

USP COMPLIANT

The use of bathless heating is fully compliant per USP General Chapter <711>.

DISTEK 2500 RTD

Dissolution Tester with In-Shaft-Temp.-Sensors







The Distek Model 2500 RTD Dissolution System offers great flexibility and configurability. It can be configured as USP Apparatus 1, 2, 5 and 6 plus intrinsic dissolution. The extensive users, method and reporting storage capabilities are enabled by a brilliant touch screen. Patent pending wireless temperature sensors continuously monitor and display the in-vessel temperature for each vessel. Unparalleled control of the instrument plus automatic storage of component serial numbers and automatic qualification reminders make the Model 2500 RTD robust and reliable enough for QC applications yet flexible enough for R&D use.

WIRELESS IN-SHAFT TEMPERATURE SENSORS

"Patent Pending" wireless temperature sensors control and monitor the temperature.

- Continuously monitor, display and record the in-vessel temperature for each vessel
- Ensure and document temperature compliance throughout the entire dissolution test
- Eliminate additional labor to measure actual temperature in vessels

VOLUME FLEXIBILITY

Accommodates up to 8 vessels ranging in size from 100 mL (utilizing Distek's small volume conversion kit) to 1L, allowing the user to run a diverse range of tests.

SELF-PRIMING CIRCULATOR / HEATER

The self-priming design and precise microprocessor control allow for improved temperature uniformity and reduced heating times. The low-profile design allows the circulator to be stowed behind the bath, requiring no additional bench space.

ELECTRONIC QUALIFICATION GUIDANCE

Settable automatic electronic instrument requalification reminders eliminate missed validation dates and ensures continuous instrument uptime.

COLOR TOUCH SCREEN DISPLAY

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the dissolution test.

QUICK CHANGE PADDLES AND BASKETS

Interchangeable stirring elements coupled with the automatic height adjustment provide a fast transition between Apparatus 1 and 2 without having to remove the shaft.

AUTOMATIC HEIGHT ADJUSTMENT

Setting the height is done through a one-time adjustment and utilization of the interchangeable paddles and baskets

WAKE UP AND SLEEP MODE

Programmable wake up and sleep modes allow the user to schedule thermocirculator start up and shutdown times to save time and conserve energy.

DISTEK 2500

Dissolution Tester with great flexibility





CREATING A STIRE

The Distek Model 2500 Dissolution System offers great flexibility and configurability. It can be configured as USP Apparatus 1, 2, 5 and 6 plus intrinsic dissolution. The extensive users, method and reporting storage capabilities are enabled by a brilliant touch screen.

Unparalleled control of the instrument plus automatic storage of component serial numbers and automatic qualification reminders make the Model 2500 robust and reliable enough for QC applications yet flexible enough for R&D use.

VOLUME FLEXIBILITY

Accommodates up to 8 vessels ranging in size from 100 mL "(utilizing Distek's small volume conversion kit) to 4L, allowing the user to run a diverse range of tests.

SELF-PRIMING WATER CIRCULATOR / HEATER

The self-priming design and precise microprocessor control allow for improved temperature uniformity and reduced heating times. The low-profile design allows the circulator to be stowed behind the bath, requiring no additional bench space.

ELECTRONIC QUALIFICATION GUIDANCE

Settable automatic electronic instrument requalification reminders eliminate missed validation dates and ensures continuous instrument uptime.

COLOR TOUCH SCREEN DISPLAY

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the dissolution test.

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Setting the height is done through a one-time adjustment and utilization of the interchangeable paddles and baskets.

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DISTEK 5300

Dissolution Autosampler with Filter Changer







The Distek Eclipse 5300 Automated Dissolution Sampler offers rapid, accurate sampling using precision syringe pumps. The elimination of valves and rotary pumps along with the optimized sample pathway with a minimal 4.5 mL internal volume increases reliability while reducing common sources of sample carryover. Adding a lower-cost 'child' sampler is a cost-effective way to sample from two baths. Each of the baths may run the same method or two different independent ones. The integrated optional filter changer enables the use of most common 25 mm syringe filters instead of requiring custom filter plates and also additional bench space.

RAPID / ACCURATE SAMPLING

Precision syringe pumps and reduced sample pathway allows for rapid time point high precision collection. Unique fluid handling closely mimics manual sampling.

NO VALVES OR ROTARY PUMPS

The elimination of valves and rotary pumps along with the optimized sample pathway with a minimal internal volume of 4.5 mL increases reliability while eliminating and reducing common sources of sample carryover.

COST-EFFECTIVE DUAL BATH SOLUTION

Adding a lower-cost 'child' sampler is a cost-effective way to sample from two baths. The dual bath configuration allows two different and independent dissolution methods to be run at any time.

MEDIA RECYCLING AND REPLACEMENT

Media Recycling and Replacement offer the advantage of returning unused media and replacing the collected sample volume for ease of dissolution calculations.

COLOR TOUCH SCREEN DISPLAY

The icon driven user interface lowers overall cost by reducing training time and user errors while maximizing productivity and command of the autosampler.

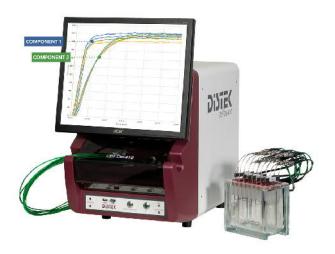
FILTER CHANGER

The optional, integrated filter changer uses readily available 25 mm syringe filters without the need for custom filter plates or additional bench space.

DISTEK Opt-Diss 410

In-situ UV Fiber-Optic System for Dissolution







No more sampling! The Distek Opt-Diss 410 in-situ fiber optic UV system measures directly in the vessel, eliminating the need for conventional sampling, and with-it consumables like filters, tubing and syringes, saving time, labor, and money. Moving light rather than liquids also allows generating near real-time dissolution data and nearly limitless sample points as frequently as every five seconds.

SIMPLE & EFFICIENT DISSOLUTION TESTING

Truly automated data collection and analysis means start of test to a complete report only takes as long as the test itself, with no operator interaction required. And collecting data as fast as every 5 seconds is no more effort.

MULTICOMPONENT ANALYSIS

Measure two components in the same dissolution test without the need for LC, including products with two APIs or interaction with excipients, coatings, capsules, or any other source of deviation of the UV spectra.

RAPID AND ROUTINE DATA COLLECTION

With acquisition speeds as fast as 5 seconds for all vessels, collecting near real-time dissolution profiles is ideal for formulators to understand complicated release dynamics as it occurs.

IN-SITU UV MEASUREMENTS

Keeping the science in the vessel! The Opt-Diss 410 measures directly in the vessel, eliminating manual or automated sampling along with the associated consumables, labor and off-line analysis.

- Choose from patented ARCH probes designed specifically for dissolution testing with negligible hydrodynamic effect
- Or conventional dip probes with interchangeable pathlengths

SINGLE SOFTWARE PACKAGE

21 CFR Part 11 compliant, the Opt-Diss 410 is the only fully integrated UV fiber optic dissolution solution with a single software package controlling the entire system.

INDUSTRY APPROVED

Top pharmaceutical companies as well as the FDA and USP have adopted the Opt-Diss by Distek.

DISTEK 3200

Bathless Disintegration Instrument







The Distek sensIR 3200 combines two exclusive technologies – bathless heating and Near IR sensing to offer the most innovative disintegration tester. Bathless heating not only reduces warm-up times but eliminates the inconveniences associated with conventional water bathbased instruments. To match your throughput requirements, the sensIR 3200 is available in two, four or six positions in the smallest foot print of any comparably equipped model.

BATHLESS HEATING

Patented Distek heater jackets raise media temperature from ambient to 37°C in less than 8 minutes, doubling the number of tests that can be performed daily. Also uses much less electricity and no algicide, further reducing operating costs.

AUTO ENDPOINT DETECTION

Optional Auto Endpoint Detection uses "Patent Pending" Near Infrared to automatically record actual disintegration times. And it works without the need for modified fluted disks, eliminating method revalidation for products not tested using modified fluted disks.

RUN MULTIPLE METHODS SIMULTANEOUSLY

Run up to three independent methods to simultaneously test different products and/or minimize method development time.

ADVANCED USER INTERFACE

Includes robust features such as: storing of 100 reports and records, running of three unique methods simultaneously, managing 50 users, setting qualification reminders and much more.

INTEGRATED TEMPERATURE SENSOR

Enables the monitoring and documenting of the individual beaker temperatures for improved regulatory compliance while eliminating the need for manually verifying temperature equilibration prior to tablet introduction.

SCALABILITY

Available in 2, 4, or 6 standard positions to meet your productivity needs.

SEMI-CIRCLE FOOTPRINT

Maximizes the placement of up to 6 disintegration stations while minimizing the amount of bench space required.

* The accuracy of auto endpoint detection is not guaranteed and results can be influenced by product and media types. Distek does not warrant the use of NIR detection technology for all products and media types.

DISTEK PrepEngine

Accelartion of your Content Uniformity Test







The PrepEngine was developed through collaborations with leaders in the pharmaceutical and biotech industry to simplify and speed up the content uniformity sample preparation process. The result - a compact benchtop design that incorporates 10 individually powered, high-output stirring stations which can prepare content uniformity samples up to 90% faster than conventional methods.

ULTRA-FAST SAMPLE PREPARATION

 Ultra-fast preparation of biotech and pharmaceutical samples including; assay, impurity and content uniformity applications. Up to 90% faster than conventional methods.

10 INDIVIDUAL STIRRING STATIONS

Individually activated, high-power stirring stations maximize productivity and significantly increases sample prep throughput.

AVAILABLE PREPTUBES

• Tube Size (mL): 50, 250 and 500

• Tube Color: Clear (Standard) or Amber

• Blade Material: Stainless Steel (Standard) or Polypropylene

• Sterility: Non-Sterilized (Standard) or Sterilized

RELIABLE & CONSISTENT RESULTS

From test to test, the sample results are fast, reliable and consistent.

PREPTUBE DESIGNED FOR SINGLE-USE

The recommended usage for a single PrepTube is a maximum of five (5) x 10 minute tests or equivalent. **Note:** All tests are application specific.

Sterilized PrepTubes are **Now Available** for a truly single-use experience. Sterilized PrepTubes guarantee cleanliness and eliminate the possibility of carry over and cross contamination.

ADJUSTABLE SPEED & TIME

The speed is adjustable from 500 to 6000 rpm and the time from 5 seconds to 4 hours.

DISTEK VIP4400

Dissolution Vessel Washer





The VIP 4400 automates one of the most time consuming and least productive aspects of the dissolution test: Post-test clean-up. The VIP 4400 dramatically reduces time between tests, increasing the throughput of the dissolution laboratory and reducing costs. It eliminates the tedious process of removing, draining and cleaning dissolution vessels and optionally, the shafts and stirring elements. The VIP 4400 is not only compatible with Distek baths, but almost every other bath on the market.

PATENTED "CYCLONE" WASH

The integrated "Cyclone" wash nozzle and drain assembly empty the vessel, then perform a 360° wash that provides a thorough cleaning of the entire vessel in only 30-45 seconds.

UNIVERSAL WASH MODULE

The universal wash module securely fits into any USP conforming 1L vessel regardless of the bath or vessel manufacturer.

SHAFT RINSE WAND

The optional integrated shaft rinse wand provides an easy and convenient method for cleaning the shaft and stirring elements in place. The rinse is captured in and removed from the vessel.

SELF-ADJUSTING DRAIN

The spring loaded, self-adjusting drain automatically compensates for vessel height variations, minimizing residual wash water remaining in the vessel after cleaning.

CLEANS UP TO 4 BATHS

Cleans up to 28, 1L vessels in under 15 minutes.

RAPID DRAIN & WASH CYCLES

Throughput is greatly increased as the VIP 4400 can drain and wash a 1L vessel in approximately 30 seconds.

LOW NOISE

The VIP 4400's contribution to laboratory noise is non-existent with pumps producing less than 65 db of noise.

QLA Accessories

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Dissolution Accessories for all brands / manufacture



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Quality Lab Accessories, LLC (QLA) is a leading manufacturer and supplier of Dissolution Accessories and Consumables, Calibration Tools and Services to Pharmaceutical Laboratories, worldwide.

We pride ourselves on being the only company in our industry that not only has a dedicated sales force but also a fully staffed machine shop and modern manufacturing facility located in Telford, PA. Our products are engineered and manufactured according to the precise specifications of the USP and Original Equipment Manufacturer (OEM).

QLA operates a Quality Management System which complies with the requirements of the ISO 9001 current standard. In addition to our commitment to ISO, we are also fully committed to all applicable regulatory standards, including U.S. Pharmacopeia General Chapters 701, 711, 724, 1092 and others, ASTM E2503 Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus, Calibration tools and services are traceable to N.I.S.T. standards.

- BASKETS, PADDLES, SHAFTS FOR ALL BRANDS
 Different mesh sizes, coatings, etc. are available with serial numbers and certificates.
- CANNULA FILTERS FOR ALL BRANDS
 Different pore sizes and styles are available with
 "QLA Pure Quality" and certificate.
- VESSELS AND VESSEL COVERS FOR ALL BRANDS
 Clear glass, amber glass, peak vessels, ultra precise vessels and different volumes are available. All vessels come with serial numbers and certificates.

- CAPSULE SINKERS
 Available for all capsule sizes and versions
- SAMPLING CANNULAS FOR ALL BRANDS
 Different lengths, stainless steel or peak and different OD's with the proper cannula stoppers.
- ALL OTHER KIND OF ACCESSORIES FOR ALL BRANDS

Take a look into our QLA product catalogue on our webpage.

RIGGTEK







Sie wünschen mehr Informationen?

- Besuchen Sie unsere Internetseite <u>www.riggtek.de</u> oder
- Rufen Sie uns an unter *Tel.: +49 89 2302469 -0* oder
- Schreiben Sie uns an <u>vertrieb@riggtek.de</u>

Sie erhalten gerne völlig unverbindlich mehr Informationen!

Wir sind für Sie da! Ihr RIGGTEK-Team

